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**THE BUREAU OF MEDICINE AND SURGERY SUPPLEMENTAL REPORT OF
HUMAN RADIATION EXPERIMENTS
31 MARCH 1994**

I. Introduction.

A. This is a supplemental report to the February 28, 1994 response to the Assistant to the Secretary of Defense (Atomic Energy) request for a DOD-wide review of Human Radiation Experiments. This review identifies medical department activities that might have conducted or sponsored human radiation experiments. Identified are the archives and record centers where records concerning such experiments might exist and a description of the steps taken to search those records. All efforts have been taken to include any studies which may involve exposure to ionizing radiation. As such, studies are included where exposure was received as part of, but not for the purpose of the study. The information in this report incorporates data available as of March 23, 1994. Additional information and details of individual studies continues to arrive and will be consolidated into future reports.

B. The Assistant to the Secretary of Defense (Atomic Energy) directed locating and reporting all records of:

(1) **Experiments** on individuals involving intentional exposure to ionizing radiation **This category does not include common and routine clinical practices, such as established diagnosis and treatment methods, involving incidental exposures to ionizing radiation**

(2) Experiments involving intentional releases of radiation that.

(a) Were designed to test human health effects of ionizing radiation.

(b) Were designed to test the extent of human exposure to ionizing radiation.

The scope of this guidance was interpreted to include research involving human test subjects in which the subjects receive exposure to ionizing radiation which they would not receive if they were not part of a study. Consequently this definition includes clinical research protocols where the patient receives exposure from diagnostic tests which are incidental but integral to the study.

II. Searches.

The following summarizes searches conducted, record retention policies and administrative controls for use of human test subjects:

A. SECNAVINST 5212.5C, 11 JULY 85, provides current guidance for records retention and disposal requirements. Guidance prior to 1985 has yet to be reviewed. Briefly, present guidance states:

(1) Medical and dental research and development project files as well as preliminary, interim, and final reports are to be retained permanently. They are to be transferred to the nearest Federal Records Center after 5 years and offered to the National Archives Regional Administrator after 20 years.

(2) Supporting records (excluding reports) are to be transferred to the nearest Federal Records Center after 5 years. After being held for 10 years they are to be destroyed by the Federal Records Centers.

(3) Non-record copies of research project files are to be retained on board. These copies are to be destroyed after 5 years, or upon project completion/termination, whichever is later.

B. A search for instructions governing human use testing was conducted. **The Navy Manual of the Medical Department in 1951 provided formal guidance for conducting experiments using human use test subjects. Human Use Test protocols were to be reviewed and approved by the Secretary of the Navy. Further guidance was issued in DOD and BUMED instructions in 1964, 1982, 1983, 1984, 1988 and 1989.** In addition, from 1963 to 1975 the Nuclear Regulatory Commission reviewed and approved or disapproved all human uses of investigational radiopharmaceuticals in humans and all human use testing with radioactive material.

C. Key researchers, both active duty and retired, were questioned concerning research activities at various commands and documentation practices from 1944 to the present. They identified approximately seventeen activities where humans may have been exposed as part of a study.

D. The reports at the Defense Technical Information Center (DTIC) were searched to identify applicable studies. Copies of research reports funded under a specific contract or budget line are supposed to be forwarded to DTIC upon completion of work. The DTIC computerized Title Index contains all reports (700,000) provided to DTIC since 1972 (Some of the reports reflect research performed prior to 1972, e.g. work performed in the 1940's and 1950's, but not submitted to DTIC until after 1972). Reports provided to DTIC prior to 1972 are maintained on index cards. DTIC performed a search by key words of their computerized and card indexes. The search identified over 3,600 Titles representing Army, Navy, Air Force, Defense Nuclear Agency, Defense Atomic Support Agency, Atomic Energy and other US Agency work, and translations of foreign work. Review of the Titles, Abstracts and Reports identified six sponsored by the Navy. **Search is complete.**

E. The Naval Environmental Health Center, manager of the medical department's Radioactive Material Use Permits, was asked to review Nuclear Regulatory Commission Licenses and Permits to identify activities authorized to use radioactivity on human test subjects, and provide an estimate of the time periods when various commands had active programs. In addition, copies of any curriculum vitae (CV) containing publications of studies on humans were requested **Search is complete.**

F. The Nuclear Regulatory Commission (NRC) was asked via the Chief of Naval Operations, N-45, (Captain Malinoski, MSC, USN) to identify the location and number of licenses and protocols used in investigational radiopharmaceuticals. **From 1963 to 1975 NRC reviewed and approved all protocols using investigational radiopharmaceuticals in humans. Search is pending.**

G. Federal Records Centers and National Archives were queried to identify any records from activities suspected of having performed studies. All of the Regional Archives and Federal Records Centers have conducted searches for records from activities suspected of having performed studies which exposed personnel. Records are taken care of as follows:

(1) Personnel, medical, and clinical records go to the National Records Center in St. Louis. Clinical charts and personnel medical records are retained for 75 years. Records are filed by Service Number or Serial Number. **St. Louis estimates approximately 28 million Navy medical records are held for the 1944-1994 time frame.**

(2) Research and administrative records held at the Federal Records Centers are transferred to the National Archives after 25 years, where a decision is made to either purge or retain them. Information protected by the Privacy Act is purged, e.g. names of individuals. **Only about 1-2 percent of all records sent to the Regional Records Centers go into National Archives** (legal cases, deeds, titles, etc.). The rest are destroyed

H. Each BUMED activity was tasked to search their records and report any experiments or clinical trials that involved exposure to human test subjects. **Searches completed at all but two activities (NMRI and NMRU-2).**

I. CVs were requested from researchers to identify publications of work performed at various activities. **Search is pending.**

J. A list of possible researchers was compiled to allow a literature search for publications by author **Search is pending.**

L. Records maintained at the Federal Records Center and National Archives, San Bruno, California of work performed by the Naval Radiological Defense Laboratory, 1955-1969, were physically reviewed by BUMED representatives.

III. Findings. The results of the Bureau of Medicine and Surgery's review are provided below:

A. Part I describes by activity the efforts to locate records, individuals consulted, records found and a list of studies by title. Included are studies involving human use test subjects, clinical protocols, prospective and retrospective clinical studies, and clinical case reports. Studies were included if it was not clear if the subjects would have been exposed if not part of the study.

B. Activities and studies listed on previous reports which further review indicated did not involve human testing have been deleted.

C. Previously reported Titles of studies identified from CV but still pending review are included.

D. Part II provides Information found in the course of our searches concerning studies at non-BUMED activities.

E. Part III includes Detailed information pertaining to each study identified in Parts I. and II

PART I: IDENTIFICATION OF ACTIVITIES THAT MIGHT HAVE CONDUCTED OR SPONSORED HUMAN RADIATION EXPERIMENTS

I. Introduction. Activities identified as having performed experiments or clinical studies involving exposure to humans are listed below. The summaries include a description by activity of types of work, time frame performed, efforts to locate records, individuals contacted, records found, and summaries of experiments and studies.

A. Naval Medical Research Institute (NMRI), Bethesda, MD.

The Naval Medical Research Institute established the Radiation Technology Division which did basic animal radiobiology and support work for atomic weapons testing. The division was active from the early 1940's until about 1960. Dr. Cronkite stated that doctors stationed at NMRI from 1946 until his transfer in 1954 were not allowed to see patients in the hospital. We have not ruled out that some physiology and medical tests may have occurred in collaboration with the hospital (1944-1946 and 1954-1960). Captains Erhardt and Gaugler stated that instances of their investigators conducting work on humans should be very rare, as the laboratory has been a basic animal research facility.

Efforts to locate human radiation experiment records:

- (1) Queried knowledgeable individuals as to the type of work performed at NMRI.
- (2) Searching through technical documents available in the NMRI library.
- (3) Searched through DTIC's computerized listings and index card records.
- (4) Queried Federal Records Centers for NMRI records.
- (5) Queried Federal Archives for NMRI records.
- (6) Searching Medicus Indicus for publications by NMRI investigators.
- (7) Searching NRC License File for authorization to do human use testing.
- (8) Searched Navy Environmental Health Center's NRC License File for CV of researchers.

Individuals consulted:

Dr. Vic Bond, Brookhaven National Laboratory, (516) 282-3332
Dr Eugene Cronkite, Brookhaven National Laboratory, (516) 282-7538

Captain Bob Gaugler, MSC, USN, NMRI
Captain Doug Erhardt, MSC, USN, Executive Officer, NMRI
Bob Plowman, Joseph Sheehan, Dan Bennett, National Archives
and Federal Records Center, Philadelphia, (215) 597-5694/9753
CDR Bill Merrull, MSC, USNR (ret)
CDR Bill Beckner, MSC, USNR (ret)

Records found:

- (1) Copies of all technical reports are located in the NMRI Library.
- (2) No records were located in the Regional Archives.
- (3) Radioisotope License File on file at Navy Environmental Health Center
- (4) St. Louis Records Center stated one cubic foot of logs dated 1944-1956 were destroyed Aug. 1992 by the Federal Records Center, St. Louis.
- (5) Federal Records Center at Suitland, Maryland holds approximately 475 cubic feet of records including some records from the Research Division at BUMED.

List of Experiments or Possible Experiments:

1. **"Biological Studies of Antimony Compounds Containing Radioactive Isotopes, The Blood-Tissue Exchange and Excretion of Antimony in Humans Given a Single Dose of Tartar Emetic." 1944**
2. **"Decreased Free Fraction of Thyroid Hormones After Prolonged Antarctic Residence." 1983-1984**
3. **"Nitrogen Gas Exchange in the Human Knee." 1985**
4. **"Tracer Gas Kinetic Studies for Decompression Table Design." 1978-1984**
5. **"Absorption of X-rays by Tissues of the Head and Neck." 1952**
6. **"X-Ray Therapy for Amenorrhea and Sterility." 1957**

B. **Naval Hospital St. Albans.** Naval Hospital St. Albans was disestablished in 1973. St. Albans was the major Navy cancer treatment hospital on the East Coast in the

late 1940's to early 1960's. In 1952 a medical physicist was assigned to help physicians develop therapeutic use of radioisotopes. The hospital had a radon farm constructed, but the unit was never used. Suspect clinical applications were developed using Sr-90, Gallium-74 and possibly P-32 (1952-1973).

Efforts to locate human radiation experiment records:

- (1) Interviewed individuals previously stationed or knowledgeable of activities at St. Albans to determine type of work.
- (2) Queried Federal Records Centers for the presence of records.
- (3) Queried National Archives for the presence of records.
- (4) Searched DTIC index and card files by key words for papers or reports prepared by individuals at St. Albans.
- (5) Searched Medicus Indicus for papers published by individuals while stationed at St. Albans.
- (6) Searched the NRC Radioisotope License File at the Navy Environmental Health Center.
- (7) Queried NRC to search their license files.

Individuals consulted:

Commander Tom Mitchel, MSC, USN (Ret)
Captain Pishnotti, MC, USN (Ret)
Captain Horace Chester Dudley, MSC, USN (Ret)
Captain Jim Malinoski, MSC, USN
Robert Morris, National Archives Boston (617) 647-8100
Martin Kabakoff, Federal Records Center, Boston (617) 647-8110
Lee Remero, Federal Records Center, New York (201) 823-7161
Karen Lucas, Federal Records Center, New York (201) 823-5487
Gregory J. Plunges, National Archives, New York (212) 337-1300
William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216
Joseph Sheehan, National Archives, Philadelphia
Griff Plunges, National Archives, New York

Human radiation experiment records found:

- (1) No experiment records found in the Archives.

- (2) National Archives, New York, holds 1.5 cubic feet of St. Albans records, and a 10 page command history. No experimental results or clinical trial information was found according to Mr. Plunges.
- (3) Patient's charts and military health records located in the Federal Records Center, St. Louis total 3,249 cubic feet for the years 1943-1973.
- (4) Open scientific literature may hold published papers. Another search identified several titles but work could be animal studies.
- (5) NRC Archives may hold some records of the licensed activities versus human.

List of Possible Experiments:

- (1) A search by authors of the Medicus Indicus for articles published by individuals stationed St. Albans identified the following titles. The articles have yet to be reviewed to see if they fall within the scope of the tasking

1. "Studies of the Metabolism of Gallium. Deposition in and Clearance from Bone." 1952
2. "Gallium Studies of its Deposition in and Clearance from Bone." (1953) Experiment page says 1952
3. "Studies of the Metabolism of Gallium. Effect of Gallium on Alkaline Phosphatase and Calcification in Vitro." 1953
4. "Pharmacological Studies of Radiogermanium Inhalation of Dusts." 1953
5. "Studies of the Localization of Radioactive Gallium in Bone Lesions." 1956

C. **Naval Medical Research Unit No. 3, Cairo, Egypt.** The research unit's primary purpose has been to investigate disease endemic to Africa and the Middle East.

Efforts to locate human radiation experiment records:

- (1) Used the Defense Technical Information Center's (DTIC) computer search of key words. Manual reviews of titles and abstracts conducted of key word search to identify possible human radiation experiment records

- (2) Queried Federal Records Centers.
- (3) Queried Federal Archives.
- (4) Medical Records of military located at Federal Records Center St. Louis
- (5) Tasked command to search their records.

Individuals consulted:

Captain Ed Flynn, MC, USN, Commanding Officer, Research and Development Command

CDR R. G. Hibbs, MC, USN, Commanding Officer, NMRU # 3

Mr. Rich Boyland, National Archives, Suitland, MD (301) 763-1083

Ms. Velicia Chance, Federal Records Center, Suitland, MD (301) 763-7430

Ms. Millie Sturate, Federal Records Center, Suitland, MD (202) 433-4217

Mr. Jim Smith, Federal Records Center, Fort Worth TX (Port of entry for East jkg Coast foreign generated US records.)

William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216

LCDR D. R. Tribble, NMRU # 3

Records found:

- (1) Copies of reports at NMRU 3, Cairo. Detailed records for only two studies still exist.
- (2) Two reports in DTIC files.
- (3) Radioisotope License File on record with the Navy Environmental Health Center.

List of Experiments or Possible Experiments:

1. "Calcification of Schistosoma Haematoeium Eggs: Relation of Radiologically Demonstrable Calcification to Eggs in Tissues and Passage of Eggs in Urine." 1978
2. "Urinary Schistosomiasis in Egypt: Further Radiological Correlation's." 1973
3. "Bilharzial Splenomegaly and Refractory Anemia," 1966
4. "Radioactive Renography in Schistosomal Obstructive Uropathy." 1973

5. **"Schistocolonic Polyposis: Clinical, Radiological and Parasitological Study."**1986
6. **"Schistosomiasis of the Liver, Clinical, Pathologic and Laboratory Studies in Egyptian Cases."** 1956
7. **"Acute Haemolysis With Ambilhar Treatment in Glucose-6-Phosphate Dehydrogenase Deficiency."** 1972
- 8 **"Changes in Hepatic Blood Flow and Blood Volume After Splenectomy for Bilharzial Hepatosplenic Fibrosis Dehydrogenase Deficiency."** 1972
9. **"Efficacy of Medical Treatment of Schistosomal Obstructive Uropathy as Determined by Iodine-131 Hippuran Renography Location and Time of Study."** 1978
10. **"Some Effects of Louse-Born Relapsing Fever on the Function of the Heart."** 1969
11. **"Colonic Calcification and Polyposis in Schistosomiasis."** 1971
12. **"Urinary Schistosomiasis: A 5 Year Clinical Radiological and Functional Evaluation."** 1967-1971
13. **"Treatment of Chronic Urinary Salmonella Carriers."** 1970
14. **"Intestinal Protein Loss in Schistosomal Polyposis of the Colon."** 1970
15. **"Chronic Urinary Salmonella Carriers With Intermittent Acteraemia."** 1970
16. **"Urinary Schistosomiasis Treated With Niridazole (Ambilhar). A Quantitative Evaluation."** 1970
17. **"Histologic and Lymphangiographic Studies in Patients With Clinical Lepromatous Leprosy."** 1969
18. **"Urinary Blood Loss in Schistosoma Haematobium Infection in Egyptian Farmers."** 1969
19. **"Blood Loss in Chronic Schistosoma Mansonii Infection in Egyptian Farmers."** 1967

20. **"Chromium Red Cell Half-Life in Severe Iron Deficiency Anemia." 1965**
21. **"Hydronephrosis, Bacterium, and Maximal Urine Concentration in Urinary Schistosomiasis." 1971**
22. **"Symptomatic, Radiological and Functional Improvement Following Treatment of Urinary Schistosomiasis in Egypt." 1967**
23. **"Blood Loss in Pure Ancylostoma Duodenal Infection in Egyptian Farmers." 1965**
24. **"Bilharzial Splenomegaly and Refractory Anemia." 1966**
25. **"Radioactive Renography in Schistosomal Obstructive Uropathy." 1973**
26. **"Schistosomal Colonic Polyposis: Clinical, Radiological and Parastological Study." 1986**
27. **"Needle Biopsy of the Lung." 1956**
28. **"The Diagnoses and Management of Hepatic Abscesses of Amebic Origin." 1955**
29. **"Observations on the Natural History of Amebiasis: A Preliminary Report." 1955**
30. **"Blood Loss in Egyptian Farmers Infected With Ancylostoma Duodenal." 1966**
31. **"Iron Loss and Reabsorption in Ancylostoma Duodenal Infection and Bilharzial Colonic Polyposis." 1970**
32. **"Urinary Schistosomiasis in Egypt: Clinical, Radiological, Bacteriological and Parasitological Correlation's." 1973**

D. **National Naval Medical Center, Bethesda, MD.** National Naval Medical Center, Bethesda installed a small reactor in approximately 1952 to manufacture radio pharmaceuticals. We believe clinical research has continued to the present.

Efforts to locate human radiation experiment records:

- (1) Defense Technical Information Center (DTIC) computer search by key words. Manual reviews of titles and abstracts to identify records.
- (2) Contacted National Archives.
- (3) Contacted Federal Record Centers.
- (4) Searched spaces.
- (5) Searched Journals for published articles.
- (6) Reviewed CV of previous staff members to identify studies they may have published.
- (7) Conducting literature search by author for articles published by previous staff members.
- (8) Searched Clinical Investigation Division Files.

Individuals consulted:

CDR Bill Beckner, MSC, USN (Ret) (301)657-2652
 CDR Rick LaFontaine, MSC, USN (301) 295-5002
 CDR Jim Bridges, MSC, USN
 CAPT Gene Silverman, MC, USN
 CAPT Karl Mendenhall, MSC, USN (202) 653-1182
 CAPT Peter Kirschner, MC, USN (Ret)
 Mr. Bob Plowman, National Archives, Philadelphia (215) 597-3000
 Mr. Joseph Sheehan, National Archives, Philadelphia (215) 597-5694/9753
 Mr. Dan Bennett, Federal Records Center, Philadelphia, (215) 597-3000
 Mr. Rich Boyland, National Archives, Suitland, MD (301) 763-1083
 Ms. Velicia Chance Federal Records Center, Suitland, MD (301) 763-7430
 Ms. Millie Sturate, Federal Records Center, Suitland, MD (202) 433-4217
 Mr. Jim Jensen, Records Manager for Navy, 202-433-2434
 Mr. William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216

Records found:

- (1) Whole Body Counter, 50 cubic feet: Patient charts, whole body counting data, patient logs and Occupational Radiation Safety whole body scans
- (2) Radiation therapy, approximately 11,000 Radiation Therapy Patient Treatment Charts, some of which were on protocols sponsored by the National Cancer Institute.

- (3) Federal Records Center, Suitland MD., 756 cubic feet of records, 1952-1979. Records may be BUMED records versus National Naval Medical Center.
- (4) Clinical Investigation Division. They believe they have all records since the division was established approximately 1974 with the following exception. One of their storage areas in the basement was apparently mistakenly cleaned out. The records, 1974 to approximately 1982, are presumed destroyed.
- (5) Radioisotope License File on record with the Navy Environmental Health Center.
- (6) Clinical Investigation Division, Health Science Education and Training Command. Duplicate copies of hospital's Clinical Investigation Division protocols.
- (7) Federal Personnel Records Center, St. Louis, 6,046 cubic feet from 1952-73 and 5,710 cubic feet from 1974-91.

List of Experiments or Possible Experiments:

- (1) Discussions with previous staff members indicated no radiation biology effects studies conducted. All work was clinically related.
- (2) A search of the literature by author identified the following journal articles. Articles have yet to be reviewed to determine if they fall within the scope of human radiation experimentation.

1. "Preliminary Report on the Use of Gallium in Clinical Tracer Studies." 1952.
2. "Diagnosis of Multiple Small Pulmonary Emboli With Tc-99m Micro-Spheres." 1952
3. "Practical Radioisotope Therapy." 1955
4. "The Therapeutic Use of Radioisotopes From a Practical Level." 1956
5. "Evaluation of Pancreatic Exocrine Function and Intestinal Absorption With Radioactive Fat." 1957
6. "Present Status of Radioiodine in Thyroid Disease." 1956
7. "The Use of Radioisotopes in Diagnostic Hematologic Procedures. I. The Application of the B-12 Co-60 Test in the Diagnosis of Macrocytic Anemias and Malabsorption States." 1957

8. **"The Use of Radioisotopes in Diagnostic Hemotologic Procedures, Fe-59 Erythrokinetic Studies." 1957**
9. **"The Use of Radioisotopes in Diagnostic Hemotologic Procedures, Simultaneous Cr-51 and Fe-59 Studies." 1957.**
10. **"Blood Volume Studies in Thoracic Surgical Patients Using Radioactive Iodinated Human Serum Albumin." 1956**
11. **"Studies of the Localization of Radioactive Gallium, GA-72, in Bone Lesions." 1956**
12. **"Pancreatic Exocrine Function; A Simplified Test Using Radioactive Fat Excretion." 1957**
13. **"A Study of Methods for Interstitial Implantation of Radioactive Material." 1956**
14. **"Late Follow-Up Studies After Internal Deposition of Radioactive Materials." 1956**
15. **"The Excretion of Thorium and Thorium Daughters After Thorotrast Administration." 1957.**
16. **"Barium Studies of the Comparative Action of Banthine, Tincture of Belladonna and Placebos on the Motility of the Gastrointestinal Tract in Man." 1953**
17. **"Gastrointestinal Motility in Man; Influence of a Standard Meal on the Effect of Banthine." 1954.**
18. **"Comparative Effects of Pamine, Banthine, and Placebos on Gastrointestinal Motility. Radiographic Study in Eight Adult Subjects Tested When Fasting and After Three Weeks Administration of Agents." 1955**
19. **"Comparative Effects of Pamine, Banthine, and Placebos on the Gastrointestinal Mobility. Radiographic Study in Eight Adult Subjects Tested When Fasting and Following the Administration of a Standard Meal." 1955.**
20. **"Whole Body Retention of Orally Administered Calcium-47."**

21. **"Total Body Potassium (K) as a Reference Standard for Normality of Red Blood Cell Mass."**
22. **"Evaluation of Cervical Spine Injuries Using Cinceroentgenography."**
23. **"Evaluation of Available Kits for Radioimmunoassay."**
24. **"Radioisotopic Determination of Glomerular Filtration Rate (GFR.) and Effective Renal Plasma Flow (ERPF)."**
25. **"Evaluation of Role of Thyrotrophic Hormone (TSH) in Simple and Multi Nodular Goiter and Thyroid Carcinoma."**
26. **"Diagnosis of Early Arthritis by Joint Scintiphotography."**
27. **"Diagnosis of Urinary Tract Obstruction by Scintiphotography."**
28. **"Dynamic Scintiphotography in the Evaluation of Renal Disease."**
29. **"Gallium 67 Scanning for Staging of Carcinoma of the Breast."**
30. **"Platelet Function in Patients with Lymphoma and Solid Tumor Prior to, During, and After Therapy."**
31. **"The Investigation of the Transfer of Iodine and Thyroid Hormone Across the Placenta in Early Human Gestation."**
32. **Clinical Evaluation of a Tin Electron Filter for Cobalt-60 Radiation Therapy Utilizing a Thermoluminescent Dosimetry System Effect on Skin Sparing."**
33. **"The Effect of Cholecystectomy on the Constituents and Size of the Bile Acid Pool."**
34. **"IgE Antipolymyxin B Antibody Formation in a T-Cell Depleted Bone Marrow Transplant Patient." 1974**

(2) The following studies have been identified.

35. **Spect Imaging of Regional Cerebral Blood Flow . 1988-Present**

36. **Phase III Study 131-I-Meta-Iodobenzyl-guanidine Sulfate (3BG) For the Localization of Adrenal Medullae of Humans. 1988-Present**
37. **Effects of Oral Therapy With Verapamil Upon Ventricular Diastolic Function in Hypertensive Patients. 1988-Present**
38. **Phase III Study of 131-6B-Iodomethyl-19-Norcholesterol (NP-59) for the Localization of the Adrenal Cortex in Humans. 1988-Present**
39. **Assessment of the Effect of Converting Enzyme Inhibition on Proteinuria With Steroid - Unresponsive Nephrotic Syndrome. 1990-Present**
40. **The Influence of Thyroid Disorders and Their Treatment on Nuclear Binding of T3 in Human Leukocytes (Research on blood Products only). 1990-Present**
41. **Magnetic resonance and Tc-99m HMPAO Spec Imaging in Evolving and Completed Stroke Diffusion/Perfusion Imaging and Metabolite Spectroscopy. 1991-Present**
42. **Renal and Systemic Hemodynamic response to the Creation of Vascular Access for Hemodialysis in Patients with Chronic Renal Failure. 1991-Present**
43. **Association of Bone Density and Menstrual Dysfunction with Fractures in USNA Midshipmen. 1991-Present**
44. **A Comparison of Ultrasonographic Doppler Flow Hysterosalpingography with Conventional Hysterosalpingography. 1993-Present**
45. **Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma in Stage I and Occult Stage II. 1980-Present**
46. **A Surgical Pathological Study of Women with Invasive Carcinoma of the Cervix Stage 1B and Randomly assigned Radiation Therapy Versus No Further Therapy in Selected Patients. 1981-Present**
47. **A Randomized Comparison of Hydroxyurea Versus Misonidazole As an Adjunct to radiation Therapy in Patients with Stages IIB,**

III, IVA Carcinoma of the Cervix and Negative Para-Aortic Nodes (Phase III). 1982-Present

48. **Treatment of Patients with Suboptimal (Bulky) Stage IB Carcinoma of the Cervix: A Randomized Comparison of radiation Therapy Versus Radiation Therapy Plus Adjuvant Extrafascial Hysterectomy (Phase III). 1986-Present**
49. **GOG 94, A Phase II Study of the Treatment of Stage III & IV Disease of Advanced Endometrial Carcinoma and All Stages of Papillary Serous Carcinoma and Clear Cell Carcinomas of the Endometrium With Total Abdominal Radiation Therapy. 1987**
50. **GOG 85, A Randomized Comparison of Hydroxyurea Versus 5-FU Infusion and Bolus Cisplatin As An Adjunct to Radiation Therapy in Patients with Stage II-B, III, and IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes. 1987-Present**
51. **GOG 99, A Phase III Randomized Study of Surgery Plus Adjunctive Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma. 1988-Present**
52. **Evaluation of Intraperitoneal Chronic Phosphate Suspension therapy Following Negative Second-Look Laparotomy for epithelial Ovarian Carcinoma (Stage III Phase III). 1989-Present**
53. **Treatment of Selected Intermediate Risk Patients With Stage IB Carcinoma of the Cervix After Radical Hysterectomy and Pelvic Lymphadenectomy: Pelvic Radiation Therapy versus no Further Therapy. 1989-Present**
54. **A Randomized Clinical Trial for Treatment of women With Selected Stage IC and II (A, B, C) and Selected Stage IA and IB and Ovarian Cancer (Phase-III). 1989-Present**
55. **A Randomized Comparison of Hydroxyurea Versus Hydroxyurea 5-FU Infusion & Cisplatin as Adjunct Radiation Therapy in Patients with Stages IIIB, III, and IVA Carcinoma of Cervix and Negative Para-Aortic Nodes. 1992-Present**
56. **GOG 122, Whole Abdominal radiotherapy versus combination Doxorubicin Cisplatin Chemotherapy in Advanced Endometrial Carcinoma. 1992-Present**

57. **GOG 87F, A Phase II Trial of Doxorubicin (NSC #123127) and Ifosfamide (NSC #11389) In the Treatment of Recurrent or Uterine Leiomyosarcomas. 1993-Present**
58. **GOG 123, A Randomized Comparison of Radiation Therapy and Adjuvant Hysterectomy Versus Radiation Therapy and Weekly Cisplatin and Adjuvant Hysterectomy in Patients with Bulky stage IB Carcinoma of the Cervix. 1993-Present**
59. **A Randomized Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjuvant Radiation. 1993-Present**
60. **NCI 93-11, A Phase I Trial of etoposide and Cisplatin Plus chest Radiotherapy for Patients with Limited Stage Small Cell Lung Cancer. 1993-Present**
61. **A Phase III Trial of Adjuvant Radiotherapy vs Adjuvant Radiotherapy Plus Systemic Chemotherapy for Local and Regional Neuroendocrine (Merkel) Cancer of the Skin. 1994-Present**
62. **Pilot and Phase II Study of Low Dose Rate Chest Radiotherapy for Treatment of Intrathoracic Relapse of Small Cell Lung Cancer. 1991-Present**
63. **POG 8625/26, Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIA, Hodgkin's Disease in Pediatric Patients-A Pediatric Oncology Group Phase III Study. 1991-Present**
64. **POG 9006: Alinc #15, Up Front Alternating 6-MP/MTX vs Up-Front Alternating Chemotherapy for Acute Lymphocytic Leukemia in Childhood. 1991-Present**
65. **POG #8935, A Study of the Biological Behavior of Optic Pathway Tumors-A Phase II Study. 1991-Present**
66. **POG 8653/54, A Study of child hood Soft Tissue Sarcoma (STS) Other than Rhabdomyo-Sarcoma and its Variants - POG Phase III Study. 1991-Present**
67. **POG #9136, Phase I/II Dose Escalating Trial of Hyperfractionated Irradiation in the Treatment of Supratentorial Malignant Tumors of Childhood. 1991-Present**

68. **POG #9135, Pre-Radiation chemotherapy for Children with Supratentorial Malignant Gliomas and Poorly - Differentiated Embryonal Tumors. 1991-Present**
69. **POG 9130, (INT-0128) Treatment for Newly Diagnosed Low Grade Astrocytomas. 1992-Present**
70. **POG 8862, Treatment of First Marrow and /or Extramedullary Relapse Childhood Acute T-Lymphoblastic Leukemia and/T Non Hodgkin's Lymphoma with Combination Chemotherapy Including 2' Deoxycoformycin. 1992-Present**
71. **NSABP B-24 (NCI 92-13), A Clinical Trial Evaluate the Worth of Tamoxifen in Conjunction with Lympectomy and Breast Irradiation for Treatment of Noninvasive Intraductal Carcinoma (DCIS) of the Breast. 1993-Present**
72. **NSABP (NCI 92-11) A Clinical Trial Determine Worth of Breast Radiation in Management of Patients with Node-negative Occult Invasive Breast Cancer Treated by Lympectomy. 1993-Present**
73. **Use of Radiocopper in the Diagnosis of Wilson's Disease. 1992-Present**
74. **GOG 88, A Randomized Study of Radical Vulvectomy and Bilateral Groin Radiation, Phase III. 1988-1991**
75. **Scintigraphic characterization of Para-thyroid Glands in chronic Renal Insufficiency. 1988-1991**
76. **NCI 82-8, Monoclonal Antibody Serotherapy of Chronic Lymphocytic Leukemia and Cutaneous T-cell Lymphoma and Radioimaging with radiolabeled Monoclonal antibody T-101. 1983-1988**
77. **NCI 81-3, Treatment of Limited Small Cell Bronchogenic Carcinoma: Chemotherapy Alone or with Radiation Therapy. 1982-1988**
78. **NCI 82,4, Valuation of Chemohormonal Therapy and Breast Carcinoma Patients with no Evidence of disease Following an Excised or Curatively Irradiated recurrence. 1982-1989**

79. **NCI 86-2, Treatment of Cutaneous T-Cell Lymphoma (CTCL) and Chronic Lymphocytic Leukemia (CLL) with Yttrium-90 Radiolabeled T-101 Monoclonal Antibody. 1987-1993**
80. **POG #8725, Randomized Study of Intensive Chemotherapy (MOPP/AVBD) + 1-Low-Dose Total Nodal radiation Therapy in the Treatment of Stages IIB, IIIA2, IIIB, IV Hodgkin's disease in Pediatric Patients. 1991-1993**
81. **A Phase III Study of Indium III Labeled Granulocytes for Detection of Inflammation Process in Humans. 1987**
82. **Glucose Metabolism by Positron emission tomography. 1989-1993**
83. **The Sensitivity and Specificity of MRI CT Arthrography and MRI Arthrography for the Evaluation of the Shoulder. 1992**
84. **NCI 92-7, Phase I Evaluation of Intravenously Administered 131 I-Col-1 Monoclonal Antibody in Patients with Advanced Carcinoma. 1992-1993**

E. **Naval Hospital Chelsea/Navy Blood Lab.** Naval Hospital Chelsea/Naval Blood Lab was disestablished in approximately 1968. Work is now performed under contract. Contractor: Cryopharm Corporation and St. Elizabeth's Hospital, Boston.

Efforts to locate human radiation experiment records:

- (1) DTIC search of key words. Manual reviews of titles and abstracts was conducted of the key word search to identify possible human radiation experiment records.
- (2) Contacted National Archives.
- (3) Contacted Federal Records Centers.

Individuals consulted:

Jim Owens, National Archives, Boston. (617) 647-8100
 Martin Kabakoff, Federal Records Center, Boston (617) 647-8110
 Robert Morris, National Archives Boston (617) 647-8100
 Lee Remero, Federal Records Center, New York (201) 823-7161
 Karen Lucas, Federal Records Center , New York (201) 823-5487

Gregory J. Plunges, National Archives, New York (212) 337-1300
William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216
Joseph Sheehan, National Archives, Philadelphia
Griff Plunges, National Archives, New York
CAPT Jim Alexander, MC, USN, Health Sciences and Education Command, (301) 295-5769
LCDR John Campbell, Navy Environmental Health Center, Norfolk, Virginia
(804) 444-4657 ext 413

Records found:

- (1) Federal Records Center, Boston 4 cubic feet, NH Chelsea 1968-74, surgical cases and disease categories.
- (2) Nuclear Regulatory Commission License File, Navy Environmental Health Center, Norfolk, Virginia.
- (3) Nuclear Regulatory Commission License File, Nuclear Regulatory Commission Region II, Atlanta.
- (4) Blood lab estimates a large quantity of records, with the estimated copying cost at \$100,000.

List of Possible Studies:

1. "Blood Volume Studies (51-Cr and 125-I)." 1964
2. "Red Blood Cell Survival Studies (51-Cr and 125-I)." 1964
3. "Platelet Survival Studies (51-Cr and 125-I)." 1964
4. "Blood Volume Studies (51-Cr and 125-I)." 1964-1978
5. "A Study of Carbon Monoxide Production During Anesthesia as Method of Determining Red Blood Cell Survival."
6. "Pathophysiological Adaptations in Pregnancy: A Study of Oxygen Transport Mechanisms in Normal Abnormal Pregnancy of Fetal Manifestations of Intrauterine Hypoxia, of Dysfunctional Labor and of Trace Metal Cadmium as Possible Factors in Hypertensive Syndrome"
7. "Treatment of Ankle Fractures by Anatomic Reduction and Internal Fixation with Early Motion"

8. **"The Clinical Effects of Beta-Blockade on Thyrotoxicosis"**
9. **"Evaluation of the Vectorcardiogram on Early Detection of Increased Right Heart Work in Asthma in Children"**
10. **"A Correctional Compression Osteotomy of the Distal Tibia"**
11. **"The Effects of Estrogen Therapy on Parameters of Thyroid Function in the Post-Menopausal Patient"**
12. **"Effects of Position on Results of Gastric Analysis"**
13. **"Clinical Cancer Research in Association with the ECOG"**
14. **"Detection of Occult, Venous Thrombosis by "Impedence Meter" and I125 Fibrinogen"**
15. **"Treatment of Acute and Chronic Edema Secondary to Lymphatic or Venous Insufficiency"**
16. **"Nitroblue Tetrazolium Test, its Use in (a) Diagnosis of Postoperative Fever, (b) Appendicitis"**
17. **"Evaluation of Hypophosphatemia and Blood Volume Changes Induced by Parenteral Hyperalimentation"**
18. **"Evaluation of the Cast Brace in Treatment of Femoral Shaft Fractures"**
19. **"Heparin Anticoagulation by Continuous Intravenous Infusion"**
20. **" Gallium-67 Scanning for Staging of Carcinoma of the Breast."**

F Naval Hospital San Diego, Ca.

Efforts to locate human radiation experiment records:

- (1) DTIC search of key words. Manual reviews of titles and abstracts was conducted using a key word search to identify possible human radiation experiment records.
- (2) Queried National Archives for records.
- (3) Queried Federal Records Centers for records.

- (4) Requested CV from prior staff to assist literature review.
- (5) Requested search of Nuclear Regulatory Commission License Files at the Navy Environmental Health Center for approved protocols and CV of authorized users.
- (6) Requested search of Nuclear Regulatory Commission License File to determine quantity of records.
- (7) Requested search of Clinical Investigation Files at the Health Sciences and Education and Command.
- (8) Requested search of Clinical Investigation Files at the Naval Medical Center, San Diego.
- (9) Requested search of spaces at Naval Medical Center, San Diego.
- (10) Requested literature search by author of previous staff members.

Individuals consulted:

Diane Nixon, National Archives, Laguna (714) 643-4241
Sharon Roadway, Federal Records Center, Laguna (714) 643-4241
Waverly Lowell, National Archives, San Bruno (415) 876-9009
Richard Boyden, Federal Records Center, San Bruno (415) 876-9009
LCDR Dean Taylor, MSC, USN, (619) 532-8784
CAPT C. G. Gray, MC, USN
Ms Mary Ann Jodoin, Data Base Administrator (CALGB/POG)
Ms. Colleen Murphy, NMCSO, NSABP, NSABP Protocol Manager
CAPT T. K. Burkhard, MC, USN
CAPT R. L. Cole, MC, USN
RADM Q. E. Crews, Jr, MC, USN (Ret)
CAPT T. P. Dresser, MC, USN (Ret)
CAPT W. B. Goff, II, MC, USN
Dr. R. B. Greaney
Dr. J. P. Green
CAPT J. O. Martin, MC, USN
CDR J. R. Wilcox, MC, USN

Records found:

- (1) Federal Personnel Records Center, St. Louis, 2,668 cubic feet for years 1966-1973; 11,379 cubic feet 1974-1990.

- (2) Clinical investigation records are at Naval Hospital San Diego.
- (3) Radioisotope License File on record with the Navy Environmental Health Center, Norfolk, Virginia.
- (4) Their Clinical Investigation Department holds records. Records are maintained on microfiche, CD-ROM and paper. Approximately 1,200 current and archived protocols covering the period 1972 to the present. The search identified over 250 protocols involving human medical/dental research involving exposure of the patient to ionizing radiation.
- (5) Radiology Department holds some records, may be duplicates of CID's records.
- (6) Radiation Therapy Department holds references to participation in CALGB, POG, IRS and National Surgical Adjuvant Breast and Bowel Project (NSABP) Protocols.

List of Experiments or Possible Experiments:

- (1) A preliminary literature review indicates the following studies were published or presented by staff assigned to Naval Hospital San Diego. Further review is needed to determine if these are within the scope of the tasking
- (2) **The following studies have been identified:**
 - 1. "Clinical Evaluation of Ga-76 Scanning in the Diagnosis of Anaplastic Carcinoma and Malignant Lymphoma in the Thyroid Gland."
 - 2. "The Significance of Positive Ipsilateral Nodes in Resections of Lung."
 - 3. "Chemotherapeutic Agents in the Treatment of Lung Tumors."
 - 4. "Extracranial Suspension Vs. Inter- or Intraosseous Support in Treatment of Facial Fractures."
 - 5. "Endoscopic Pancreato-cholangiography and Manometry of the Sphincter of Odi."
 - 6. "Results of Clubfoot Treatments."

- 7. "Colonoscopy in the Differential Diagnosis of Inflammatory Bowel Disease."**
- 8. "Stress Fractures of the Femur."**
- 9. Ketamine Anesthesia in Minor Otologic Procedures.**
- 10. Immunocyto-adherence Testing in Lymphoproliferative Disorders.**
- 11. Treatment of Tibial Fractures with Electronic Microcurrent.**
- 12. Early Diagnosis of Aseptic Necrosis of the Femoral Head Following Traumatic Dislocation of the Hip**
- 13. "Acromio-Clavicular Separations."**
- 14. " Use of Non-invasive Monitoring Technique to Evaluate the Pre- and Post-Operative Arterial Blood Flow A-S-O."**
- 15. "Endoscopic Electrosurgical Polypectomy."**
- 16. "Recurrent Lower Urinary Tract Infections in Woman: The Effect of Urethral Dilation."**
- 17. "Angiographic Analysis of Left Ventricular Mechanics in Young Patients with Atypical Chest Pain and Ischemic Heart Disease."**
- 18. "Fracture of the Ankle in a Military Population."**
- 19. "Abnormalities Involving the Alternate Pathway in Urticaria or Angioedema."**
- 20. " A Clinical Trial to Compare Combination Chemotherapy with and without C. Parvum in the Management of Patients with Surgically Curable Breast Cancer Who Have One or More Axillary Nodes."**
- 21. "Detection of Pericardial Effusion by Echocardiography in Hypothyroid Patients."**
- 22. "The Use of 99m Tc-Pyrophosphate Bone Scanning in the Early Detection of Stress Fractures."**

23. **"Bone and Gallium Scanning in the Evaluation of Disseminated Coccidiomycosis."**
24. **"NSABP #4"**
25. **"The Distribution of Ventilation / Perfusion Ratios in Acute and Chronic Cardiopulmonary Disease."**
26. **"Effect of Hyperthyroidism on Serum Gastrin and Gastric Acid Production Before and After Treatment."**
27. **"Vasodilated Excretory Urography - A Diagnostic Approach to Renovascular Hypertension."**
28. **"Contrast Media Reactions - The Role of Histamine, Complement, and Dilutional Skin Tests."**
29. **"Pilot Study for the Treatment of Previously Untreated Brain Tumor in Children."**
30. **"Combination Chemotherapy of Disseminated Testicular Carcinoma W/Cis Diaminodichloroplatinum W/ Diuresis, Bleomycin."**
31. **"A Clinical Trial to Evaluate Postoperative Radiation and Postoperative Systemic Chemotherapy in the Management of Resectable Rectal Carcinoma."**
32. **"A Clinical Trial to Evaluate Postoperative Immunotherapy and Postoperative Systemic Chemotherapy in the Management of resectable Colon Cancer."**
33. **"A Comparison of Three Iodinated Contrast Media For Excretory Urography."**
34. **"The Efficacy of Corticosteroid in the Treatment of Acute Asthma."**
35. **"The Usefulness of Computerized Axial Tomography in Evaluation of Pulmonary Metastases."**
36. **"Adjuvant Immunotherapy in Stage I Non-Oat Cell Lung Carcinoma."**
37. **"Bone Scanning in the Evaluation of Stress Fractures."**

38. "Treatment of Lower Respiratory Tract Infection with Ceforanide Vs. Cefazolin."
39. "Evaluation of A New Cephalosporin, HR-756, in the Treatment of Infections Caused by Susceptible Bacteria."
40. "Phase III Clinical Investigation of Indium DTPA for Cisternography."
41. "Evaluation of Ketoconazole in the Treatment of Systemic Mycoses."
42. "Controlled Study on the Use of Dopamine in Neonatal Asphyxia."
43. "An Evaluation of Profile Changes Following Vestibuloplasty Techniques."
44. "National Study of Contrast Media Reactions."
45. "A Quantitative Assessment of Facial Soft Tissue Response Following the Use of Methylprednisolone After Singular Orthognathic Surgical Procedures."
46. "Ventilatory Function After Flail Chest Injury."
47. "Combination Chemotherapy of Diffuse Malignant Pleural Mesothelioma with Either Adriamycin and Cytosan or Cytosan, Oncovin, Methotrexate and 5-Fluorouracil."
48. "Radionuclide Biliary Imaging Utilizing 99m TC - Pipida."
49. "Ventilation Changes Resulting from Drainage and Pleurodesis for Malignant Pleural Effusion."
50. "Terminal Deoxynucleotidyl Transferase (TdT) Immunofluorescence of Bone Marrow Smears."
51. "Surgical Adjuvant Chemotherapy of Stage II Breast Cancer: Two CMFVP regimens with or without a Subsequent Adriamycin Combination."

52. "A Protocol to Compare Segmental Mastectomy and Axillary Dissection with and without Radiation of the Breast and Total Mastectomy and Axillary Dissection."

53. "A Protocol to Compare Alkeran (L-PAM) + 5-Fluorocil (5-FU) with and without Adriamycin in the Management of Patients with Primary Breast Cancer and Positive Axillary Nodes Whose Tumors are Negative for Estrogen Receptors."

54. "A Protocol to Compare Alkeran (L-PAM) + 5-FU With and Without Adriamycin in the Management of Patients With Primary Breast Cancer and Positive Axillary Nodes Whose Tumors are Negative for Estrogen Receptors."

55. "A Randomized Controlled Trial of Indomethacin, PG12 and Heparin in the Acute Phase of Cerebral Ischemia."

56. "Radionuclide Biliary Imaging Utilizing 99m TC-P-Butyl-Ida."

57. "A Double Blind Controlled Study Comparing Indomethacin and Placebo in Prevention of Radiation Esophagitis."

58. "Combination Chemotherapy, Whole Body Radiotherapy and Non-Cross Resistant Chemotherapy for Small Cell Carcinoma of the Lung, Extensive Disease."

59. "A Comparative Study of Cefadroxil Vs. Cephalexin in the Treatment of Bacterial Pneumonia in Ambulatory Patients."

60. "Serial Angiographic Assessment of the Effect of Risk Factor Modification in Young Active Duty Navy Men."

61. "Establishment of Radioimmunoassay for Measuring Human Immunoglobulin."

62. "The Comparative Effectiveness of Combination Chemotherapy Alone With Radiation Therapy to Involved Field or Extended Field, in Poor Risk Patients with Stage I and II Hodgkin's Disease."

63. "Combination Chemotherapy of Multiple Myeloma."

64. "Protocol for Clinical Evaluation of Percutaneous Coronary Angioplasty."

- 65. "Use of VP16-213 in Combination with Cisplatin for Treatment of Recurrent Testicular Cancer in a Single Patient."**
- 66. "Emergency Use of Investigational Drug VM-26 Mono-Octnoin in the Case of R. Nevills."**
- 67. "Chemotherapy of Advanced Pancreatic Cancer- A Comparative Phase II Study."**
- 68. "A Study of the Effectiveness of Intensification with Two Courses of Cytosin Arabinoside and Daunorubicin Following Remission Induction with Acute Lymphocytic Leukemia."**
- 69. "A Randomized Study Comparing the Combination of Hormonal Therapy and Chemotherapy with Chemotherapy Alone for the Treatment of Advanced Breast Cancer in Women."**
- 70. "Surgical Adjuvant Chemotherapy of Stage II Breast Cancer: Two CMFVP Regimens with or without a Subsequent Adriamycin Combination."**
- 71. "Localized Small Cell Carcinoma of the Lung - A Phase II Study of Simultaneous Chemotherapy and Radiotherapy Vs. Sequential Therapy Vs. Chemotherapy Alone."**
- 72. "A Comparative Study of High Dose ARA-C Alone or Given Sequentially With L-Asparaginase for Remission Induction in Patients with Acute Myelogenous Leukemia After Failure of Initial Induction or in Relapse."**
- 73. "Vinblastine, DTIC, and Cis-Platinum (DDP) in the Treatment of Advanced or Recurrent Metastatic Malignant Melanoma."**
- 74. "Therapy of Chronic Myelogenous Leukemia in Blast Crisis with 5-Azacytidine Plus VP-16-213."**
- 75. "A Clinical Trial to Assess Sequential Methotrexate + 5-Fluorouracil in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors are Negative for Estrogen Receptors."**
- 76. "A Clinical Trial to Assess Tamoxifen in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors are Positive for Estrogen Receptors."**

77. **"Combination Chemotherapy with Mastectomy or Radiotherapy for Stage III Breast Carcinomas."**
78. **"Continuous Infusion Vinblastine with Bleomycin and Cisplatin for Treatment of Cancers of the Upper Digestive Tract and Lung."**
79. **"Evaluation of Light Scanning as a New Modality for Screening Women for Breast Cancer."**
80. **"A Phase II Trial of a Three Drug Regimen Consisting of Cytosan, 5-FU, and Cis-Platinum in Stage D Adenocarcinoma of the Prostate."**
81. **"Intergroup Rhabdomyosarcoma Study II (IRS 2)."**
82. **"A-Cop Plus for Non-Hodgkin's Lymphoma in Children."**
83. **"Intermittent High Dose Cytarabine for Treatment of Colorectal Adenocarcinoma: A Phase II Study."**
84. **"Stress Fracture as the Etiology of Acute Chondromalacia, Patella."**
85. **"A Comparative Study of Two Remission Induction Regimens of ARA-C for Acute myelogenous Leukemia: A Phase III Study."**
86. **"Treatment of Advanced Hodgkin's Disease: A Randomized Phase III Trial Comparing MOPP vs. ABVD vs. MOPP Alternating with ABVD."**
87. **"Emergency Use of Cis- Platinum (DDP), Vindesine (DVA), and Bleomycin in the Treatment of Esophageal Carcinoma."**
88. **"Therapy of CML in Blast Crisis with 5-Azacytidine Plus VP-16-213."**
89. **"Combination Chemotherapy for Metastatic Recurrent Cancer of the Breast. A Randomized Phase III Trial Comparing CAF VATH Vs. VATH Alternating with CMFVP."**
90. **"A Randomized Phase III Trial of Cytosine Arabinoside (ARA-C) and Platinum (CDDP) Vs. Vinblastine (VLG) and Platinum (CDDP) in Advanced Non-small Cell Lung Carcinoma."**

91. **"The Effect of Verapamil on Patients with Irritable Bowel Syndrome Who Have Diarrhea with or without Abdominal Pain."**
92. **"Computed Tomography and Peritoneal Lavage in Determining the Severity of Visceral Injury After Blunt Abdominal Trauma."**
93. **"Phase I Study of Indium-111 Labeled Murine Monoclonal Antibody for External Photoscanning of Melanoma and Other Tumors."**
94. **"Nonalcoholic Liver Disease in the Alcoholic."**
95. **"Indium-111 Oxine Labeled Granulocytes for Detection of Inflammatory Process in Humans."**
96. **"The Use of Isotretinoin in Prevention of Basal Cell Carcinoma."**
97. **"Protocol for the Evaluation of Radical Mastectomy and Total Mastectomy with and without Radiation in the Primary Treatment of Cancer of the Female Breast."**
98. **"A Clinical Trial to Compare L-PAM with L-PAM and 5-FU in the Management of Primary Breast Cancer Who Have One or More Positive Nodes."**
99. **"A Clinical Trial to Compare L-PAM and 5-FU vs. L-PAM and 5-FU and Methotrexate in the Management of Patients with Primary Breast Cancer Who Have One or More Positive Axillary Nodes."**
100. **"Emergency Drug Use of Investigational Drug AZQ ICO Theresa Fousel."**
101. **"Approval of the Final Case Report on the Emergency use of Investigational Drugs Methyl-GAG and Ifosphamide."**
102. **"Carboplatin (CBDCA) vs. Iproplatin (CHIP) in Advanced Non-small Cell Lung Carcinoma, Phase II."**
103. **"Regional Stage III NSCLC Chemotherapy and Radiation Therapy vs. Radiation Therapy Alone."**

104. **"Mitomycin C and Cisplatin vs. Adriamycin and Cisplatin for Malignant Mesothelioma Phase II."**
105. **"Cytosine Arabinoside and Cisplatin for Advance Stage Breast Cancer."**
106. **"Cold Cardioplegia - Effects on Phrenal Nerve Conduction, Diaphragm Motion Lung Volumes."**
107. **"Diagnostic Utility of Bone Scans in Sarcoidosis and Correlation of Bone Involvement in Disease Activity."**
108. **"Adjuvant CDF for Pathologic Stage II Breast Cancer: Randomization among Intensive CDF for Four Months vs. Standard Dose CDF for Six Months."**
109. **"Three Arm Clinical Trial Comparing Short Intensive Adriamycin-Cyclophospham IDE With or Without Interval Reinduction Chemotherapy (CMF) to Conventional CMFIN Positive Node Patients Who Are Age 49 or Younger."**
110. **"Three Arm Clinical Trial Comparing Tamoxifen Alone or With Short Intensive Adriamycin-Cyclophosphamide and Tamoxifen in Node Positive Patients Ages 50-59 With Positive Primary Assays and 50-70 Regardless of Receptor Status."**
111. **"National Intergroup Protocol for Intermediate Thickness Melanomas 1.0 to 4.0 mm."**
112. **"Approval of the Final Report on the Emergency Use of Investigational Drug Cyanoacrylate."**
113. **"One Time Emergency Use of Investigational Agent Cicplatin/Thiosulfate ICO t. Ary"**
114. **"Emergency Use of VM-26 ICO Y. Borjas"**
115. **"Non-Emergency Use of an Investigational Procedure ICO Mckinley Wright."**
116. **"Comparison of Four Methods of Measuring Extension of the Lumbar Spine."**
117. **"Treatment of Calcinosis Circumscripta with Probecid - A Pilot Study"**

118. **"One Time Use of Investigational Drug, Absolute Alcohol, on a Single Patient ICO Brenda L. Ferrin"**
119. **"Fever and Bacteremia Following Bronchoscopy: A Prospective Study to Determine Frequency, Source of Bacteria, and Implications for Endocarditis Prophylaxis."**
120. **"Investigational Agent Status Report (Ifosphamide, VP-16)"**
121. **"A Clinical Trial to Evaluate Natural History and Treatment of Patients with Non-Invasive Intraductal Adenocarcinoma."**
122. **"Phase III Trial of Intensive Treatment for Adult Acute LL: A Comparison of Combination Chemotherapy Plus ALternating Mitoxantrone and Daunorubicin vs. Combination Chemotherapy Plus Daunorubicin."**
123. **"Echinomycin for Advanced Breast Cancer: A Phase II Study."**
124. **"Combination Chemotherapy for Remission Induction and Maintenance for 1) Recurrent CLL Occurring 6 Months or Greater After Elective Cessation of Therapy - Hodgkin's Lymphoma and 2) Children with Occult Testicular LL After 3 Years of Continuous Complete Remission."**
125. **"Utility of Endoscopy for X-ray Negative Dysphagia: A Prospective Analysis."**
126. **"Management Strategies Based on Risk After Acute Myocardial Infarction."**
- 127.. **"Trimetrexate (NSC #352122) for Non-Hodgkin's Lymphoma - Phase II."**
128. **"Combination Chemotherapy With Intensive ACE/PCE and Radiation Therapy to the Primary Tumor and Pro-Phylactic Whole Brain Radiation Therapy With or Without WAR-Farin in Limited Small Cell Carcinoma of the Lung Phase III."**
129. **"The Epidemiology of the Acute Leukemia's in Adults With Special Reference to Cytogenetically Determined Sub Group."**

130. **"Combination Chemotherapy for Advanced Hodgkin's Disease."**
131. **"Cyclophosphamide Versus Cyclophosphamide Plus Alpha-2 Interferon in the Treatment of Follicular, Low Grade Lymphomas: Phase III."**
132. **"A Master Protocol to Study Single Agent Induction Chemotherapy Versus Standard Chemo for Stage IV."**
133. **"Recombinant Interleukin-2 and B-Interferon for the Relapsed or Refractory Lymphoma. A Limited Access Phase II Study."**
134. **"A Dose Response Trial of Megestrol Acetate in Advanced Breast Cancer: A Phase III Study."**
135. **"An Epidemiologic Study of the Etiologic Agents of Pneumonia Among Recruits at Recruit Training Center, San Diego, and the Utility of Rapid Diagnostic."**
136. **"Pulmonary Function Test in Normal Filipino Males."**
137. **"5-Axacytidine to Induce Differentiation in Myelodysplastic Syndromes, A Phase I-II Study."**
138. **"Carboplatin for Malignant Mesothelioma Phase II"**
139. **"Randomized Comparison of M-BACOD and CHOP Combination Chemotherapy in Advanced Stage Diffuse Large Cell (Histiocytic) and Diffuse Mixed Non-Hodgkin's Lymphoma."**
140. **"A Dose Range Study of Recombinant Gamma Interferon in the Treatment of NSCLC Assessing Disease Response and Serial Measurements of Immunomodulatory Effects: Phase II."**
141. **"Recombinant B Interferon in Advanced NSCLC: a Phase II Study."**
142. **"Comprehensive therapy of Ewing's Sarcoma: Tailored vs. Standard Radiation Therapy."**
143. **"Emergency One Time Use of Rifampin on a Single Patient."**
144. **"PACE and Gamma-Interferon for Extensive Small Cell Carcinoma of the Lung."**

145. **"A Clinical Trial to Compare Adjuvant Leucovorin and 5-FU (LV + 5-FU) with Adjuvant MeCCNU Vincristine and 5-FU (MOF) in Patients with Duke's B and C Colon Cancer."**
146. **"Incidence of Deep Venous Thrombosis in Major Oral and Maxillofacial Surgical Patients."**
147. **"Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia: A Multi Center Cooperative Study."**
148. **"Treatment of Children with Newly Diagnosed ANLL Using High Dose Cytosine Arabinoside and Etoposide + 5 Azacytidine for Intensification of Early Therapy."**
149. **"Management of Stress Fractures with Pneumatic Leg Brace."**
150. **"The Utility of Urinalysis for Screening for Occult Renal Injury in Patients with Minor Trauma."**
151. **"The Treatment of Advanced Hodgkin's Disease with Model C Followed by MVPP: A Limited Access Pilot Study."**
152. **"PACE and Gamma Interferon Recombinant B Interferon in Advanced NSCLC: A Phase II Study."**
153. **"Evaluation of UGI Bleeding in Military Personnel Utilizing Duodenoscopy."**
154. **"A Pilot Study of Cyclophosphamide, Doxorubicin, Vincristine, Prednisone, Etoposide, (CHOPE) in Diffuse Lymphomas."**
155. **"Trial of Cystectomy Alone Versus Neoadjuvant M-VAC + Cystectomy in Patients With Locally Advanced Bladder Cancer."**
156. **"Phase II Trial of a 5-Drug Induction Regimen With Intensive Consolidation in Adult Lymphoblastic Leukemia."**
157. **"CHOPE/ABVD for Advanced Hodgkin's Disease, A Limited Access Phase II Study."**
158. **"A Clinical Trial to Determine the Worth of Chemo and Tamoxifen Over Tamoxifen Alone in the Management of Patients"**

With Primary Invasive Breast Cancer, Negative Axillary Nodes and Estrogen Positive Tumors."

159. "A Clinical Trial to Compare Sequential Methotrexate 5-FU (M-F) With Conventional CMF in Primary Cancer Patients With Negative Nodes and Estrogen Receptor Negative Tumors."

160. "A Unified Trial to Compare Short Intensive Pre-Op Systemic Adriamycin Cyclophosphamide Therapy With Similar Therapy Administered in Conventional Post-Operative Fashion."

161. "A Clinical Trial to Determine the Worth of Tamoxifen and the Worth of Breast Radiation in the Management of Patients With Node-Negative, Clinically Occult, Invasive Breast Cancer Treated by Lumpectomy."

162. "Studies of Thrombocytopoiesis in Patients with Myeloproliferative Disorders."

163. "GRPC Protocol - Fundarabine Phosphate in patients with Refractory CLL."

164. "Abrogation of Drug Resistance to Cisplatin and 5-FU in Patients with Metastatic Colorectal Cancer Through the use of Diltiazam."

165. "Protocol for Prospective Correlative Clinical Trial of the Anti Cancer Drug Response Assay - Recurrent Breast Cancer Treated with Adriamycin."

166. "The Effects of Terfenadine Alone and in Combination with Ipratropium Bromide on Pulmonary, Cardiovascular and Cognitive Function in Military Personnel with Mild or Moderate Asthma."

167. "Treatment of Acute Infectious Arthritis in Adults: A Prospective Comparison of Drainage Methods."

168. "Phase III Comparison of Adjuvant Chemotherapy With or Without Endocrine Therapy in High-Risk, Node-Negative Breast Cancer Patients."

169. "Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer With Cisplatin Plus Etoposide With Either Bleomycin or Ifosfamide."

170. "Phase II - Conservative Treatment of Adenocarcinoma of the Distal Rectum: Local Resection Plus Adjuvant 5-FU/Radiation Therapy."

171. "A Phase II Study of Etoposide, Vinblastine, Doxorubicin (EVA) and Subtotal Nodal Radiation in Poor Risk, Early Stage Hodgkin's Disease."

172. "A Clinical Trial to Evaluate the Effect of Dose Intensification and Increased Cumulative Dose of Postoperative Adriamycin-Cyclophosphamide (AC) Therapy on the Disease-Free Survival."

173. "A Clinical Trial to Assess the Relative Efficacy of 5-FU+Leucovorin, 5-FU+Levamisole, and 5-U+Leucovorin+Levamisole in Patients With Duke's B and C Carcinoma of the Colon."

174. "National Wilms' Tumor Study."

175. "Utility of Endoscopy for X-Ray Negative Dysphagia : A Prospective Analysis."

176. "Single Dose Cefotetan or Cefoxitin vs. Multiple Dose Cefoxitin as Prophylaxis in Patients Undergoing Appendectomy for Non-Perforated Appendicitis."

177. "Methods of Diagnosis of Cartilaginous and Ligamentous Knee Injuries Associated With Lower Extremity Fractures Using Physical Exam, Stress Radiographs and Magnetic Resonance Imaging."

178. "Use of Magnetic Resonance Imaging to Prospectively Evaluate the Healing Ability of Scaphoid Fractures."

179. "Hyperfractionation Radiotherapy and Chemotherapy in Limited Stage Small Cell Lung Carcinoma."

180. "Dose Intensification of Methotrexate and 6-Mercaptopurine for Acute Lymphocytic Leukemia in Children (Alinc # 15)."

181. "Up-Front Alternating 6-MP/MTX Versus Up-Front Alternating Chemotherapy for Acute Lymphocytic Leukemia in Children (Alinc # 15)."

182. "Underlying Metabolic Bone Disease in Femoral Neck Stress Fractures."

183. **"The Efficacy of Arthroscopic Bankart Repair in First Time Anterior Shoulder Dislocation."**
184. **"Oral Versus Intravenous Etoposide in Combination With Intravenous Cisplatin in Extensive Small Cell Lung Cancer: Phase III."**
185. **"A Phase III Intergroup Trial - A Prospective Random Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus - Chemotherapy + Surgery Versus Surgery Alone for Patients With Local Regional Disease."**
186. **"Intensive Doxorubicin, Surgery, CMF and Radiation Therapy for Stage III Breast Cancer - A Study of Efficacy With Pharmacokinetic and Antigenic Monitoring Phase II."**
187. **"Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex + Tamoxifen) in Premenopausal Women With Axillary Node Positive, Receptor Positive Breast Cancer."**
188. **"Phase III Comparison of Combination Chemotherapy (CAF) and Chemo-hormonal Therapy (CAF + Zolodex or CAF + Tamoxifen) in Premenopausal women with Axillary Node Positive, Receptor Positive Breast Cancer."**
189. **"Phase III Comparison of Adjuvant Chem-Dendocrine Therapy With CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal PWS/Involved Axillary Lymph Nodes and Positive Receptors."**
190. **"A Phase Trial of G-CSF Versus Placebo During Remission Induction and Consolidation Chemotherapy for Adult Acute Lymphoblastic Leukemia."**
191. **"A Phase III Trial of Vinblastine/Cisplatin/ Radiation Therapy With or Without Carboplatin (NSC #241240) for Inoperable Stage IIIA Stage IIIB Non-Small Cell Lung Cancer."**
192. **"A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin with or without Interferon Alpha-2a in Patients with Dukes' B and Carcinoma of the Rectum."**

193. **"Subcutaneously Administered Recombinant Human Interleukin-2 and Interferon Alpha 2a for Advanced Breast Cancer."**
194. **"A Phase III Study of CAF-Leucovorin vs CAF for Visceral Crisis Breast."**
195. **"Intergroup Post-Operative Adjuvant Interferon Alpha-2B in Interferon Alpha-2B in Resected High Risk Primary and Regionally Metastatic Melanoma."**
196. **"Trial of Adjuvant Chemo-Radiation After Gastric Resection for Adenocarcinoma."**
197. **"Bone Structure Analysis: Tibial Bone Mineral Density (BMD) as a Predictive Factor for Tibial Stress Fractures in Navy SEAL Trainees."**
198. **"Phase III Randomized Study of ALL-Trans Retinoic Acids Versus Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients With Previously Untreated Acute Promyelocytic Leukemia."**
199. **"A Randomized Study Comparing Standard Versus Moderately High Megestrol Acetate in Advanced Prostate Cancer."**
200. **"Cryovalve Heart Valve Allografts."**
201. **"A Clinical Trial to Evaluate the Dose Intensification and Increase in the Cumulative Dose of Post-Operative Adriamycin-Cyclophosphamide (AC) Therapy With G-CSF on the Disease Free Breast Cancer."**
202. **"High Intensity, Brief Duration Chemotherapy for Diffuse Small Non-cleaved Cell Lymphoma and the L-3 Subtype of ALL: A Pilot Study of a Multidrug Regimen."**
203. **"Edatrexate (20-ethyl-diaza-aminopterin) for Malignant Melanoma : A Phase II Study."**
204. **"Color Doppler Ultrasound Finding in Transitional Cell Carcinoma of the Bladder and Kidney."**
205. **"A Phase II Study of High Dose Cyclophosphamide + Recombinant Granulocyte-Colony Stimulating Facto in the Treatment of Follicular, Low Grade, Non-Hodgkin's Lymphoma."**

206. "Phase III Protocol for the Evaluation of 5-FU Versus 5-FU + PALA or 5-FU + Oral Leucovorin or 5-FU + IV Leucovorin or 5-FU + NIFN Alpha 2A in Patients With Advanced Colorectal Cancer."
207. "A Comparison of "Best Local-Regional Therapy" With or Without Chemotherapy for Stage IIIA (N2) Non-Small Cell Lung Cancer: A Randomized Phase III Study."
208. "Impact of Stellate Ganglion Blockade of Diaphragmatic Function."
209. "Randomized Treatment of Jones' Fractures."
210. "Recombinant Urokinase vs. Operative Intervention as Initial Therapy for Acute Lower Limb Arterial Occlusion."
211. "Treatment of AIDS-Associated Non-Hodgkin's Lymphoma With Cyclophosphamide/ Doxorubicin Vincristine/ Prednisone/ Etoposide (CHOPE), Zidovu-Dine Granulocyte-Colony Factor (GCSF) and RHEPO."
212. "A Phase II Trial of 2-Chlorodeoxyadenosine in Advanced Stage, Previously Untreated Low-Grade Lymphomas."
213. "A Phase II Trial of 2-Chlorodeoxyadenosine (2-CDA) in B-Cell Chronic Lymphocytic Leukemia Patients Who Have Previously Failed Therapy With Fludarabine Phosphate."
214. "A Phase II Trial of Induction Chemo-Therapy Plus Concurrent Chemotherapy for Poor Prognosis Locally Advanced, Previously Untreated Carcinomas of the Anal Canal."
215. "Hip Arthrodesis: A New Technique."
216. "Phase II Study of Taxotere (NSC 628503) in Previously Treated Non-Hodgkin's Lymphoma."
217. ""Phase I Study of Topotecan and Taxol."
218. "Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil Versus 5-FU and Levamisole in Selected Patients With Completely Resected Colon Cancer."
219. "Topotecan for Advanced Breast Cancer a Phase II Study."

- 220. "Dose Intensive Multi-Modality Therapy in Limited Small Cell Lung Cancer: A Phase II Limited Access Study."**
- 221. "A Feasibility Study of Adjuvant Chemotherapy With Dose-Intensified Cyclophosphamide/Doxorubicin (CA)+G-CSF in Patients With Operable Breast Cancer and Histologically Involved Axillary Lymph."**
- 222. "Treatment of Advanced Hodgkin's Disease: A Randomized Phase III Trial Comparing MOPP Versus ABVD Versus MOPP Alternating With ABVD."**
- 223. "Randomized Trial of Subtotal Nodal Irradiation Versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III."**
- 224. "Evaluation of the Biliary Tree During Laproscopic Cholecystectomy: Ultrasonography vs. Intraoperative Cholangiography."**
- 225. "Angiographic Antioxidant Atherosclerosis Trial (AAAT)"**
- 226. "Phase II Study of Cyclophosphamide, Prednisone, and Infusional Doxorubicin, Vincristine and Etoposide (I-CHOPE) in Diffuse Lymphomas Relapsed/Refractory to Bolus Therapy."**
- 227. "Etoposide, Cisplatin and Radiation Therapy With or Without Tamoxifen in Limited Stage Small Cell Lung Cancer: A Randomized Phase III Study."**
- 228. "A Phase II Trial of Lineage-Specific Consolidation Therapy for Adult Acute Lymphoblastic Leukemia (ALL): Anti-B4-Blocked Ricin for B-Lineage ALL and High Dose Cytarabine for Non-B-Lineage ALL."**
- 229. "Comparison of Central Venous Pressures in the Superior and Inferior Vena Cava in Children."**
- 230. "Hip Arthrodesis: Allergic Fungal Sinusitis, Immunotherapy."**
- 231. "Hematopoietic Growth Factor Versus Prophylactic Antibiotic Support in Advanced Non-Small Cell Lung Cancer: A Prospective Double-Blind Randomized Control Trial."**

- 232. **"A Dose Response Trial of Megestrol Acetate for the Treatment of Cachexia in Patients With Advanced Lung or Colorectal Cancer."**
- 233. **"Trial of Shortened Therapy Without Maintenance for the Treatment of Localized Non-Hodgkin's Lymphoma: A Phase III Study."**
- 234. **"Analysis of Proto-Oncogene Expression in Acute Nonlymphocytic Leukemia."**
- 235. **"T-Cell, #3 Pilot Study."**
- 236. **"Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood."**
- 237. **"Etoposide, Vinblastine, Doxorubicin, (EVA) as the Primary Treatment of Advanced Hodgkin's Disease in Relapsed From MOPP or MOPP Variants: Phase II."**
- 238. **"A Phase III Comparative Study of Post Remission Intensive ARA-C in Patients With Acute Non-Lymphocytic Leukemia in First Remission."**

G. **Naval Hospital Oakland.** Present structure opened in 1968 with Nuclear Medicine opening in 1970.

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Queried individuals stationed at NH Oakland
- (5) Requested CV from primary researchers to assist in literature review.

(6) Search of the Nuclear Regulatory License File at the Navy Environmental Health Center.

(7) Search of the Nuclear Regulatory Commission License files.

(8) Literature Search by Author.

Individuals consulted:

Diane Nixon, National Archives, Laguna (714) 643-4241

Sharon Roadway, Federal Records Center, Laguna (714)643-4241

Waverly Lowell, National Archives, San Bruno (415) 876-9009

Richard Boyden, Federal Records Center, San Bruno (415)-876-9009

William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216

LCDR Mary Jo Ramsey, MSC, USN, NH Oakland (510) 633-5771

Dennis Honeychurch, Radiopharmist, NH Oakland

LCDR Dean Taylor, MSC, USN, NH San Diego

Records found:

(1) Clinical investigation records are at NAVHOSP Oakland for the years 1976 to the present.

(2) No records found in the regional archives.

(3) Federal Personnel Records Center, St. Louis holds 1,412 cubic feet from 1968-1978 and 385 cubic feet from 1974-1990.

(4) Copies of studies may be in journals.

(5) Radioisotope License File on record with the Navy Environmental Health Center.

(6) Radioisotope License File on record with the Nuclear Regulatory Commission.

List of Experiments or Possible Experiments: Following titles of studies have been found or reported. Some represent protocols and some represent studies reported in the open literature.

1. "Localization of Ga-67 Citrate in Plasma Cell Granuloma of the Lung."

2. **"Supernumerary Toe Arising From the Medial Cuneiform."**
1979
3. **"Splenic Artifact Caused by Barium in the Colon."**
4. **"Functional Asplenia After Thorotrast Administration."**
5. **"Gallium-67 Uptake in a Benign Thymic Cyst."**
6. **Soft-Tissue Uptake of Tc-99m MCP in Secondary Scrotal Lymphodema."**
7. **The Early Determination of the Incidence and Healing of Aseptic Necrosis of the Femoral Head following Trauma Utilizing Radioisotope Scan**
8. **The Hepatic Abnormalities of Diabetes Mellitus. The Abnormalities of Radionuclide Scan in Relation to Diabetic Control**
9. **Xenon 127 Gas for Inhalation (IND 14,5437) 1978**
10. **Indium Oxine In 111 Labeled Cellular Blood Components**
1981
11. **Technetium 99m Sulfur Colloid of Oral Use 1981**
12. **NCOG 0R81 All Sites, Phase I & II Protocol of Heavy Charged Particle Radiotherapy for Locally Advanced and or Recurrent Cancers of Multiple Sites and Types 1981**
13. **NCOG 3L91 Liver**
14. **NCOG 7H61, A Randomized Phase III Study of Radiation Therapy with or without Chemotherapy for Remission Induction and Multidrug Chemotherapy Program for Remission Consolidation and Maintenance in Inoperable Squamous Cell Carcinoma of the Head and Neck**
15. **NCOG 9M91 A Phase I-II Study of Combination Chemotherapy and Sequential Hemibody Radiation Therapy in the Treatment of High**
17. **Tumor Burden Multiple Myeloma**

- 18. NCOG 13L-80-1 Treatment of Adult Lymphoblastic Lymphoma, A Phase II Study using Intrathecal Methotrexate with Whole Brain Radiotherapy Combined with Systemic Methotrexate**
- 19. NCOG 50-82-1 A Phase II Study of Pelvic and Abdominal Radiotherapy vs. Cisplatin Adriamycin, and Cyclophosphamide**
- 20. NCOG 20-83-1, A Phase III Trial of Seven-drug Versus Three-drug Chemotherapy Regimens with or without Cranial Irradiation (PCI) for Undifferentiated Small Cell Anaplastic Lung Cancer**
- 21. Scintigraphic Arthrography Using 99m Technetium Sulfur Colloid**
- 22. Early Determination of Femoral Head Vascularity Using Technetium 99m Sulfur Colloid and Quantitative Technique**
- 23. Use of Quantitative Computed Tomography (QCT) in Assessing Bone Mass Changes in Diabetic Patients**
- 24. 99m Tc-HMPAO Labeled Leukocytes and Platelets: Basic and Clinical Studies**
- 25. Comparison of Thallium Scintigraphic Images after Transesophageal Atrial Pacing (TAP) and Dipyridamole for the Detection of Atherosclerotic Coronary Artery Disease**
- 26. Evaluation of Subcutaneous Gallium-Citrate Injection for the Imaging of Malignant Abdominal Adenopathy**
- 27. Radiographic Correlation of Leg Length Inequality in Patients with Total Hip Arthroplasty**
- 28. Radionuclide Imaging of Chronic Anterior Cruciate Ligament Deficient Knees**
- 29. A Prospective Comparison of Air-Contrast Barium Enema Plus Procto-Sigmoidoscopy with Colonoscopy in the Screening of Asymptomatic Persons with a History of Colorectal Cancer in First Degree Relatives**
- 30. CALGB 9130, A Phase II Trial of Vinblastine/Cisplatin/Radiation Therapy with or without Carboplatin for Inoperable Stage IIIA and Stage IIB Non-small Cell Lung Cancer**

- 31. Acromion Morphology in the Active Duty Population: Plain Roentgenogram Analysis**
- 32. NSAP C-01, A Clinical Trial to Evaluate Post-operative Immunotherapy and Postoperative Systemic Chemotherapy in the Management of Resectable Colon Cancer**
- 33. NSABP B-11, A Clinical Trial to Compare PF with and without Adriamycin in the Management of Patients with Primary Breast Cancer and Positive Axillary Nodes Whose Tumors are Negative for Estrogen Receptors**
- 34. NSABP B-14, A Clinical Trial to Assess Tamoxifen in Patients with Primary Breast Cancer and Negative Axillary Nodes whose Tumors are Positive for Estrogen Receptors**
- 35. NSABP B-12, A Clinical Trial to Compare PFT with and without Adriamycin in the Management of Patients with Primary Breast Cancer and Positive Axillary Nodes whose Tumors are Positive for estrogen Receptors**
- 36. NSABP B-13, A Clinical Trial to Assess Sequential Methotrexate 5 Fluorouracil in Patients with Primary Breast Cancer and Negative Axillary Nodes whose Tumors are Negative for Estrogen Receptors**
- 37. NSABP B-16, A Three-Arm Clinical Trial Comparing Tamoxifen Alone with L-PAM, 5-FU, and Tamoxifen or Short Intensive Adriamycin-Cyclophosphamide and Tamoxifen in Positive Node Patients**
- 38. NSABP B-18, A Unified Trial to Compare Short Intensive Preoperative Systemic Adriamycin Cyclophosphamide Therapy with Similiar Therapy Administered in Conventional Postoperative Fashion**
- 39. NSABP B-20, A Clinical Trial to Determine the Worth of Chemotherapy and Tamoxifen over Tamoxifen Alone in the Management of Patients with Primary Invasive Breast Cancer, Negative Axillary Nodes, and Estrogen Receptor Positive Tumors**
- 40. NSABP C-04, A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin, 5-FU + Levamisole, and 5-FU + Leucovorin + Levamisole in Patients with Dukes' B and C Carcinoma of the Colon**

41. CALGB 9033, Oral Versus Intravenous Etoposide in Combination with Intravenous Cisplatin in Extensive Small Cell Lung Cancer: Phase III

42. NSABP B-23, A Clinical Trial Comparing Short, Intensive AC + Tamoxifen with Conventional CMF + Tamoxifen in Node-Negative Breast Cancer Patients with ER-Negative Tumors

43. NSABP C-05, A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin with or without Interferon ALFA-2A

H Naval Hospital Portsmouth: Radiation Oncology's records extend back to the early 1950's where therapeutic X-Ray units were in use. First brachytherapy case was a Sr-90 treatment in 1956. Nuclear Medicine studies started in 1961 or 1962.

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Queried Command Historian, and prior Chiefs of Radiology.
- (5) Search of the Nuclear Regulatory License File at the Navy Environmental Health Center.
- (6) Search of the Nuclear Regulatory Commission License files

Individuals consulted:

Bob Plowman, National Archives, Philadelphia (215) 597-3000
Joseph Sheehan, Federal Records Center (215) 5694/9753
Dan Bennett, Federal Records Center, Philadelphia (215) 951-5698
Rich Boyland, National Archives, Suitland, MD (301) 763-1083
Velicia Chance, Federal Records Center, Suitland, MD (301) 763-7430
Millie Sturate, Federal Records Center, Suitland, MD (202) 433-4217
Tom Steinichen, Federal Records Center, Atlanta, GA (404) 763-7474
William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216
CDR Paul Blake, MSC, USN, NH Portsmouth
CAPT Pishnotti, MC, USN (Ret), NH Portsmouth

CAPT Theodore Conoway, MSC, USN (Ret) Historian
CAPT Francis Holmes, MC, USN (Ret) Chief, Radiology 1959-1969

Records found:

- (1) No records were located in the Regional Records Centers or National Archives.
- (2) The Federal Personnel Records Center, St. Louis holds 1,937 cubic feet for the years 1969-1973 and 9,809 cubic feet for the years 1974-1990 (Volume of records for years prior to 1969 was not requested on the original request based on estimate of start of nuclear medicine clinic. Volume of records starting in 1944 has been requested).
- (3) CAPT Conoway stated that in the late 1950's BUMED directed all the East Coast naval hospitals to ship their retired hospital records to the GSA Record Center, Garden City, Long Island, NY. CAPT Conoway shipped NAVHOSP Portsmouth's records for 1944-1951 to this center. These records were subsequently destroyed by GSA.
- (4) Radiation Safety Committee minutes 1976 to present.
- (5) Radioisotope License File on record with the Navy Environmental Health Center.
- (6) Radioisotope License File on record with the Nuclear Regulatory Commission.

List of Experiments or Possible Experiments:

- (1) Interviews of previous staff and search of the Radiology Department's files identified the following studies:
 - 1 "Postpartum Chest X-Ray Studies of 1,000 Patients to determine Incidence of Pneumopericardium and Pneumomediastinum."
 2. "Closed Internal Fixation of Fractures Using Image Intensifier Control."
 3. "Evaluation of Post-Due Obstetric Patients."
 4. The Management of Cervical Intrasphthelial Neoplasia with CO2 Laser

- 5. Diagnosis and Presurgical Evaluation of Biliary and Pancreatic Disorders Utilizing a Fiberisfunoscope**
- 6. Evaluation of Inferior Esophageal Sphincter Competence by Esophagoscopy**
- 7. Evaluation to Post-Due Obstetric Patients**
- 8. Ambulatory Treatment of Legg-Calve-Perthes' Disease**
- 9. Participation in Acute Leukemia Group B**
- 10. Closed Internal Fixation of Fractures Using the Image Intensifier**
- 11. Protocol for the Treatment of Acute Mvelocytic Leukemia and Related Disorders. Number PWH 001**
- 12. Protocol for the Use of Adrianvcin in Certain Matastatic Malignant Tumors**
- 13. Immunologic Evaluation and Therapy of Patients with Carcinoma of the Lung**
- 14. Clinical Use of a Hypothalamic Releasing Hormone: Conadotropin Releasing Hormone**
- 15. Evaluation of Freeze-Dried Bone in the Treatment of Periodontal Osseous Defects**
- 16. Classification and Treatment of Fractures of the Base of the Fifth Metacarpal**
- 17. Study of Gastric Ulcers**
- 18. Use of CA(OB)2 to Prevent. Arrest and/or Reverse the External and/or Resorption of Teeth Following Their Luxation or Avulsion**
- 19. Platinum-Adrianycin Therapy**
- 20. Prospective Study of Ankle Fractures**
- 21. Minoxidil as an Antihypertensive in Patients Refractory to Available Medications**

- 22. Immunologic Evaluation and Phase One Immunotherapy Trial in Patients with Carcinoma**
- 23. Extracranial Cerebrovascular Reconstruction-Cerebral Blood Flow and Neuropsychological Function**
- 24. ECOG EST 5177. Phase III An Adjuvant Clinical Trial to Compare Cyctoxan. Methoraxate. 5FO (CMF) Lo CMF. Prednisone (CMFP) With or Without Tamoxifen in Pre-menopausal Women with Stage II Breast Cancer**
- 25. GOG 44. Evaluation of Adjuvant Vincristine. Dactinonycin and Cyclophosphanide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of All Gross Tumor**
- 26. GOG 45. Evaluation of Vinblastine. Bleomycin and Cisplatin to Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary**
- 27. GOG 63. A Clinical Pathologic Study of Stages IIB. III and IVA Carcinoma of the Cervix**
- 28. GOG 56. A Randomized Comparison of Hydroxyurea vs Misonidazole as an Adjuvant To Radiation Therapy in Patients with Stages IIB, III, and IVA Carcinoma of the Cervix and Negative Para-zortic Nodes. Phase III**
- 29. GOG 59. Extended Field Radiation Therapy and Hydroxydrea Followed By a Randomized Comparison of Ciaplatin or no Further Therapy in Patients with Cervical Squamous Cell Carcinoma Metestatic to High Common IIIac and/or Para-aortic Lymph Nodes. Phase III**
- 30. GOG 37. A Randomized Study of Radiation Therapy vs Pelvic Node Resection for Patients with Invasive Squamous Cell Carcinoma of the Vulva Having Positive Groin Nodes. Phase III**
- 31. GOG 49. A Surgical Pathologic Study of Women with Invasive Carcinoma of the Cervix and Randomly Assigned Radiation Therapy vs No Further Therapy in Selected Patients. Phase III**
- 32. GOG 50. A Study of Adrianycin as as Post-operative therapy of Ovarian...**

- 33. GOG 14. GOG 7602. All Stage 1C and II (A,B,C) and Selected Stage...**
- 34. GOG 54. The Treatment of Women with Malignant Tumors of the Ovarian Stroma with Combination...**
- 35. GOG 34. A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma Stage I and Occult Stage II**
- 36. CCG-193. Treatment of Previously Untreated Acute Lymphoblastic Leukemia for Pediatric Patients with Defavorable Prognostic Features**
- 37. GOG 64. A Randomized Comparison of Rapid vs Prolonged (24 hour) Infusion of Cisplatin in Therapy of Squamous Cell Carcinoma of the Cervix**
- 38. GOG 42. Treatment of Recurrent of Advanced Uterine Sarcoma-A Randomized Comparison of Adriamycin vs Adriamycin and Cyclophosphamide**
- 39. GOG 73. A Clinicopathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy**
- 40. GOG 261. A Phase II Trial of Tamoxifen in Patients with Advanced Epithelial Ovarian Carcinoma**
- 41. GOG 56. Ultrastructural Staging and Therapeutic Considerations in Small Cell Carcinoma of the Cervix. Phase II**
- 42. GOG 77. A Randomized Study of Carboplatin vs CHIP in Advanced Carcinoma of the Cervix**
- 43. GOG 75. Postoperative Pelvic Radiation in Stage I and II Mixed Mesodermal Tumors of the Uterus. Phase II**
- 44. GOG 20W. A Phase II Trial of Echinomycin in Patients with Advanced Pelvic Malignancies**
- 45. GOG 81A. Master Protocol for Hormonal Treatment of Advanced or Recurrent Carcinoma of the Endometrium**

46. **GOG 78. Evaluation of Adjuvant 7P16. Bleomycin and Cisplatin Therapy in Totally Resected Choriocarcinoma. Endodermal Sinus Tumor. Embryonal Carcinoma and Grade 3 Lanoture Teratoma of the Ovary. Pure and Mixed with Other Elements**
47. **GOG 82. A Phase III Trial Comparing Combination Chemotherapy with Whole Abdominal Radiation Therapy for Stage III Optimal Epithelial Ovarian Cancer with No Gross Residual Disease or Gross Residual Disease Less Than 1 cm.**
48. **GOG 71. Treatment of Patients with Suboptimal (Bulky) Stage 18 Carcinoma of the Cervix**
49. **GOG 76D. A Phase II Trial of Dibromoducito in Patients with Advanced Squamous Cell Carcinoma of the Cervix**
50. **GOG 90. Evaluation of Cisplatin. Etoposide and Bleomycin (BEP) Induction Followed by Vincristine. Dactinomycin and Cyclophomphenide (VAC). Consolidation in Advanced Ovarian Germ Cell Tumors**
51. **GOG 97. A Phase III Randomized Study of Cyclophosphanide and Cisplatin in Patients with Suboptimal Stage III and Stage IV Epithelial Ovarian Carcinoma Comparing Intensive and Bonintensive Schedules.**
52. **GOG 81E. A Phase III Trial of High vs Intermediate Dose Medroxyprogesterone Acetate (MPA) in Patients with Advanced or Recurrent Endometrial Carcinoma with Unknown Estrogen and Progesterone Levels**
53. **GOG 95. Randomized Clinical Trial for the Treatment of Women with Selected Stage IC and II (A, B, C) and Selected Stage lai. IRI and IRii and IBii Ovarian Cancer**
54. **GOG 81C. A Phase I-II Trial of Medroxyprogesterous Acetate (MPA) in Patients with Advanced or Recurrent Endometrial Carcinoma Negative for Estrogen and Progestone Receptors**
55. **GOG 85. A Randomized Comparison of Hydroxyurea vs 5FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stages IIB. III and IV Carcinoma of the Cervix and Negative para-aortic Nodes**

- 56. GOG 86E. A Phase II Trial of Vincristine (TCR) Given as a Weekly Intravenous Bolus in Advanced or Recurrent Carcinoma**
- 57. GOG 76F. A Phase II Trial of Gallium Nitrate in Patients with Advanced Squamous Cell Carcinoma of the Cervix**
- 58. GOG 101. A Phase II Evaluation of Pre-operative Chemoradiation for Advanced Vulvar Cancer**
- 59. Effect of Radiation Therapy on Serum Angiotensin Converting Enzyme Levels in Patients with Bronchogenic Carcinoma**
- 60. Diagnosis of Sarcoidosis: Correlation of Gallium-67 Scanning, Minor Salivary Biopsy, Parotid Gland Biopsy and Trans-bronchial lung Biopsy**
- 61. Lateral Tonograms of the Scaphoid**
- 62. Utility of Endoscopy for X-ray Negative Dysphagia: A Prospective Analysis**
- 63. Spontaneous Pneumothorax: Treatment Using Standard Tube Thoracostomy vs Cook Catheter with a Heimlich Valve**
- 64. GOG 8901. A Phase I Evaluation of Multiple Daily Fraction Radiation and 5-Fluorouracil Plus Cisplatin in Stage IIB, III and IVA Carcinoma of the Cervix with Negative Para-aortic Nodes**
- 65. GOG 8801. A Phase I Evaluation of Multiple Daily Fraction Radiation and Hydroxyurea in Patients with Stage IIB, III and IVA Carcinoma of the Cervix with Negative Para-aortic Nodes**
- 66. GOG 99. A Phase III Randomized Study of Surgery vs Surgery Plus Adjunctive Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma**
- 67. GOG 94. A Phase II Study of the Treatment of Stage II and III Disease of Advanced Endometrial Carcinoma and All Stages of Papillary Serous Carcinoma and Clear Cell Carcinoma of the Endometrium with Total Abdominal Radiation Therapy**
- 68. GOG 125. Extended Field Radiation Therapy with Concurrent 5FU Infusion and Cisplatin Chemotherapy in Patients with Cervical Carcinoma Metastatic Para-Aortic Lymph Nodes**

- 69. GOG 120. A Randomized Comparison of Hydroxyurea vs Hydroxyurea. 5FU Infusion and Bolus Cisplatin vs Weekly Cisplatin Adjunct to Radiation Therapy in Patients with Stages IIB, III, IVA Carcinoma of the Cervix and Negative Para-aortic Nodes.**
- 70. Treatment of Chronic Glatomyelitis with Hyperbaric Oxygenation**
- 71. Chemolumnotherapy of Carcinoma of the Lung Using High Dose Methotrexate and BCS**
- 72. Thallium Chloride for Myocardial Imaging**
- 73. Cardiovascular Dynamics of Toxemia of Pregnancy. Effects of Magnesium Sulfate Therapy and Epidural Anesthesia**
- 74. Urinary Tract Evaluation of DES Exposed Proganry**
- 75. The Use of Electrosipinal Instrumentation in Idiopathic Scoliosis**
- 76. Computerized Axial Tomography versus Complex Motion Tomography as a Predictor of Surgical Finding to Middle Ear and Mastoid Cholesteotoma**
- 77. GOG 260. A Phase II Trial of Aminothiadiatzols in Patients...**
- 78. Radiation Esophagitis**
- 79. GOG 80. Cytoraductive Surgery and PAC Chemotherapy...**
- 80. GOG 79. Single Agent Weekly Methotrexate Therapy in the Treatment...**
- 81. C-Reactive Levels in Asthma**
- 82. GOG *70. A Randomized Comparison of Single Agent Methotrexate and Methotrexate...**
- 83. GOG *77. A Randomized Study of Carboplatia (GDBCA- MSC *241240) versus CHIP...**
- 84. GOG *89. A Randomized Comparison of Intravenous Cyclophosphamide. Dororubicin**

85. **High Resolution CT in the Evaluation of Hemoptysis**
86. **GOG *92. Treatment of Selected Patients with Stage IB...**
87. **GOG *109. A Randomized Comparison of 5FU Infusion and Bolus Cisplatin...**
88. **GOG *117. Adjuvant Ifosfamide (MSC *109724) and Mesna...**
89. **Thyroid Dysfunction Following Therapy for the Head and Neck**
90. **The Effect of the Addition of Electrical Stimulation...**
91. **Supine Cephalometrics in Obstructive Sleep Apnea**
92. **Effect of Race in Responsiveness to Atrial Natriuretic Peptide...**
93. **ECOG *2580. Phase II Master Protocol for the Evaluation of New Agents in...**

I. **Naval Hospital Great Lakes.** Naval Hospital Great Lakes is the primary treatment for the Naval Recruit Training Center. In addition it has a sharing agreement with the North Chicago Veterans Hospital (a psychiatric and alcoholic treatment facility).

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Searched Radioisotope License File at the Navy Environmental Health Center
- (5) Searched Radioisotope License File at the Nuclear Regulatory Commission.
- (6) Searched files at NH Gt Lakes.

Individuals consulted:

Peter Bunce, National Archives, Chicago (312) 581-7816
Don Jackanice, National Archives, Chicago
Anthony Beard, Federal Records Center, Chicago
William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216
LCDR Ray Fong, MSC, USN, RHO, NH Gt. Lakes
CAPT C. De Krey, MSC, USN, Commanding Officer, NAVHOSP GreatLakes
LT Tom Mohaupt, MSC, USN, inactive, RHO 1985-1989
CAPT David George, MSC, USN, RHO 1976-1981

Records found:

- (1) Federal Records Center, Chicago, 100-150 cubic feet of boxes labeled "Flu Shots" 1953-1972.
- (2) Federal Personnel Records Center, St. Louis holds 8,586 cubic feet for years 1944-1973 and 2,903 cubic feet for 1974-89. In addition holds 7 cubic feet labeled "Radioisotope Lab Treatment Records for years 1960-1963."
- (3) File cabinet in Chief of Radiology's office.
- (4) Radioisotope License File on record with the Navy Environmental Health Center.
- (5) Radioisotope License File on record with the Navy Environmental Health Center.
- (6) Radioisotope License File on record with the Nuclear Regulatory Commission.

List of Experiments or Possible Experiments:

1. **"Correlation of Exercise Tolerance Testing and Coronary Angiography."**
2. **"Diagnostic Accuracy of Fiber Optic Duodenoscopy in Upper Gastrointestinal."**
3. **"Bedside Study of CVP and Wedge Pressure in Acute Myocardial Infarction."**
4. **"Evaluation of Time-Saving Potential of Persistence Scope."**

5. **"To Evaluate Percutaneous Cervical Cordotomy in the Management of Pain."**
6. **"A Study of the Oral Cavity During Hyperalimentation."**
7. **"Evaluation of the Oral Surgery Patient for I.V. Sedation."**
8. **"Evaluation of Oral Surgery Implants."**
9. **"VA Cooperative Bowel Prep Study."**
10. **"Evaluation of Long-Term Maintenance Therapy for Patients in Complete Remission From Metastatic Breast Carcinoma."**
11. **"Adjuvant Therapy With Tamoxifen Vs. Placebo in Older Post Menopausal Patients With Stage II Breast Cancer."**
12. **"Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer."**
13. **"Phase II Master Protocol for the Evaluation of New Treatment in Patients With Advanced Soft Tissue Sarcomas, Bone Sarcomas and Mesothelioma."**
14. **"Radiotherapy With and Without Chemo-Therapy for Malignant Pleural Mesothelioma Localized to One Hemithoraxan Intergroup Study."**
15. **"Phase III Treatment of Advanced Malignant Mesothelioma: A Comparison of CIA Vs. CA Intergroup II."**
16. **"Chemotherapy of Adrenal Cortical Carcinoma."**
17. **"Combination Chemotherapy or Chemo-Hormonotherapy of Recurrent or Metastatic Breast Cancer in Premenopausal Women."**
18. **"Phase III Combination Chemotherapy of Metastatic Breast Cancer Followed by Maintenance or No Maintenance Therapy an Evaluation of DAVTH as Induction Regimen."**
19. **"Phase II-III Evaluation of Combination of Methyl CCNU, Mitomycin-C, Adriamycin and 5-Fluorouracil in Advanced Measurable Gastric Cancer."**

20. **"Phase II Master Protocol for the Evaluation of New Agents in Patients With Esophageal Carcinoma."**
21. **"Phase III Comparative of Soft Tissue Sarcomas."**
22. **"Adjuvant Chemotherapy of Soft Tissue Sarcomas."**
23. **"Phase II Study of New Agents in Treatment of Advanced Cancer of the Head and Neck."**
24. **"Phase III Multiple Myeloma: Evaluation of Combination Chemotherapy in Previously Untreated Patients."**
25. **"Protocol for the Treatment of Lympho-Blastic Lymphoma in Adults."**
26. **"Patients With Advanced Hodgkin's Disease Who Have Relapsed."**
27. **"Phase II Master Protocol for the Evaluation of New Treatment in Patients With Malignant Melanoma."**
28. **"Phase II Study of Chemotherapy of Advanced Ovarian Cancer Using Low of High Dose Cisdiamminedi-Chlorplantinum."**
29. **"Phase II Master Protocol for the Evaluation of New Treatment in Patients With Endometrial Cancer."**
30. **"A Phase II Study of Disseminated Transitional Cell Carcinoma of the Urinary Tract."**
31. **"The Management of Resectable Locally Advanced Primary Breast Cancer."**
32. **"Studies in Chemotherapy of Islet Cell Carcinoma."**
33. **"Phase II and III Chemotherapy of Advanced Soft Tissue Sarcomas, Bone Sarcomas and Mesothelioma."**
34. **"The Treatment of Acute Non-Lymphocytic Leukemia in the Elderly Full Dose Versus Attenuated Dose."**
35. **"Localized Radiotherapy Vs. Localized Radiotherapy and Chemotherapy Vs. Localized Radiotherapy and Half-Body Irradiation for Advanced Non Small Cell Lung Carcinomas Confined**

to the Thorax."

36. "Phase II Master Protocol for the Evaluation of New Agents in the Treatment of Non Small Bronchogenic Carcinoma."

37. "Testicular Cancer Intergroup Study."

38. "Surgical Adjuvant Protocol for Resectable Rectal Carcinoma Modified Duke's B, C1, and CS."

39. "Phase III Protocol for the Treatment of Favorable Non-Hodgkin's Lymphomas."

40. "Multiple Myeloma: Timed Sequential High Dose Cyclophosphamide and Vincristine in the Treatment of Multiple Myeloma."

41. "Phase II Master Protocol for the Evaluation of New Agents on Patients With Small Cell Bronchogenic."

42. "Phase III Adjuvant Clinical Trial to Compare CMFPT to Alternating CMF(P)TH and TSAVBTH and Short-Versus Long Term Tamoxifen in Premenopausal Patients With Operable N+ Breast Cancer."

43. "Phase III Comparative Evaluation of Three Intensive Induction Chemotherapy Regimens and Controlled Evaluation of Adjuvant Radiotherapy Consolidation for Unfavorable (Diffuse) Histologic Subtypes of Non-Hodgkin's Lymphoma"

44. "Phase III Chemohormonal Therapy of Previously Treated Metastatic Breast Cancer in Patients with No Prior Exposure to Adriamycin or Tamoxifen"

45. "Phase III Combination Chemotherapy of Advanced Breast Cancer for Women Who Have Received Prior Tamoxifen, but No Prior Adriamycin"

46. "Phase III Comparison of Cyclophosphamide, Adriamycin, Vincristine, to an Alternating Sequence of CAV and Intensive Hexamethylmelamine, Etoposide (VP-16), Methotrexate Following by a Comparison of Maintenance Vs. No-Maintenance"

47. "Phase II Master Protocol for the Evaluation of New Agents in the Treatment of Breast Cancer"

- 48. ECOG 7181. Phase III Chemohormonal Therapy of Previously Treated Metastatic Breast Cancer in Patients with No Prior Exposure to Adriany or Tanoxifen: A Comparative Evaluation of DATB vs D(DATH)TH**
- 49. EST 1177. Evaluation of Long-Term Maintenance Therapy for Patients in Complete Remission Iron Metastatic Breast Carcinoma**
- 50. EST 1878. A Comparative Phase III Trial of cis-Diaminedichloroplatinum vs Adrianycin. Cyclophosphanide.. and cis-Diaminedichloroplatinum and A Phase II Study of TM-26 in Disseminated Transition Cell Carcinoma of the Urinary Tract**
- 51. EST 1291. Phase II-III Studies of Adrianycin and 5FU vs. Streptozotoris + 5FU in the Treatment of Carcinoid Tumor**
- 52. EST 1390. Radiotherapy With and Without Chemotherapy for Malignant Pieural Mesothelioma Localized to one Hemithorax - An Intergroup Study**
- 53. EST 1480. Phase II Master Protocol for the Evaluation of New Agents and Combinations in Patients with Lymphoma**
- 54. EST 1481. Combination Chemotherapy and Radiotherapy for Advanced Hodgkin's Disease**
- 55. EST 1580. Phase III Combination Chemotherapy With of Without Consolidation Radiation Therapy for Localized Small Cell Carcinoma of the Lung**
- 56. EST 2177. Combination Chemotherapy or Chemohormonotherapy of Recurrent of Metastatic Breast Cancer in Pre-menopausal Women: Oopharectomy Plus CAF vs CAF Without Oophorectomy**
- 57. EST 2278. Phase II Master Protocol for the Evaluation of New Agents in Patients with Esophageal Carcinoma**
- 58. EST 2279. Phase II-III Master Protocol for Treatment of Advanced Pancreatic Adenocarcinoma PALA vs Streptozotocin + ADE ADR + MeCCMD (SAM)**
- 59. EST 2377. Adjuvant Chemotherapy of Soft Tissue Sarcomas**

60. EST 2481. A Protocol for the Treatment of Lymphoblastic Lymphoma in Adults
61. ECOG 4176. Surgical Adjuvant Protocol for Resectable Rectal Carcinoma
62. ECOG EST 4477. Phase III Combined Modality Treatment Protocol for Stages III and IV Favorable (Modular) Histologic Subtypes of Non-Hodgkin's Lymphoma
63. ECOG 4591. Phase II Master Protocol for Evaluation of New Agents in Patients with Small Cell Bronchogenic Carcinoma
64. ECOG 5477. Phase III Comparative Evaluation of 3 Intensive Induction Chemotherapy...
65. ECOG 4181. Phase III Adjuvant Therapy for Post-menopausal Women with Breast Cancer
66. "Clinical Protocols, Rationales and Procedures for using Two Diagnostic Drugs, HIDA and DMSA."
67. "Phase III Combination Chemotherapy With or Without Consolidation Radiation Therapy for Localized Small Cell Carcinoma for the Lung."
68. "Combination Chemotherapy and Radiotherapy for Advanced Hodgkin's Disease."

J. Naval Hospital Philadelphia, PA.

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Solicited CV from individuals previously assigned there
- (5) Search of the Nuclear Regulatory License File at the Navy Environmental Health Center.

- (6) Search of the Nuclear Regulatory Commission License files.

Individuals consulted:

Bob Plowman, National Archives, Philadelphia (215) 597-3000
Joseph Sheehan, Federal Records Center (215) 5694/9753
Dan Bennett, Federal Records Center, Philadelphia (215) 951-5698
Rich Boyland, National Archives, Suitland, MD (301) 763-1083
Velicia Chance Federal Records Center, Suitland, MD (301) 763-7430
Millie Sturate, Federal Records Center, Suitland, MD (202) 433-4217
William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216
LCDR Paul Tveten, MSC, USN (Ret) (804)444-7575 ext 413

Records found:

- (1) No records found at Regional Archives or Records Centers.
- (2) Federal Personnel Records Center, St. Louis has not reported their holdings.
- (3) Nuclear Regulatory License File at the Navy Environmental Health Center
- (4) Nuclear Regulatory Commission License files.
- (5) Titles and abstracts of Clinical Investigation Projects are located at the Health Science and Education Command.

List of Experiments or Possible Experiments:

- (1) Nuclear Regulatory License authorized use of xenon for a liver Study. No records of the study were found.
- (2) The Clinical Investigation Program identified the following studies:
1. "Evaluation of the Cardiovascular and Anti-Anginal Effect of Mixidine"
 2. "Preventive Control of Hyperlipemia in Naval Personnel"
 3. "Histochemical Determination of Enzymatic Activity in Blood Disorders"
 4. "Chemotherapy of Selected Blood Disease"

5. **"A Study of Incidence of Deep Vein Thrombosis in Post OP and Bed Ridden Patients Using Impedence Phlebography Techniques"**
6. **"The Use of Cephalothin Peritoneal Irrigation in Appendicitis"**
7. **"Vitamin E Levels in Patients with Cirrhosis"**
8. **"Evaluation of Small Bowel Microflora in Cancer Patients with and without Therapy and their Possible Role in Systemic Infectious Complications"**
9. **"Treatment and Retention of Naval Personnel Evaluation of False Master's Test"**
10. **"Inflammatory Dermatophytosis in Military Personnel: The Role of Delayed Hypersensitivity in Prevention of Infection"**
11. **"Assessment of Platelet Function in Patients with Coronary Artery Disease"**
12. **"Cholinergic Therapy of Reflux Esophagitis in Post-Gastrectomy Patients: A Randomized Double-Blind Crossover Study"**
13. **"Evaluation of Cardiorespiratory Effects of Perhexiline in Patients with Angina Pectoris"**
14. **"Ileal Reflux After Gastric Alkalinization Coagulation System in Patients with Chronic Hypoxia"**
15. **"Urinary Acidification and Ammonia Levels in Cirrhotic and Normal Subjects"**
16. **"The Clinical Effect of Topical 1% 8-Methoxypsoralen Followed by Near Ultraviolet Light on Proven Dermatophytosis"**
17. **"The Behavior of Gaviscon in Gastric Fundus in Erect and Supine Position"**
18. **"Study of Gastric Ulcers"**
19. **"Phase I-II Study Using Adriamycin and Cis-Diamminodichloroplatinum in Advanced Solid Tumors"**

20. **"Comparison of Four Methods of Bowel Preparation for Colonoscopy"**
21. **"Efficacy of Sacralfate in the Treatment of Gastric Ulcers."**
22. **"Effect of Combination Oral Contraceptives on Heprogenous Cyclic Adenosine Monophosphate"**
23. **"Tamoxifen w/wo Sequential Chemotherapy for Recurrent Metastatic Breast Cancer in Patients with Positive Estrogen Receptors"**
24. **"Monoamine Oxidase: Clinical Use as an Indicator of Incipient Hepatic Fibrosis"**
25. **"Study of the Effect of Jogging on Cardiorepiratory Fitness of Alcoholics in the NRMCA Alcohol Rehab Unit"**
26. **"A Comparison Study of Ultrasound and Oral Cholecystography in Detecting Gallstones"**

K. Naval Medical Research Unit, Taipei.

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Solicited CV from individuals previously assigned there.
- (5) Search of the Nuclear Regulatory License File at the Navy Environmental Health Center
- (6) Search of the Nuclear Regulatory Commission License files.

Individuals consulted:

CDR Bill Beckner, MSC, USN (Ret), (301) 657-2652

CDR Robert Devine, MSC, USN (Ret), (505) 665-2102
LCDR Paul Tveten, MSC, USN (Ret) (804) 444-7575 ext 413
Philip Lothyea, National Archives, Seattle(206) 526-6507
Kent Carter, National Archives, Fort Worth, (817) 334-5525
John Smith, Federal Records Center, Fort Worth, (817) 334-5525
Diane Nixon, National Archives, Laguna (714) 643-4241
Sharon Roadway, Federal Records Center, Laguna(714) 643-4241
Waverly Lowell, National Archives, San Bruno (415) 876-9009
Richard Boyden, Federal Records Center, San Bruno (415) 876-9009
William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216

Records found:

- (1) No records in the Federal Records Centers or Archives.
- (2) CV of some staff members listing publications.
- (3) Radioisotope License File on record with the Navy Environmental Health Center.
- (4) Federal Personnel Records Center, St. Louis holds 205 cubic feet medical records for the years 1962-1973 and 65 cubic feet for 1974-1979.

List of Experiments or Possible Experiments:

- (1) Unit had a whole body counter and performed basic physiology and metabolic studies.
- (2) The CV of some of the above officers indicate the following studies were performed. Publications have to be reviewed.
 1. **"Chromium-51 Studies in Wilson's Disease."**
 2. **"Copper Absorption in Wilson's Disease."**
 3. **"Muscle Copper, Zinc and Manganese Levels in Wilson's Disease: Studies With the Use of Neutron Activation Analysis."**
 4. **"Abnormalities of the Physiology of Copper in Wilson's Disease: The Whole-Body Turnover of Copper."**
 5. **"Decreased Calcium Absorption (CaAb) on Cholestyramine Therapy."**

6. **"Hypersplenism in Wilson's disease."**
7. **"Turnover Studies of Copper and Homozygotes and Heterozygotes for Wilson's Disease and Controls: Isotope Tracer Studies Using Copper-67 and Copper-64."**
8. **"Clinical Studies of Capillariasis Philippinensis."**
9. **"Cesium-137 Turnover Rates in Human Subjects of Different Ages."**
10. **"Body Composition and Starvation."**
11. **"Isotope Studies in Intestinal Capillariasis."**
12. **"Iodine-131 Studies in Schistosomiasis."**
13. **Intestinal Capillariasis: A New Disease in Man**
14. **Preliminary Observations on a New Disease in Man - Intestinal Capillariasis.**

K. Submarine Medical Research Laboratory, Groton.

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.

Individuals consulted:

CDR Steve Warlick, MC, USN, COMSUBLANT Medical (804) 444-6885
 William Seibert, National Personnel Records Center, St. Louis (314) 538-4216
 CDR Dave Sacks, MC, USN & LCDR Tom Hasselbacher, MSC, USN Naval
 Medical Institute, Groton, CT.

Records found:

- (1) No records located in the Archives or Federal Record Centers.

- (2) CDR Warlick had copies of supporting information for the review of radium treatments for submariners.
- (3) Radioisotope License File on record with the Navy Environmental Health Center.
- (4) National Personnel Records Center, St. Louis holds 3 cubic feet of records labeled "Administrative Progress Records, 1942-1952." One cubic feet of logs were destroyed in 1978.
- (5) NSMRL holds records on bony necrosis study. No other records located at NSMRL or NUMI, Groton.

List of Experiments or Possible Experiments:

- (1) "Aerotitis Media in Submariners." 1946
- (2) "Radium Therapy in Aerotitis Media."
- (3) "Aseptic Bone Necrosis Among U.S. Navy Divers: Survey of 934 Non-randomly Selected Personnel."

L Naval Medical Clinic, Annapolis

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Reviewed Clinical Investigators Program files.

Individuals consulted:

Bob Plowman, Joseph Sheehan, Dan Bennett, National Archives
and Federal Records Center, Philadelphia, (215) 597-5694/9753
Mr. Rich Boyland, National Archives, Suitland, MD (301) 763-1083
Ms. Velicia Chance Federal Records Center, Suitland, MD (301) 763-7430

Ms. Millie Sturate, Federal Records Center, Suitland, MD (202) 433-4217
Mr. Jim Jensen, Records Manager for Navy, 202-433-2434
CDR Marianne Bentz, NC, USN, CID, NNMC
CAPT Jim Alexander, MC, USN, CID, HSET

Records found:

- (1) Clinical Investigation files at NNMC and HSETC.

List of Experiments or Possible Experiments:

1. **Comparison of Various Means of Evaluation the Severity of Inversion Ankle Sprains**
2. **Radiological Evaluation of Cervical Spine of Collegiate Football Players**
3. **Study of 2 Medial Collateral Ligament Sprains of the Knee**
4. **Study to Establish Normal Range of Ankle Mobility During Inversion Stress**
5. **The Role for Endoscopic Procedures in the Transmission HAA**
6. **The Rate of the Acromioclavicular Joint in Athletic Injuries**
7. **Evaluation of the Modified Bristow Procedure in the Treatment of Recurrent Subluxations and Dislocations of the Shoulder**
8. **Evaluation of the Brostrom Procedure for Repair of Chronic Ruptures of the Lateral Ligaments of the Ankle**
9. **Elmslie-Trillat Procedures for the Management of Dislocations and Subluxations of the Patella**
10. **Functional Instability of the Ankle Joint**
11. **Clinical Study of Intraocular Lens Implantation After Cataract Extractions Primary or Secondary**

M. Naval Hospital, Jacksonville

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Reviewed Clinical Investigators Program files.
- (5) Tasked Command to search records.

Individuals consulted:

Mr. Jim Jensen, Records Manager for Navy, 202-433-2434
Gayle Peters, East Point, GA (404) 763-7477
Tom Steinichen, Federal Records Center, Atlanta, GA (404) 763-7474
CDR Marianne Bentz, NC, USN, CID, NNMC
CAPT Jim Alexander, MC, USN, CID, HSET

Records found:

- (1) CID files at Naval Health Sciences and Education Command.

List of Experiments or Possible Experiments:

**1. Prospective Cooperative Study into Etiology of Reye's Syndrome
and Effectiveness of Current Modes of Therapy**

N. Naval Hospital, Guam

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Reviewed Clinical Investigators Program files.
- (5) Tasked Command to search records.

Individuals consulted:

CDR Marianne Bentz, NC, USN, CID, NNMC
CAPT Jim Alexander, MC, USN, CID, HSET

Records found:

- (1) CID files at Naval Health Sciences and Education Command

List of Experiments or Possible Experiments:

1. **Radionuclide Biliary Imaging Utilizing 99MTC EHIDA**

O. Naval Hospital, Pensacola

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Reviewed Clinical Investigators Program files.
- (5) Tasked Command to search records.

Individuals consulted:

CDR Marianne Bentz, NC, USN, CID, NNMC
CAPT Jim Alexander, MC, USN, CID, HSET

Records found:

- (1) CID files at Naval Health Sciences and Education Command.

List of Experiments or Possible Experiments:

1. **Alterations in Renal Clearance of Digoxin as Modified by Volume Loading, Alkalinization and Diuritics and Measured by Radio-Immunoassay Technique**

2. Clinical Study of Intraocular Lenses

P. Naval Hospital, Orlando

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Reviewed Clinical Investigators Program files.
- (5) Tasked Command to search records.

Individuals consulted:

CDR Marianne Bentz, NC, USN, CID, NNMC
CAPT Jim Alexander, MC, USN, CID, HSET

Records found:

- (1) CID files at Naval Health Sciences and Education Command

List of Experiments or Possible Experiments:

- 1. Acute Respiratory Disease in Recruits at the Naval Training Center, Orlando Florida**
- 2. Smoking and Lung Cancer**

Q. Naval Hospital, Memphis

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives
- (3) Queried Federal Record Centers.
- (4) Reviewed Clinical Investigators Program files.

Individuals consulted:

CDR Marianne Bentz, NC, USN, CID, NNMC
CAPT Jim Alexander, MC, USN, CID, HSET

Records found:

- (1) CID files at Naval Health Sciences and Education Command.

List of Experiments or Possible Experiments:

1. **Clinical Study of Intraocular Lenses Implantation After Cataract Extraction Precision-Cosmet**

R. Naval Hospital, Charleston

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records.
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Reviewed Clinical Investigators Program files

Individuals consulted:

CDR Marianne Bentz, NC, USN, CID, NNMC
CAPT Jim Alexander, MC, USN, CID, HSET

Records found:

- (1) CID files at Naval Health Sciences and Education Command.

List of Experiments or Possible Experiments:

1. **Inderal Treatment of Menopausal Vasomotor Symptoms**
2. **Double Blind Prospective Study of Aerosolized Steroids in Group**

S. Naval Hospital, Naples

Efforts to locate human radiation experiment records:

- (1) Searched through DTIC's computerized records and index card records
- (2) Queried National Archives.
- (3) Queried Federal Record Centers.
- (4) Reviewed Clinical Investigators Program files.

Individuals consulted:

CDR Marianne Bentz, NC, USN, CID, NNMC
CAPT Jim Alexander, MC, USN, CID, HSET

Records found:

- (1) CID files at Naval Health Sciences and Education Command.

List of Experiments or Possible Experiments:

1. Full Thickness Skin Cultures in Betadine Scrubbed and Betadine Sprayed Surgical Patients

T. Naval Research and Development Command.

Efforts to locate human radiation experiment records:

- (1) Searched DTIC files and card index.

Individuals Consulted: N/A

Records found:

- (1) One report in DTIC files.

List of Experiments or possible experiments:

1. "Investigation of Hemotologic and Pathologic Response to Decompression."

PART II: IDENTIFICATION OF NON-BUMED NAVY ACTIVITIES THAT MIGHT HAVE CONDUCTED OR SPONSORED HUMAN RADIATION EXPERIMENTS

I. Introduction.

During searches for studies related to BUMED activities, the following Navy activities and studies were identified:

A. Naval Radiological Defense Laboratory. The laboratory provided support for the nuclear weapons testing program from approximately 1946 to its closing in 1969. Dr. Bond states no human test subjects during his times at the laboratory, 1946-1954. The Nuclear Regulatory License did not authorize human use testing until 1956. The NRC License authorized 4 studies using human test subjects between 1956 and 1961. NRDL letter indicates plans to discontinue human physiology experiments about 1959-1960.

Efforts to locate human radiation experiment records:

- (1) Queried National Archives.
- (2) Queried Federal Records Center.
- (3) Searched DTIC files and card index.
- (4) Nuclear Regulatory Commission reviewed the license for NRDL.
- (5) Interviewed previous staff members.
- (6) Manually searched NRDL records in San Bruno Archives for years 1954-1969.

Individuals Consulted:

Richard Boyden, Federal Records Center, San Bruno (415) 876-9084
Dr. Eugene Cronkite, Brookhaven National Laboratory,
Dr. Vic Bond, Brookhaven National Laboratory.
Dr. Armand Yander, University of Missouri
Don Newland, National Archives, San Bruno, (415) 876-9009
Kathleen O'Connoer, National Archives, San Bruno (415) 876-9009

Richard Boyden, Federal Records Center, San Bruno (415) 876-9006
Daniel M. Jones, CAPT, MC, USN (Ret) (216) 522-5955
William Seibert, National Personnel Records Center, St. Louis, (314) 538-4216

Records found:

- (1) The Federal Records Center at San Bruno had 73 cubic feet of records (20 cubic feet classified Secret, 5 cubic feet were Confidential, 48 cubic feet were Unclassified).
- (2) National Archives, San Bruno, 145 boxes, 1/2 classified, NRDL 1946-1959.
- (3) Federal Personnel Records Center, St. Louis holds 3 cubic feet of records from 1954-1956.
- (4) Nuclear Regulatory Commission has a copy of the NRDL license.

List of Experiments or possible experiments:

- (1) Anecdotal information: Dr. Bond stated that in 1946-54 only animal studies were done. Only two studies were classified and have since been declassified. Dr. Yander remembered a study in 1955-1958 where a summer medical school investigator (Dr. Daniel Jones) solicited volunteers to do a tracer study. Dr. Yander stated several people ingested or drank a tracer and Dr. Jones collected urine and feces for about two weeks for analysis. Dr. Jones did not remember the experiment.
- (2) A veteran requesting exposure history, submitted a copy of a letter describing a test called HYDRA IIA. Apparently HYDRA IIA studied the fallout pattern from 10,000 pound high explosive charge containing tracer amounts of radioactivity. Further reports on HYDRA IIA have been identified: HYDRA IIA was a series of 13 tests involving 10,000 pound high explosive charges set off underwater to compare the hydrodynamics, bubble mechanics and seismic signal with those of a nuclear explosion. Four tests included tracers (3-Lutium-177, 617 to 776 Ci; 1-Xenon-133, 429 Ci) to study the distribution of fission products and inert gases in the bubble and water column. Tests constituted a release to the environment. Personnel exposure were within occupational exposure limits. California Fish and Game Commission participated in the environmental assessment.
- (3) Review of the Nuclear Regulatory License identified the following possible human tests:

1. Amendment 04-487-02: Issued 8/21/56 - Terminated 1/30/57.
Authorized Lanthanum-140 in the form of La-chloride, 50 microCi to measure contamination on the skin of human subjects.
2. Amendment 04-487-04. Issued 5/7/58 - Terminated 9/21/59.
Authorized Hydrogen-3 in the form of tritiated water, 50 mCi, Potassium-42, K-chloride, 3 mCi and Bromine-82, ammonium bromide, 9 mCi to measure total exchangeable potassium, chloride and body water simultaneously in a total of 40 normal adults.
3. Amendment 04-487-05. Issued 8/4/58 - Terminated 9/16/59.
Authorized Lanthanum-140, any form, 500 Ci to be used as a tracer in decontamination studies. Other documents identify this to have supported operation Stoneman II.
4. Amendment 04-487-07. Issued 9/21/59 - Terminated 8/2/61.
Authorized Hydrogen-3 in the form of tritiated water, 50 mCi, Potassium-42, K-chloride, 3 mCi and Bromine-82, ammonium bromide, 9 mCi to measure total exchangeable potassium, chloride and body water simultaneously in a total of 60 normal adults.

(4) The DTIC search identified the following study. The study has yet to be reviewed to determine if the measurements are on humans or animals or in-vivo or in vitro.

1. "Observations on the Thermal Fragility of Erythrocytes." 1950

Compared the survivability of animal and human blood cells as a function of temperature, mechanical stress and radiation exposure.

(5) Search of the San Bruno Archives identified the following references to studies:

- 2. Decontamination of Synthetic Radioactive Fallout from Intact Human Skin. 1956.**
- 3. Protecting and Cleaning Hands Contaminated by Synthetic Fallout under Field Conditions. 1959**
- 4. Some Aspects of Recent Findings Pertaining to the Body Composition of Athletes, Obese Individuals and Patients. 1959**
- 5. Total Exchangeable Potassium and Chlorids and Total Body Water in Healthy Men of Varying Water and Fat Content. 1959**

6. Rapid Assay Procedures for Tritium Labeled Water in Body Fluids. 1959

7. Some Factors Influencing the B-dosage of Troops.

(6) A number of reports on the HYDRA experiments were also found in the San Bruno Archives. The HYDRA project, previously thought to fall within the scope of this tasking, was a series of tests, HYDRA I, HYDRA IIA and IIB which examined the hydrodynamics and seismic signals from shallow water explosions. In some of the tests radioisotopes were used as tracers to aid in the analysis of the explosion, bubble formation and plume dynamics. While some of the workers were occupationally exposed, the HYDRA tests were physics experiments, not human test experiments.

PART III IDENTIFICATION OF POSSIBLE HUMAN RADIATION EXPERIMENTATION

Study # NMRI-01: Biological Basis of Antimony Compounds Containing Radioactive Isotopes, The Blood-Tissue Exchange and Excretion of Antimony in Humans Given a Single Dose of Tartar Emetic.

Location: Naval Medical Research Institute and NNMC, Bethesda

Date: April 1946

Primary

Researchers: R. E. Smith, R. T. Stormont, A. A. Bianco, and R. L. Evans

Sponsors: Carnegie Institution of Washington

Human

Subjects: Two ambulatory male patients volunteered as subjects.

Purpose: The purpose of this study was to evaluate the distribution and retention time of *antimony in the human body*. Administration of antimony was a standard treatment for parasites that cause elephantiasis. Knowledge of the distribution and retention time of antimony in the human body allowed for a better treatment protocol. Use of the radioactive isotope of antimony incorporated into tartar emetic made possible two kinds of measurements.

1. The concentration of antimony in the blood and blood fractions in successive samples down to the order of 0.01 microgram per gram of samples and similar determinations on total excretion.
2. *In vivo* estimation of accumulation of antimony in the liver, muscles, brain and thyroid, etc., by placing a Geiger counter externally over the appropriate body areas and recording the radioactivity emitted.

Category: Other research, diagnostic tracer study.

Records: NMRI

Classification: Unclassified

Study # NMRI-02: Decreased Free Fraction of Thyroid Hormones After Prolonged Antarctic Exposure

Location: NMRI, Port Hueneme, CA, and McMurdo Sound, Antarctica,

Date: August 1983 - September 1984

Primary

Researchers: H. L. Reed, D. Brice, K. M. Mohammed Shakir, K. D. Burman, M. M. D' Alesandro, J. T. O'Brian

Sponsors: National Science Foundation and NMRI

Human

Subjects: Fifteen healthy euthyroid male volunteers. All members of the US Navy 1983-84 annual winter-over party at McMurdo Sound, Antarctica.

Purpose: To measure the role of Antarctic residence in modifying hormonal and physiological responses to cold air. This was an iodine-125 thyroid function study.

Category: Other research, diagnostic tracer study.

Records: NMRI

Classification: Unclassified

Study # NMRI-03: Nitrogen Gas Exchange in the Human Knee

Location: Naval Medical Research Institute and Lawrence Livermore National Laboratory

Date: 1986

Primary

Researchers: P. K. Weathersby, P. Meyer, E. T. Flynn, L. D. Homer, and S. Survanshi

Sponsors: Naval Medical Research and Development Command, Research Work Unit No. M0099PN.01-A.0001.

Human

Subjects: Nine male volunteers ranging in age from 24 to 41 y/o who provided informed consent.

Purpose: Symptoms of human decompression sickness occur in many organ systems, but most notably in skeletal joints. This study was designed to obtain quantitative measures of nitrogen exchange rates in human knees using a radioactive isotope of nitrogen.

Category: Other research, diagnostic tracer study.

Records: NMRI

Classification: Unclassified

Study # NMRI-04: Tracer Gas Kinetic Studies for Decompression Table Design.

Location: Naval Medical Research Institute and Lawrence Livermore National Laboratory

Date: 1978-1984

Primary

Researchers: P. K. Weathersby, E. T. Flynn and L. D. Homer

Sponsors: NMRI and Lawrence Livermore National Laboratory

Human

Subjects: Divers stationed at NMRI. Volunteers.

Purpose: *To study gas behavior during diving operations. Radioactive gases including xenon-133, argon-41, and nitrogen-13 were used to study gas uptake and elimination in individual tissues*

Category: Other research, radioactive tracer study.

Records: NMRI

Classification: Unclassified

Study # NMRI-05: Absorption of X-rays by Tissues of the Head and Neck.

Location: *Naval Medical Research Institute*

Date: 1952

Primary

Researchers: Unknown

Sponsors: NMRI

Human

Subjects: Unknown

Purpose: Unknown, study has yet to be reviewed.

Category: Other research.

Records: NMRI

Classification: Unclassified

Study # NMRI-06: X-Ray Therapy for Amenorrhea and Sterility.

Location: Naval Medical Research Institute

Date: 1957

**Primary
Researchers:**

Sponsors: NMRI

**Human
Subjects:** Unknown.

Purpose: Unknown, paper has yet to be review.

Category: Other research .

Records: NMRI

Classification: Unclassified

Study #NHSTALB -01: Studies of the Metabolism of Gallium. Deposition in and Clearance from Bone

Location: Naval Hospital, St. Albans

Date: 1952

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

Study #NHSTALB-02: Gallium Studies of its Deposition in and Clearance from Bone

Location: Naval Hospital, St. Albans

Date: 1952

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

Study #NHSTALB -03: Studies of the Metabolism of Gallium. Effect of Gallium on Alkaline Phosphatase and Calcification in Vitro

Location: Naval Hospital, St. Albans

Date: 1953

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study # NMRU3-07: Acute Haemolysis with Ambilhar Treatment in Glucose-6-phosphate Dehydrogenase Deficiency

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1972

Primary

Researchers: Ronald McCallry, Zoheir Farid, Donald Kent

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 2 male Egyptians with Schistosomiasis

Purpose: Clinical study of survival of Cr-51 labeled red cells.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study#NHSTALB-04: Pharmacological Studies of Radiogermanium Inhalation of Dusts

Location: Naval Hospital, St. Albans

Date: 1953

**Primary
Researchers:**

Sponsors:

**Human
Subjects**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NHSTALB-05: Studies of the Localization of Radioactive Gallium in Bone Lesions.

Location: Naval Hospital, St. Albans

Date: 1956

Primary

Researchers: H. C. Dubley, H. A. Markowitz, and T. G. Mitchell

Sponsors: NH St. Albans

Human

Subjects: 66 patients with malignant bone lesions

Purpose: A method was developed for the study and localization of bone lesions through the administration of radioactive gallium by external scintillation counting.

Category: Other research, diagnostic tracer.

Records: NH St. Albans

Classification: Unclassified

#

Study # NMRU3-01: Calcification of Schistosoma Haematobium Eggs: Relation of Radiologically Demonstrable Calcification to Eggs in Tissues and Passage of Eggs in Urine

Location:

Date: 1978

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study # NMRU3-02: Urinary Schistosomiasis in Egypt: Further Radiological Correlation's

Location:

Date: 1973

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study # NMRU3-03: Bilharzial Splenomegaly and Refractory Anemia

Location: Cairo University and Kasr-el-Aini Hospital, Cairo University, Cairo, Egypt

Date: July 1966

Primary

Researchers: Z. Farid, A.R. Schulert, S. Bassily, J.H. Nichols, S. Guindy, M. Serif, and F. Raasch

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 1 twelve year-old Egyptian boy, 1 sixty-one year-old Egyptian man

Purpose: Demonstrate the occurrence of hypersplenism and hypervolemia in the splenomegaly of schistosomiasis using Cr-51 tagged red cells.

Category: Other research

Records: Reprints of articles are archived in the library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-04: Radioactive Renography in Schistosomal Obstructive Uropathy

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1973

Primary

Researchers: S. Bassily, S. W. Young, Z. Farid, M.M.E. Nofal

Sponsors: NAVMEDRSCU THREE

Human

Subjects: 10 Male Egyptians with obstructive uropathy secondary to Schistosoma haematobium and with associated bacteriuria

Purpose: To evaluate subjects before and after medical treatment using serial urograms using I-131 iodohippurate and renal function tests (endogenous creatinine clearance, maximal urinary concentration and total hydrogen ion excretion).

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study # NMRU3-05: Schistosomal Colonic Polyposis: Clinical, Radiological, and Parasitological Study.

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1986

Primary

Researchers: N. Ayad El-Masry, Z. Farid, S. Bassily, M.E. Kilpatrick, and R.H. Watten

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 108 male Egyptian farmers with schistosomal colonic polyposis

Purpose: Xray analysis was undertaken to examine bone formation.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study # NMRU3-06: Schistosomiasis of the Liver: Clinical, Pathologic, and Laboratory Studies in Egyptian Cases.

Location: NAVMEDRSCHU THREE and University Hospital, Cairo, Egypt

Date: 1956

Primary

Researchers: Moufid Ragheb

Sponsors: NAVMEDRSCH THREE

Human

Subjects: 115 male and 10 female Egyptians with Schistosomiasis

Purpose: Subjects were studied clinically by liver biopsy and laboratory tests of liver function. Xray examination of the lower esophagus by barium paste to demonstrate varices was done uniformly and evacuation films with air distention were done in cases demonstrating papillomas by sigmoidoscopy.

Category: Other research

Records: Search of records ongoing. Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-08: Changes in Hepatic Blood Flow and Blood Volume after Splenectomy for Bilharzial Hepatosplenic Fibrosis Dehydrogenase Deficiency

Location: NAVMEDRSCHU THREE and AIN SHAMS University, Cairo, Egypt

Date: 1972

Primary

Researchers: M.M. Nofal, M.A. Hidayat, A.A. Mahran, J.A. Haxton

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 14 male and 1 female Egyptian (average age 28 years, age range 16 to 50 years) with Bilharzial disease

Purpose: Evaluate the effect of splenectomy (for treatment of patients suffering with Bilharzial hepatosplenomegaly) on liver function and peripheral blood haemodynamic pattern.

Procedure: Radioisotope studies using Au-198 were conducted from which the effective hepatic blood flow was calculated. Plasma volume was determined using I-131 labeled human serum albumin. Red blood cell volume was measured using Cr-51 sodium chromate.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study # NMRU3-09: Efficacy of Medical Treatment of Schistosomal Obstructive Uropathy as Determined by I-131 Hippuran Renography

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1978

Primary

Researchers: S.W. Young, Z. Farid, S. Bassily, N.A. El Masry

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 10 males with obstructive uropathy secondary to Schistosoma Haematobium and with associated bacteriuria

Purpose: Evaluated subjects with serial urograms, renograms (using intravenous I-131 Iodohippurate (hippuran)), and renal function tests (endogenous creatinine clearance, maximal urinary concentration, and total hydrogen ion excretion) before and after medical treatment.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-10: Some Effects of Louse-borne Relapsing Fever on the Function of the Heart

Location: Department of Medicine, Haile Selassie I University, Addis Ababa, Ethiopia; The Ahmadu Bello University, Zaria, Nigeria; The Hammersmith Hospital, London W. 12. England; NAVMEDRSCHU THREE, Field Facility, Addis Ababa, Ethiopia; St. Paul's Hospital, Addis Ababa, Ethiopia; and the Institute of Dermatology, St. John's Hospital for Diseases of the skin, London E. 9, England

Date: 1969

Primary

Researchers: E.H.O. Parry, D.A. Warrell, P.L. Perine, D. Vukotich, A.D.M. Bryceson

Sponsors: Uncertain, but presumed to be NAVMEDRSCHU THREE, Field Facility, Addis Ababa, Ethiopia

Human

Subjects: 50 Ethiopian patients with louse-borne relapsing fever

Purpose: Clinical, electrocardiographic, and hemodynamic studies were made on 31 patients in Ethiopia; more detailed physiologic studies were made in 19 additional patients. In some cases, posteroanterior chest roentgenograms were taken.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study # NMRU3-11: Colonic Calcification and Polyposis in Schistosomiasis

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1971

Primary

Researchers: J.S. Lehman, Jr., Z Farid, S. Bassily, D.C. Kent

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 1 thirty-three year old Egyptian male farmer admitted for evaluation of diarrhea, bloody stools, and tenesmus

Purpose: Description of clinical and radiographic features of case of mixed infection by *Schistosoma mansoni* and *S. haematobium*.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-12: Urinary Schistosomiasis: A 5-Year Clinical, Radiological, and Functional Evaluation

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1967-1971

Primary

Researchers: S.W. Young, Z. Farid, S. Bassily, N.A. El-Masry

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 10 Egyptian male farmers aged 9 to 29 years who were initially infected with *S. haematobium*

Purpose: Patients were followed during approximately 5-year period. They were studied before and after effective antischistosomal treatment (1967, 1970) and again in 1971 after they returned home. Urograms were conducted in the course of these studies.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study # NMRU3-13: Treatment of Chronic Urinary Salmonella Carriers

Location: NAVMEDRSCHU THREE, Cairo, Egypt and the Abbassia Fever Hospital, Ministry of Public Health, Cairo, Egypt.

Date: 1970

Primary

Researchers: S.W. Young, Z. Farid, S. Bassily, N.A. El-Masry

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 26 Egyptian male farmers aged 4 to 30 years

Purpose: Study of clinical management of urinary salmonella carriers. During the course of the study, micturating cystograms were performed on 5 patients.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study # NMRU3-14: Intestinal Protein Loss in Schistosomal Polyposis of the Colon

Location: NAVMEDRSCHU THREE, Cairo Egypt and Kasr-el-Aini Hospital, Cairo University, Cairo, Egypt

Date: 1970

Primary

Researchers: J.S. Lehman, Jr., Z. Farid, S. Bassily, J. Haxton, M.F.A. Wahab, and D. Kent

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 6 Egyptian male farmers with clonic polyposis due to *Schistosoma mansoni*

Purpose: Excessive protein loss was demonstrated in 5 of 6 patients with clonic polyposis due to *Schistosoma mansoni* infection. Measurement of intestinal protein loss was conducted using Cr-51 labeled human albumin using a modification of the Waldmann technique.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study # NMRU3-15: Chronic Urinary Salmonella Carriers with Intermittent Acteraemia

Location: NAVMEDRSCHU THREE, Cairo, Egypt; Abbassia Fever Hospital, Ministry of Public Health; and the Tropical Disease Unit, Kasr-el-Aini Hospital, Cairo University, Cairo, Egypt

Date: 1970

Primary

Researchers: Z. Farid, S. Bassily, D.C. Kent, W.R. Sanforn, A. Hassan, M.F. Abdel-Wahab, J.S. Lehman, Jr.

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 15 Egyptian male farmers with urinary tract damage caused by Schistosoma haematobium infection

Purpose: Study chronic urinary enteric carriers. This study was a follow-up to a study of 40 patients. The 15 patients in this study were examined in the hospital for 6 to 12 months. Urinary tract damage was verified by xray.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3- 16: Urinary Schistosomiasis Treated with Niridazole (Ambilhar): A Quantitative Evaluation

Location: NAVMEDRSCHU THREE; Tropical Medicine Unit, Kasr-el-Aini Hospital; and Abbassia Fever Hospital, Ministry of Health, Cairo, Egypt

Date: 1970

Primary

Researchers: Z. Farid, S. Bassily, M.F. Abdel-Wahab, J.S. Lehman, Jr., A. Hassan, D.C. Kent

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 17 Egyptian male farmers

Purpose: Study to examine the use of niridazole (Ambilhar) in the treatment of *S. haematobium*. *During the study, kidney function tests were performed which included plain xrays.*

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study # NMRU3-17: Histologic and Lymphangiographic Studies in Patients with Clinical Lepromatous Leprosy

Location: NAVMEDRSCHU THREE; Tropical Disease Center, St. Clare's Hospital, New York City; and Leprosy Control Section, Ministry of Health, United Arab Republic

Date: 1969

Primary

Researchers: F.O. Raasch, Jr., K.M. Cahill, Latif Kamal Hanna

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 10 Egyptian males from Abu Zabaal Leprosarium near Cairo

Purpose: Study to define the histology of the inguinal lymph nodes and bone marrow of lepromatous patients classified clinically as having lepromatous leprosy and relate this to lymphangiographic (x-ray) findings in five of these cases.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-18: Urinary Blood Loss in Schistosoma Haematobium Infection in Egyptian Farmers

Location: NAVMEDRSCHU THREE; Kasr-el-Aini Hospital, Cairo University, United Arab Republic

Date: 1968

Primary

Researchers: Z. Farid, S. Bassily, A.R. Schulert, A.S. Zeind, E. McConnell, M.F. Abdel Wahab

Sponsors: NAVMEDRSCHU THREE and Kasr-el-Aini Hospital, Cairo University

Human

Subjects: 18 Egyptian males with S. haematobium infection

Purpose: Study to measure blood and iron losses in the urine of patients suffering from various stages of urinary schistosomiasis. In the course of the study, Fe-59 labeled red cells were used to measure urinary blood and iron losses.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-19: Blood Loss in Chronic Schistosoma Mansoni Infection in Egyptian Farmers

Location: NAVMEDRSCHU THREE; Kasr-el-Aini Hospital, Cairo University, United Arab Republic

Date: 1967

Primary

Researchers: Z. Farid, S. Bassily, A.R. Schulert, F. Raasch, A.S. Zeind, A.S. El Rooby, M. Sherif

Sponsors: NAVMEDRSCHU THREE and Kasr-el-Aini Hospital, Cairo University

Human

Subjects: 7 Egyptian farmers screened for treatment of schistosomiasis.

Purpose: Study using Cr-51 tagged red cells to measure gastrointestinal blood loss in patients with bilharzial colonic and rectal polypi.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-20: Chromium Red Cell Half-Life in Severe Iron Deficiency Anemia

Location: NAVMEDRSCHU THREE, Cairo, Egypt; Division of Nutrition and Department of Biochemistry, Vanderbilt University School of Medicine

Date: About 1965

Primary

Researchers: Z. Farid, J.H. Nichols, A.R. Schulert, S. Bassily

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 27 Egyptian patients who had been previously infected with *Ancylostoma Duodenale*

Purpose: Study using Cr-51 tagged red cells to measure red cell survival in patients infected with *Ancylostoma duodenale*.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-21: Hydronephrosis, Bacteriuria, and Maximal Urine Concentration in Urinary Schistosomiasis

Location: NAVMEDRSCHU THREE

Date: About 1971

Primary

Researchers: J.S. Lehman, Jr., Z. Farid, S. Bassily, D.C. Kent

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 84 Egyptian males with Schistosoma haematobium infection

Purpose: Study of renal function in patients with Schistosoma haematobium. During the course of the study, conventional intravenous urography was performed on all patients.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU-22: Symptomatic, Radiological, and Functional Improvement Following Treatment of Urinary Schistosomiasis in Egypt

Location: NAVMEDRSCHU THREE; Ain-Shams Hospital, Ain-Shams University; Kasr-el-Aini Hospital, Cairo University, Cairo, Egypt

Date: 1967

Primary

Researchers: Z. Farid, S. Bassily, E. McConnel, A. Schulert, M. Sabour, M.F. Abdel Wahab

Sponsors: NAVMEDRSCHU THREE; Ain-Shams Hospital, Ain-Shams University; Kasr-el-Aini Hospital

Human

Subjects: 10 Egyptian male farmers, aged 9 to 43, with Schistosomal haematobium infection and urological complications

Purpose: Study of effects of treatment with tartar emetic or sodium dimercaptosuccinate. Results were assessed clinically, radiologically (plain x-ray of bladder), and functionally.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3- 23: Blood Loss in Pure Ancylostoma Duodenale Infection in Egyptian Farmers

Location: NAVMEDRSCHU THREE, Cairo, Egypt; Vanderbilt University School of Medicine

Date: 1965

Primary

Researchers: Z. Farid, J.H. Nichols, S. Bassily, A.R. Schulert

Sponsors: NAVMEDRSCHU THREE; Vanderbilt University School of Medicine

Human

Subjects: 12 Egyptian farmers infected with pure A. Duodenale

Purpose: Study to measure daily blood and iron loss in infected patients, to measure the blood loss per worm per day, the blood loss per 1000 eggs per gram of feces, and to assess the relationship between egg count, worm load, blood and iron loss, and degree of anemia. During the course of this study, blood loss was measured using Cr-51 labeled red cells.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-24: Bilharzial Splenomegaly and Refractory Anemia

Location: Cairo University; Kasr-el-Aini Hospital, Cairo University, Cairo, Egypt

Date: July 1966

Primary

Researchers: Z. Farid, A.R. Schulert, S. Bassily, J.H. Nichols, S. Guindy, M. Serif, F. Raasch

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 1 twelve year old boy and 1 sixty-one year old man

Purpose: Demonstrate occurrence of hypersplenism and hypervolaemia in the splenomegaly of schistosomiasis using Cr-51 tagged red cells.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-25: Radioactive Renography in Schistosomal Obstructive Uropathy

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1973

Primary

Researchers: S. Bassily, S.W. Young, Z. Farid, M.M.E. Nofal

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 10 male Egyptians with obstructive uropathy secondary to Schistosoma haematobium and with associated bacteriuria

Purpose: Evaluate patients before and after treatment using serial urograms, renograms (using I-131 iodohippurate), and renal function tests (endogenous creatinine clearance, maximal urinary concentration, and total hydrogen ion excretion).

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-26: Schistosomal Colonic Polyposis: Clinical, Radiological, and Parasitological Study

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1986

Primary

Researchers: N. Ayad El-Masry, Z. Farid, S. Bassily, M.E. Kilpatrick, R.H. Watten

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 108 male Egyptian farmers

Purpose: One patient with uropathy secondary to Schistosoma haematobium and with associated bacteriuria was evaluated before and after treatment using serial urograms, renograms (using I-131 iodohippurate) and renal function tests (endogenous creatinine clearance, maximal urinary concentration, and total ion excretion)

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-27: Needle Biopsy of the Lung

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1956

Primary

Researchers: Dr. Paul C. Golvan

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 13 Male Egyptians

Purpose: Report on the use of the Vin Silverman needle for lung biopsy and comparison with standard aspiration technique in 13 patients with cancer of various types. X-rays used to accurately identify the position of the lesion for biopsy.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3- 28: The Diagnosis and Management of Hepatic Abscess of Amebic Origin

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1955

Primary

Researchers: J. H. Killough

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 3 Male Egyptians

Purpose: Description of three diagnostically difficult cases of hepatic amebic abscess and treatment documented by the use of fluoroscopy.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-29: Observations of the Natural History of Amebiasis: A Preliminary Report

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1955

Primary

Researchers: H. L. Jones

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 19 Male Egyptians

Purpose: Thirteen patients asymptomatic for amebiasis but positive on stool examination and 13 normal controls were followed over 23 weeks. Routine chest x-rays were done at the beginning and at the end of the study. Fluoroscopy was done on all individuals at the end of the time period.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-30: Blood Loss in Egyptian Farmers Infected with Ancylostoma Duodenale

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1966

Primary

Researchers: Z. Farid and S. Hassily

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 12 Male Egyptians

Purpose: To determine the overall blood loss during the course of infection and therapy 13 patients red cells were radiolabeled with $\text{Na}_2^{51}\text{CrCO}_4$ according to standard clinical methods. Blood samples, stools and red cells were collected over a 4 day period and measured for radioactivity.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-31: Iron Loss and Reabsorption in Ancylostoma Duodenale Infection and Bilharzial Colonic Polyposis

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1970

Primary

Researchers: Z. Farid and S. Bassily

Sponsors: NAVMEDRSCHU THREE

Human

Subjects: 7 Male Egyptians

Purpose: To Determine iron loss and reabsorption in the gastro intestinal track during the infection and subsequent treatment. 7 patients were radiolabeled with $\text{Na}_2^{51}\text{CrCO}_4$ according to standard clinical methods. Blood samples, stools and red cells were collected over a 4 day period and measured for radioactivity.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NMRU3-32: Urinary Schistosomiasis in Egypt: Clinical, Radiological Bacteriological and Parasitological Correlations

Location: NAVMEDRSCHU THREE, Cairo, Egypt

Date: 1973

Primary

Researchers: J. Lehman, Z. Farid and S. Bassily

Sponsors:

Human

Subjects: 200 Male Egyptians

Purpose: Intravenous excretory urography was performed on 200 patients with urinary schistosomiasis to assess the extent of urinary involvement using 50% sodium diatrizoate.

Category: Other research

Records: Reprints of articles are archived in library of NAVMEDRSCHU THREE.

Classification: Unclassified

#

Study #NNMC-01: Preliminary Report on the Use of Use of Gallium in Clinical Tracer Studies.

Location: NNMC, Bethesda

Date: 1952

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NNMC-02: Diagnosis of Multiple Small Pulmonary Emboli With Tc-99m
Micro-Spheres**

Location: NNMC, Bethesda

Date: 1952

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-03: Practical Radioisotope Therapy

Location: NNMC, Bethesda

Date: 1955

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-04: The Therapeutic Use of Radioisotopes From a Practical Level

Location: NNMC, Bethesda

Date: 1956

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-05: Evaluation of Pancreatic Exocrine Function and Intestinal Absorption With Radioactive Fat

Location: NNMC, Bethesda

Date: 1957

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-06: Present Status of Radioiodine in Thyroid Disease

Location: NNMC, Bethesda

Date: 1956

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NNMC-07: The Use of Radioisotopes in Diagnostic Hematologic Procedures. I.
The Application of the B-12 Co-60 Test in the Diagnosis of Macrocytic Anemias and
Malabsorption States**

Location: NNMC, Bethesda

Date: 1957

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-08: The Use of Radioisotopes in Diagnostic Hemotologic Procedures, Fe-59 Erythrokinetic Studies.

Location: NNMC, Bethesda

Date: 1957

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NNMC-09: The Use of Radioisotopes in Diagnostic Hemotologic Procedures,
Simultaneous Cr-51 and Fe-59 Studies**

Location: NNMC, Bethesda

Date: 1957

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NNMC-10: Blood Volume Studies in Thoracic Surgical Patients Using
Radioactive Iodinated Human Serum Albumin**

Location: NNMC, Bethesda

Date: 1956

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-11: Studies of the Localization of Radioactive Gallium, GA-72, in Bone Lesions

Location: NNMC, Bethesda

Date: 1956

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-12: Pancreatic Exocrine Function; A Simplified Test Using Radioactive Fat Excretion

Location: NNMC, Bethesda

Date: 1957

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-13: A Study of Methods for Interstitial Implantation of Radioactive Material

Location: NNMC, Bethesda

Date: 1956

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-14: Late Follow-Up Studies After Internal Deposition of Radioactive Materials

Location: NNMC, Bethesda

Date: 1956

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-15: The Excretion of Thorium and Thorium Daughters After Thorotrast Administration

Location: NNMC, Bethesda

Date: 1957

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-16: Barium Studies of the Comparative Action of Banthine, Tincture of Belladonna and Placebos on the Motility of the Gastrointestinal Tract in Man

Location: NNMC, Bethesda

Date: 1953

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-17: Gastrointestinal Motility in Man; Influence of a Standard Meal on the Effect of Banthine

Location: NNMC, Bethesda

Date: 1954.

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-18: Comparative Effects of Pamine, Banthine, and Placebos on Gastrointestinal Motility. Radiographic Study in Eight Adult Subjects Tested When Fasting and After Three Weeks Administration of Agents

Location: NNMC, Bethesda

Date: 1955

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-19: Comparative Effects of Pamine, Banthine, and Placebos on the Gastrointestinal Mobility. Radiographic Study in Eight Adult Subjects Tested When Fasting and Following the Administration of a Standard Meal.

Location: NNMC, Bethesda

Date: 1955

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-20: Whole Body Retention of Orally Administered Calcium-47

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-21: Total Body Potassium (K) as a Reference Standard for Normality of Red Blood Cell Mass.

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NNMC-22: Evaluation of Cervical Spine Injuries Using
Cineroentgenography**

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-23: Evaluation of Available Kits for Radioimmunoassay

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NNMC-24: Radioisotopic Determination of Glomerular Filtration Rate (GFR.)
and Effective Renal Plasma Flow (ERPF).**

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-25: Evaluation of Role of Thyrotrophic Hormone (TSH) in Simple and Multi Nodular Goiter and Thyroid Carcinoma.

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-26: Diagnosis of Early Arthritis by Joint Scintiphotography.

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-27: Diagnosis of Urinary Tract Obstruction by Scintiphotography.

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-28: Dynamic Scintiphotography in the Evaluation of Renal Disease.

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-29: Gallium 67 Scanning for Staging of Carcinoma of the Breast

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NNMC-30: Platelet Function in Patients with Lymphoma and Solid Tumor
Prior to, During, and After Therapy**

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-31: The Investigation of the Transfer of Iodine and Thyroid Hormone Across the Placenta in Early Human Gestation.

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-32: Clinical Evaluation of a Tin Electron Filter for Cobalt-60 Radiation Therapy Utilizing a Thermoluminescence Posimetry System Effect on Skin Sparing.

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-33: The Effect of Cholecystectomy on the Constituents and Size of the Bile Acid Pool.

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-34: IgE Antipolymyxin B Antibody Formation in a T-Cell Depleted Bone Marrow Transplant Patient

Location: NNMC, Bethesda

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NNMC-35: Spect Imaging of Regional Cerebral Blood Flow

Location: NNMC, Bethesda

Date: May, 1988 - Present

Primary

Researchers: CAPT Eugene Silverman, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 16 psychiatric patients with a Diagnostic and Statistical Manual diagnosis of schizophrenia who were voluntary participants. A credentialed staff psychiatrist, other than the one who obtained informed consent, verified competency of the patient to give informed consent.

Purpose: Protocol: 87-06-2399-00

Determine whether schizophrenics have rCBF patterns which differ between resting and stimulated conditions; demonstrate differences between the pre-treatment and post-treatment conditions using SPECT imaging.

Procedure: Total dosage of 20 millicuries HIPDM IV administered over period of one month. I-123 in the HIPDM pharmaceutical is a phase III investigational drug. IND request was to be submitted to the FDA.

Category: Other Research

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-36: Phase III Study 131 I-Meta-Iodobenzl-guanidine Sulfate (3BG) for the Localization of Adrenal Medullae of Humans

Location: NNMC, Bethesda

Date: August, 1988 - Present

Primary

Researchers: CDR Eugene Silverman, MC USN, LCDR Aaron Michael Kistler, MC USN, Howard Stoops, RPh, CNPh

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 100 patients diagnosed with pheochromocytoma, paraganglioma or medullary hyperplasia. Informed consent obtained.

Purpose: Protocol: 88-06-2406-00

Evaluate the use of ¹³¹I-MIBG as an aid in the diagnosis, evaluation and localization of pheochromocytomas, paragangliomas, neuroblastomas and/or the localization of agent in adrenal medullary hyperplasia.

Category: Therapeutic Research Involving Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study # NNMC-37: Effects of Oral Therapy with Verapamil Upon Ventricular Diastolic Function in Hypertensive Patients

Location: NNMC, Bethesda

Date: November, 1988 - Present

Primary

Researchers: LCDR Richard S. Bakalar, MC USN, CDR Eugene D. Silverman, MC USN, LCDR David B. Turton, MC USNR, CDR William M. Yudt, MC USN and CDR Larry Parr, MSC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 20 patients with untreated or recently diagnosed hypertension assigned to the Study group and twenty to the control group.

Purpose: Protocol: 89-06-2464-00

To demonstrate differences in one or more parameters of diastolic function (e.g. peak filling rate and time to peak filling rate) in hypertensive patients before and after administration of oral therapy with Verapamil, a calcium channel blocker, upon left ventricular diastolic function in hypertensive patients.

Procedure: Initial total daily dose of 120 mg of Verapamil administered orally with dosage adjustment made to achieve satisfactory BP control.

Category: Other Research

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-38: Phase III Study of 131-6B-Iodomethyl-19-Norcholesterol (NP-59) for the Localization of the Adrenal Cortex in Humans

Location: NNMC, Bethesda

Date: August, 1989 - Present

Primary

Researchers: CDR Eugene Silverman, MC USN, CDR William Yudt, MC USN, CDR A. M. Kistler, MC USN and Daniel Driver, RPh

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 100 adult patients (>18 years old) having known or suspected adrenal diseases.

Purpose: Protocol: 88-06-2463-00

To evaluate the use of NP-59 as an aid in the diagnosis, evaluation and localization of Aldosteronism, Cushing's syndrome, excess production of androgens, and for patients with a missing, or an abnormally enlarged adrenal gland, the evaluation of incidental growth of the adrenal cortex.

Category: Other Research

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-39: Assessment of the Effect of Converting Enzyme Inhibition on Proteinuria with Steroid - Unresponsive Nephrotic Syndrome

Location: NNMC, Bethesda

Date: April, 1990 - Present

Primary

Researchers: Przemyslaw (Mac) Hirszel, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 10 patients over the age of 18

Purpose: Protocol: 88-06-2378-01

To study the effect of converting enzyme inhibition on renal hemodynamics and proteinuria in patients with focal segmental glomerulosclerosis.

Category: Other Research

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-40: The Influence of Thyroid Disorders and their Treatment on Nuclear Binding of T3 in Human Leukocytes

Location: NNMC, Bethesda

Date: December, 1990 - Present

Primary

Researchers: LCDR A. J. Drake III, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 160 total patients

Purpose: Protocol: 91-06-2883-00

To determine the effects of thyroid disorders and their treatment on the nuclear T₃ receptor characteristics in human leucocytes.

Category: Research on blood products only

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-41: Magnetic Resonance and TC-99M HMPAO Spec Imaging in Evolving and Completed Stroke Diffusion/Perfusion Imaging and Metabolite Spectroscopy

Location: NNMC, Bethesda

Date: May, 1991 - Present

Primary

Researchers: T. DeGraba, M. D.

Sponsors: Clinical Investigation Program, NNMC conducted with National Institute of Neurological Disorders and Stroke and National Institutes of Health.

Human

Subjects: 150 patients with stroke of recent onset

Purpose: Protocol: B 91-020

To establish whether or not advanced magnetic resonance techniques will permit an earlier and more precise diagnosis of stroke and also facilitate a more accurate followup of stroke in human patients.

Category: Other Research

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-42: Renal and Systematic Hemodynamic Response to the Creation of Vascular Access for Hemodialysis in Patients with Chronic Renal Failure

Location: NNMC, Bethesda

Date: May, 1991 - Present

Primary

Researchers: Dr. P. Hirszel, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 20 adult patients with CRF and creatinine clearance below 15 ml/min.

Purpose: Protocol: B91-039

Test the hypothesis that after the creation of arteriovenous anastomosis, renal vascular resistance will decline, which in turn may ameliorate intraglomerular hyperfiltration.

Category: Other Research

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-43: Association of Bone Density and Menstrual Dysfunction with Fractures in USNA Midshipmen

Location: NNMC, Bethesda

Date: March, 1992 - Present

Primary

Researchers: LCDR A. Drake, MC USN

Sponsors: Clinical Investigation Program, NNMC conducted with USNA, Annapolis, MD

Funded by: Naval Medical Research and Development Command

Human

Subjects: 480 Midshipman, 240 male and 240 female, who have sustained a documented stress fracture or bone stress injury during the enrollment at the USNA. Informed consent obtained.

Purpose: Protocol: B91-067

To investigate the high incidence of stress fractures that occur in Midshipmen during training at the U. S. Naval Academy. Specifically, the association between stress fractures and decreased bone mineral density is being investigated.

Category: Other research

Records: NNMC, Bethesda

Classification: Unclassified

#

**Study #NNMC-44: A Comparison of Ultrasonographic Doppler Flow
Hysterosalpingography with Conventional Hysterosalpingography**

Location: NNMC, Bethesda

Date: June, 1993 - Present

Primary

Researchers: LT J. Tichenor, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 150 couples seeking evaluation and treatment of infertility at the NNMC who at the time of initial infertility evaluation do not have obvious causal factors.

Purpose: Protocol: B93-027

To compare the diagnostic accuracy of doppler flow US-HSG with conventional X-HSG and to identify the types of tubal disease most likely to be accurately diagnosed by each HSG procedure.

Category: Other Research

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-45: Randomized Study of Adriamycin as an Adjuvant after Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma in Stage I and Occult Stage II

Location: NNMC, Bethesda

Date: February, 1980 - Present

Primary

Researchers: CAPT J. Nash, MC USN, Sanford Sall, M. D., David Levy, M. D. and C. Paul Morrow, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Unknown

Purpose: Protocol: 80-06-1338-11

Study differences in morbidity and patient survival as functions of various growth patterns as well as treatment in high risk Stage I and, optionally, high risk Stage II occult endometrial carcinoma.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-46: A Surgical Pathological Study of Women with Invasive Carcinoma of the Cervix Stage 1B and Randomly Assigned Radiation Therapy Versus No Further Therapy in Selected Patients

Location: NNMC, Bethesda

Date: April, 1981 - Present

Primary

Researchers: CAPT J. Nash, MC USN, Dr. Gregorio Delgado, M. D., Dr. Wesley C. Fowler, Jr., M. D., Dr. Robert Kurman, M. D., and Dr. Henry Keys, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with primary, previously untreated histologically confirmed invasive Stage 1B carcinoma of the cervix. Informed consent in writing obtained.

Purpose: Protocol: 81-06-1338-23

1. To determine by observations, the validity of current FIGO staging to given histopathologic prognostic factors.
2. To rapidly accumulate prospectively significant surgical pathologic data which would expedite development of further protocols.
3. To determine morbidity of primary radical surgical therapy.
4. To determine if Radiation Therapy will improve survival in selected patients with positive nodes.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-47: A Randomized Comparison of Hydroxyurea Versus Misonidazole as an Adjunct to Radiation Therapy in Patients with Stages IIB, III, IVA Carcinoma of the Negative Para-Aortic Nodes Cervix and Negative Para-Aortic Nodes (Phase III)

Location: NNMC, Bethesda

Date: February, 1982 - Present

Primary

Researchers: CAPT J. Nash, MC USN, Dr. Vernon W. Jobson, M. D., Dr. Gerrit D'Ablaing, M. D., Dr. Henry M. Keys, M. D., and Dr. Hyman B. Muss, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with primary, previously untreated histologically confirmed invasive squamous cell carcinoma of the uterine cervix, clinical Stages IIB through IVA confined to the pelvis.

Purpose: Protocol: 81-06-1338-29

1. To determine whether hydroxyurea or misonidazole is superior as a potentiation of radiation therapy in advanced cervical cancer.
2. To compare the toxicity of hydroxyurea versus misonidazole when given concurrently with radiotherapy.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-48: Treatment of Patients with Suboptimal Stage IB Carcinoma of the Cervix: A Randomized Comparison of Radiation Therapy Versus Radiation Therapy Plus Adjuvant Extrafascial Hysterectomy

Location: NNMC, Bethesda

Date: January, 1986 - Present

Primary

Researchers: CAPT J. Nash, MC USN, Dr. Jackson B. Beecham, M. D., Dr. Marvin Rotman, M. D., Dr. Ned Hornback, M. D., Dr. Takashi Okagaki, M. D., Dr. Henry M. Keys, M. D., and Dr. Frederick B. Stehman, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with primary, untreated, histologically confirmed invasive carcinoma of the uterine cervix. Informed consent obtained in writing.

Purpose: Protocol: 86-06-1338-54

1. Evaluation of the role of adjunctive extrafascial hysterectomy in the treatment of suboptimal Stage IB carcinoma of the cervix.
2. Evaluation of survival and patterns of failure in suboptimal IB cervix cancer.
3. The study of toxicity of a combined radiation and surgical therapeutic program.
4. Evaluation of the prognostic value of various surgical/pathological characteristics in suboptimal Stage IB carcinoma of the cervix.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-49: A Phase II Study of the Treatment of Stage III & IV Disease of Advanced Endometrial Carcinoma and all Stages of Papillary Serous Carcinoma and Clear Cell Carcinomas of the Endometrium with Total Abdominal Radiation Therapy

Location: NNMC, Bethesda

Date: November, 1987

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Janice H. Axelrod, M. D., Dr. Tapan Roy, and Dr. Mary King, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 1 patient reported through 1989

Purpose: Protocol: 88-06-1338-69

1. To determine the survival and progression free interval of patients with maximally debulked advanced endometrial carcinoma treated with abdominal radiation therapy.
2. To determine the progression free interval and site of recurrence in patients with Stage I and II papillary serous carcinoma of the endometrium treated with abdominal radiation therapy with pelvic boost.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-50: A Randomized Comparison of Hydroxyurea Versus 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stage II-B, III and IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes

Location: NNMC, Bethesda

Date: November, 1987 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Charles W. Whitney, M. D., Dr. William T. Sause, M. D., Dr. Philip Bonomi, M. D., Dr. Shu-Yuan Liao, M. D., Dr. William Gordon, Jr., M. D., Dr. John C. Weed, Jr., M. D., Dr. Leslie R Laufman, M. D., and Dr. Frederick B. Stehman, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma of the uterine cervix, Stages II-B, III-A, III-B, and IV-A, with negative para-aortic nodes.

Purpose: Protocol: 88-06-1338-68

1. To determine whether hydroxyurea of the combination of 5-Fluorouracil and Allopurinol with Cisplatin is superior as a potentiator of radiation therapy in advanced cervical carcinoma.
2. To determine the relative toxicities of hydroxyurea versus the combination of 5-Fluorouracil and Cisplatin when given concurrently with radiation therapy.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-51: A Phase III Randomized Study of Surgery Plus Adjunctive Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma

Location: NNMC, Bethesda

Date: June, 1988 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. James A. Roberts, M. D., Dr. Jeffrey Gliedman, M. D., and Dr. Ned B. Hornback, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with primary histologically confirmed Grades 2 and 3 endometrial adenocarcinoma. Informed consent obtained in writing.

Purpose: Protocol: 88-06-1338-78

1. To determine if patients with intermediate risk endometrial adenocarcinoma, who have no spread of disease to their lymph nodes, benefit from postoperative pelvic radiotherapy.
2. To evaluate how the addition of pelvic radiotherapy will alter the site and rate of cancer recurrence in these intermediate risk patients.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-52: Evaluation of Intraperitoneal Chronic Phosphate Suspension Therapy Following Negative Second-Look Laparotomy for Epithelial Ovarian Carcinoma(Stage III Phase III)

Location: NNMC, Bethesda

Date: May, 1989 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Mahesh Varia, M. D. ,Dr. John L. Currie, M. D. and Dr. Jo Benda, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Numbers unknown. Patients with primary histologically confirmed epithelial carcinoma of the ovary who are in complete clinical remission. Informed consent obtained in writing.

Purpose: Protocol: 88-06-1338-83

Evaluate the role of intraperitoneal chronic phosphate suspension therapy in patients with Stage III epithelial ovarian carcinoma who have no detectable evidence of disease at the second-look laparotomy.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-53: Treatment of Selected Intermediate Risk Patients with Stage IB Carcinoma of the Cervix after Radical Hysterectomy and Pelvic Lymphadenectomy: Pelvic Radiation Therapy Versus No Further Therapy

Location: NNMC, Bethesda

Date: March, 1989 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Alex Sedlis, M. D., Dr. Marvin Rotman, M. D. and Dr. Richard J. Zaino, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects:

Purpose: Protocol: 88-06-1338-95

1. To determine the value of adjunctive pelvic radiation in the treatment of Stage IB carcinoma of the cervix, but with selected high-risk factors.
2. To determine the recurrence-free interval, survival and patterns of failure in these patients.
3. To determine the morbidity of adjunctive pelvic radiation following radical hysterectomy.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-54: A Randomized Clinical Trial for Treatment of Women with Selected Stage IC and II (A, B, C) and Selected Stage IA and IB and Ovarian Cancer (Phase III)

Location: NNMC, Bethesda

Date: June, 1989 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Robert C. Young, M. D., Dr. Leslie Walton, M. D., Dr. Ned B. Hornback, M. D. and Dr. Roberta M. Nieberg, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with a histopathologic diagnosis of epithelial ovarian cancer. Informed consent obtained.

Purpose: Protocol: 89-06-1338-96

1. To compare the progression-free interval and overall survival of the two treatment regiments.
2. To determine the patterns of relapse for each form of therapy.
3. To define the relative toxicities of the two treatment approaches.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #55: A Randomized Comparison of Hydroxyurea Versus Hydroxyurea 5-FU Infusion & Cisplatin as Adjunct Radiation Therapy in Patients w/ Stages IIIB, III, & IVA Carcinoma of Cervix & Negative Para-Aortic Nodes

Location: NNMC, Bethesda

Date: August, 1992 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Peter G. Rose, M. D., Dr. Edwin Watkins, M. D., Dr. Lynn Feun, M. D., Dr. Kristina Amyot, M. D. and Robin Sommers, R. N.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma of the uterine cervix, Stages II-B, III-A, III-B, and IV-A with negative para-aortic disease. Informed consent obtained in writing.

Purpose: Protocol: B92-060

1. To determine whether hydroxyurea, hydroxyurea, 5-FU infusion and bolus cisplatin, or weekly cisplatin is superior as a potentiator of radiation therapy in locally advanced cervical carcinoma.
2. To determine the relative toxicities of hydroxyurea, hydroxyurea, 5-FU infusion and bolus cisplatin, or weekly cisplatin given concurrently with radiation therapy.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

**Study #NNMC-56: Whole Abdominal Radiotherapy Versus Combination
Doxorubicin Cisplatin Chemotherapy in Advanced Endometrial Carcinoma**

Location: NNMC, Bethesda

Date: November, 1992 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Marcus E. Randall, M. D., Dr. Nicola Spirtos, M. D., Dr. Phil Dvoretzky, M. D. and Dr. William Hurushesky, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with advanced endometrial carcinoma, of any histology including clear cell and serous papillary carcinomas. Informed consent obtained in writing from patient and/or guardian.

Purpose: Protocol: B92-083

1. To compare treatment outcomes and failure patterns in patients with stages III-IV endometrial carcinoma treated with whole abdominal irradiation versus circadian-timed combination doxorubicin-cisplatin chemotherapy.
2. To determine and compare the incidence and type of acute and late adverse events observed with the two treatment regimens.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-57: A Phase II Trial of Doxorubicin (NSC #123127) and Ifosfamide (NSC 11389) in the Treatment of Recurrent or Uterine Leiomyosarcomas

Location: NNMC, Bethesda

Date: February, 1993 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Gregory P. Sutton, M. D. and Dr. Robert Asbury, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Plan to use average sample size of 30 valuable patients per drug studied. Informed consent obtained in writing.

Purpose: Protocol: B92-094

1. Identify new agents and combinations of agents for treating specific malignancies.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-58: A Randomized Comparison of Radiation Therapy and Adjuvant Hysterectomy Versus Radiation Therapy and Weekly Cisplatin and Adjuvant Hysterectomy in Patients with Bulky Stage IB Carcinoma of the Cervix

Location: NNMC, Bethesda

Date: September, 1993 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Henry B. Keys, M. D., Dr. Deborah Gersell, M. D., Dr. Frederick Stehman, M. D., Dr. Sarah Lincoln, M. D. and Lorraine Dennis, R. N.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients within eight weeks of diagnosis with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma of the uterine cervix Stage IB. Informed consent obtained in writing.

Purpose: Protocol: B93-068

1. To determine if weekly cisplatin infusion improves local regional control and survival when added to radiation therapy plus extrafascial hysterectomy.
2. To determine the relative toxicities of these two treatment arms.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-59: A Randomized Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjuvant Radiation

Location: NNMC, Bethesda

Date: December, 1993 - Present

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Rolland J. Barrett, M. D., Dr. Richard Stock, M. D., Dr. Frederick Stehman, M. D., Dr. Gillian Thomas, M. D., Dr. Robert C. Park, M. D., Dr. John Blessing, Ph. D., Dr. J. Tate Thigpen, M. D. and Dr. William Hoskins, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Numbers unknown. Patients must have *primary, histologically confirmed* invasive squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma of the uterine cervix. clinical Stages I-A2, I-B or II-A. Informed consent obtained in writing.

Purpose: Protocol: B94-018

1. To determine whether the combination of 5-flourouracil (f-FU) and cisplatin used as an adjunct to radiation therapy will improve survival rate of progression-free survival and decrease extra pelvic failure compared to radiation therapy alone in patients iwth positive pelvic lymph nodes, positive parametrial involvement or positive surgical margins following radical hysterectomy and lymph node dissection for Stages I-A2, I'B and II-A carcinoma of the cervix.

2. To determine the increase in toxicities due to 5-FU and cisplatin as an adjunct to radiation therapy versus radiation therapy alone.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-60: A Phase I Trial of Etoposide and Cisplatin Plus Chest Radiotherapy for Patients with Limited Stage Small Cell Lung Cancer

Location: NNMC, Bethesda

Date: December, 1993 - Present

Primary

Researchers: CAPT J. Phares, MC USN and Dr. Bruce E. Johnson, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with histologically confirmed diagnosis of SCLS and no previous chemotherapy or thoracic/cranial radiotherapy. Informed consent obtained in writing.

Purpose: Protocol: B93-082

1. To determine the maximum tolerated dose of cisplatin and a 12-21 day course of oral etoposide with 45 Gy of BID concurrent chest radiotherapy.
2. To determine the maximum tolerated dose of chest radiotherapy administered with the maximum tolerated dose of etoposide cisplatin for patients with limited stage small cell lung cancer.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-61: A Phase III Trial of Adjuvant Radiotherapy Versus Adjuvant Radiotherapy Plus Systemic Chemotherapy for Local and Regional Neuroendocrine (Merkel) Cancer of the Skin

Location: NNMC, Bethesda

Date: January, 1994 - Present

Primary

Researchers: CAPT J. Phares, MC USN, CAPT Gary Sladek, MC USN and Dr. Bruce Johnson, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with Clinical State I or II NECS based on history, physical exam and laboratory studies. Patients enrolled may have undergone any number or extent of surgical procedures. Patients enrolled no later than 8 weeks after the last surgical procedure.

Purpose: Protocol: B93-084

1. Determine the survival, disease-free survival, and pattern of relapse of local and regional NECS treated with adjuvant regional radiotherapy or postsurgical adjuvant combined regional radiotherapy and systemic chemotherapy following surgical excision.
2. Assess the toxicity of treatment with adjuvant regional radiotherapy or postsurgical adjuvant combined regional radiotherapy and systemic cisplatin and etoposide following surgical excision in patients with local and regional NECS.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-62: Pilot & Phase II Study of Low Dose Rate Chest Radiotherapy for Treatment of Intrathoracic Relapse of Small Cell Lung Cancer

Location: NNMC, Bethesda

Date: December, 1991 - Present

Primary

Researchers: LCDR M. Georgiadis, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with histologically confirmed diagnosis of SCLC or predominant small cell admixed with other cell types and will have relapsed with their predominant disease in the chest. Informed consent obtained in writing.

Purpose: Protocol: B91-087

1. To determine the technical feasibility of treating patients with low dose rate external beam therapy.
2. To determine the overall and complete response rate in patients with relapsed SCLC given twice a day radiotherapy delivered at a low dose rate.
3. To determine the pulmonary, esophageal, hematologic, and other toxicities of this regimen.
4. To determine the local control rates and survival of treated patients.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-63: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIA Hodgkin's Disease in Pediatric Patients - A Pediatric Oncology Group Phase III Study

Location: NNMC, Bethesda

Date: March, 1991 - Present

Primary

Researchers: CAPT B. Duval-Arnould, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown

Purpose: Protocol: B91-044

1. To compare the effectiveness of 3 cycles of MOPP/ABVD versus 2 cycles of MOPP/ABVD plus low dose radiation therapy in terms of duration of remission and eventual survival in children with early stage Hodgkin's disease.

2. To compare the incidence and severity of acute/long-term toxicity of MOPP/ABVD versus MOPP/ABVD plus involved field, low dose radiation therapy.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-64: Aline #15 Up Front Alternating 6-MP/MTX Versus Up-Front Alternating Chemotherapy for Acute Lymphocytic Leukemia in Childhood

Location: NNMC, Bethesda

Date: May, 1991 - Present

Primary

Researchers: CAPT B. Duval-Arnould, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects:

Purpose: Protocol: B91-058

To compare, in a randomized trial of children with ALL at higher risk for relapse, the efficacy and toxicity of A: 12 early intensive courses of IV methotrexate (MTX plus IV 6-mercaptopurine (6-MP) versus B: 12 early intensive courses of alternating intensive chemotherapy combinations (6 MP/MTX), VM-26/Ara-C, vincristine/prednisone/PEG-L-asparaginase/daunomycin/Ara-C.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-65: A Study of the Biological Behavior of Optic Pathway Tumors - A Phase II Study

Location: NNMC, Bethesda

Date: December, 1991 - Present

Primary

Researchers: CAPT B. Duval-Arnould, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients ≤ 21 years with diagnosis of an intraorbital of chiasmatic mass with or without visual loss who have no prior chemotherapy or radiation therapy. Informed consent obtained in writing.

Purpose: Protocol: B91-089

1. To assess time to progression of optic pathway tumors.
2. To estimate the response rate of radiation therapy in children with OPTs, when measured at 2 years post-irradiation.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-66: A Study of Childhood Soft Tissue Sarcoma (STS) Other Than Rhabdomyo-Sarcoma and Its variants - A POG Phase III Study

Location: NNMC, Bethesda

Date: December, 1991 - Present

Primary

Researchers: CAPT B. Duval-Arnould, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown.

Purpose: Protocol: B91-090

1. To determine whether adjuvant chemotherapy with vincristine, Adriamycin, cyclophosphamide, and actinomycin D (VACA) increases the relapse-free survival of patients with localized soft tissue sarcoma who are in complete response status after surgery with or without postoperative radiation.

2. To compare VACA with VACA plus DTIC (VACAD) therapy in regard to CR and RFS rates in patients with: (1) metastatic STS at diagnosis or (2) previously "untreated" recurrent STS or (3) localized persistent gross residual STS after surgery and radiation therapy.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-67: Phase I/II Dose Escalating Trial of Hyperfractionated Irradiation in the Treatment of Supratentorial Malignant Tumors of Childhood

Location: NNMC, Bethesda

Date: December, 1991 - Present

Primary

Researchers: CAPT B. Duval-Arnoud, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients ≥ 3 and ≤ 21 years old with histological confirmation of malignant glioma or poorly-differentiated embryonal tumor that is supratentorial in location.

Purpose: Protocol: B91-094

1. To determine the feasibility of using limited volume hyperfractionated radiation therapy to treat children with localized supratentorial malignant gliomas.
2. To determine the feasibility of using hyperfractionated craniospinal irradiation to treat children with poorly-differentiated supratentorial embryonal tumors or supratentorial malignant gliomas associated with neuraxis dissemination (Group B).

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-68: Pre Radiation Chemotherapy for Children with Supratentorial Malignant Gliomas and Poorly-Differentiated Embryonal Tumors

Location: NNMC, Bethesda

Date: January, 1991 - Present

Primary

Researchers: CAPT B. Duval-Arnoud, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients age ≥ 3 years and ≤ 21 years with histologically confirmed primary malignant glioma or poorly-differentiated embryonal tumor that is supratentorial in location. Informed consent obtained in writing.

Purpose: Protocol: B92-001

1. To estimate the response of children with supratentorial malignant glioma or poorly-differentiated embryonal tumors to three cycles of either BCNU plus continuous-infusion cisplatin or cyclophosphamide plus continuous-infusion etoposide (VP-16)
2. To determine the acute and sub-acute toxicities of these combination chemotherapies.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-69: Treatment for Newly Diagnosed Low Grade Astrocytomas

Location: NNMC, Bethesda

Date: June, 1992 - Present

Primary

Researchers: CAPT B. Duval-Arnoud, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown.

Purpose: Protocol: 92-026

1. Determine the beneficial effects of irradiation in newly diagnosed low-grade astrocytomas of the brain in childhood.
2. Define the role of surgical resection in newly diagnosed low-grade astrocytomas of the brain in childhood.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

**Study #NNMC-70: Treatment of First Marrow and/or Extramedullary Relapse
Childhood Acute T-Lymphoblastic Leukemia and/T Non Hodgkin's Lymphoma with
Combination Chemotherapy including 2' Deoxycoformycin**

Location: NNMC, Bethesda

Date: December, 1992 - Present

Primary

Researchers: CAPT B. Duval-Arnoud, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients ≤ 21 years of age with diagnosis of T-ALL or T-NHL with life expectancy of >1 month. Informed consent obtained in writing.

Purpose: Protocol: 93-019

1. To assess the toxicity and efficacy of low dose deoxycoformycin given as IV bolus injection in prolonging the duration of remission for patients with T-ALL/T-NHL in second remission.
2. To determine the correlation of clinical responses and toxicities with plasma levels of adenoxine deaminase (ADA), adenosine (ado) and deoxyadenosine (dado), dATP/ATP ratios in RBCs, and in vitro sensitivity of leukemia cells to DCF plus dado.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-71: A Clinical Trial to Evaluate the Worth of Tamoxifen in Conjunction with Lumpectomy & Breast Irradiation for Treatment of Noninvasive Intraductal Carcinoma (DCIS) of the Breast

Location: NNMC, Bethesda

Date: April, 1993 - Present

Primary

Researchers: CDR James N. Frame, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Female patients with DCIS and being treated by breast conservation.

Purpose: Protocol: 92-090

Evaluate the effectiveness of Tamoxifen for preventing the occurrence of invasive and non-invasive cancers, both ipsilateral and contralateral, in patients with intraductal cancers treated by lumpectomy and breast irradiation.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-72: A Clinical Trial to Determine Worth of Breast Radiation in the Management of Patients with Node-Negative, Occult Invasive Breast Cancer Treated by Lumpectomy

Location: NNMC, Bethesda

Date: April, 1993 - Present

Primary

Researchers: CDR James N. Frame, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Female patients having occult, invasive primary breast cancer treated by lumpectomy with axillary dissection and histologically proven negative axillary nodes; with a life expectancy of at least 10 years, excluding her diagnosis of cancer. Informed consent obtained in writing.

Purpose: Protocol: B92-091

Determine whether long-term treatment with tamoxifen (with and without breast radiation) is effective in prolonging DFS in patients with occult, invasive cancer.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-73: Use of Radiocopper in the Diagnosis of Wilson's Disease

Location: NNMC, Bethesda

Date: July, 1992 - September, 1993 (one time use)

Primary

Researchers: CAPT Eugene Silverman, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: 1 patient with Wilson's Disease

Purpose: Protocol: 92-13 NIDRB

To resolve a questionable diagnosis of Wilson's Disease and allow initiation of appropriate therapy in a single patient. This involves a rare case wherein the usual diagnostic procedures are unable to rule out or confirm the diagnosis.

Category: Therapeutic Research Involving Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-74: A Randomized Study of Radical Vulvectomy and Bilateral Groin Radiation, Phase III

Location: NNMC, Bethesda

Date: March, 1988 - August, 1991

Primary

Researchers: CAPT J. D. Nash, MC USN, Dr. Frederick B. Stehman, M. D., Dr. Mahesh Varia, M. D. and Dr. Takashi Okagaki, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma of the vulva. Informed consent obtained in writing.

Purpose: Protocol: B88-002

1. To evaluate the comparative efficacy and morbidity of groin radiation therapy in lieu of groin dissection for selected patients with invasive squamous cell carcinoma of the vulva.
2. To monitor patterns of recurrence and survival of patients treated with groin radiation therapy in lieu of groin dissection.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-75: Scintigraphic Characterization of Parathyroid Glands in Chronic Renal Insufficiency

Location: NNMC, Bethesda

Date: July, 1988 - February, 1991

Primary

Researchers: Dr P. Hirszel, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Approximately 6. Patients greater than 18 years old who have chronic renal disease.

Purpose: **Protocol:** 88-06-2400-00

To delineate the scintigraphic pattern and extent of parathyroid abnormalities in chronic renal insufficiency.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-76: Monoclonal Antibody Serotherapy of Chronic Lymphocytic Leukemia and Cutaneous T-Cell Lymphoma and Radioimaging with Radiolabeled Monoclonal Antibody T-101

Location: NNMC, Bethesda

Date: February, 1983 - July, 1988

Primary

Researchers: CAPT S. R. Veach, MC USN and Dr. P. A. Bunn, Jr., M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients > 18 years of age with histologically confirmed diagnosis of CLL or CTCL refractory to standard therapy.

Purpose: Protocol: 83-06-1660-21

1. Evaluate the clinical response, optimal dose, and toxicity of multiple dose administration of T101 antibody in patients with CLL and CTCL given by slow intravenous infusion.
2. Monitor patients for the presence of free antigen, free antibody, antigenic modulation, and antimurine antibody formation following administration of T101.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

**Study #NNMC-77: Treatment of Limited Small Cell Bronchogenic Carcinoma:
Chemotherapy Alone or With Radiation Therapy**

Location: NNMC, Bethesda

Date: October, 1982 - July, 1988

Primary

Researchers: CAPT S. Veach, MC USN, Dr. Martin H. Cohen, M. D., Dr. John D. Minna, M. D., Dr. Paul A. Bunn, M. D., Dr. Daniel C. Ihde, M. D., Dr. Byron E. Fossieck, M. D., Dr. Mary J. Matthews, M. D. and Dr. Anita Johnston-Early, RN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with inoperable histologically confirmed small cell carcinoma. Informed consent obtained.

Purpose: Protocol: 82-06-1660-09

1. To determine whether the addition of radiation therapy during remission induction will increase the complete response rate and will prolong the survival of limited small cell patients when compared to randomized patients treated with chemotherapy only.
2. To determine patterns of relapse of patients treated with chemotherapy alone or with radiation therapy.
3. To determine the toxicity of radiotherapy in this treatment program.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-78: Valuation of Chemohomonal Therapy and Breast Carcinoma Patients with No Evidence of Disease Following an Excised or Curatively Irradiated Recurrence

Location: NNMC, Bethesda

Date: October, 1982 - December, 1989

Primary

Researchers: CDR M. Anderson, MC USN and Dr. Marc Lippman, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with histologically documented recurrence of mammary carcinoma.

Purpose: Protocol: 82-06-1660-15

Increase survival and potentially cure some patients with breast cancer recurrence.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-79: Treatment of Cutaneous T-Cell Lymphoma (CTCL) and Chronic Lymphocytic Leukemia (CLL) with Yttrium-90 Radiolabeled T-101 Monoclonal Antibody

Location: NNMC, Bethesda

Date: March, 1987 - June, 1993

Primary

Researchers: CAPT J. Phares, MC USN, Dr. Barnett S. Kramer, M. D. and Dr. Andrew Raubitschek, M. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients with histologically confirmed diagnosis of CLL or CTCL which is refractory to standard therapy.

Purpose: Protocol: 87-06-1660-50

1. Assess the therapeutic efficacy and toxicity of the T101 monoclonal antibody radiolabeled with the beta emitter yttrium-90 in patients with refractory cutaneous T-cell lymphoma or chronic lymphocytic leukemia.
2. Compare the localization and biodistribution of radiolabeled T101 after therapeutic intravenous or intralymphatic administration.
3. Determine the maximum tolerated dose for intravenous and for intralymphatic administration of 90Y-T101.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-80: Randomized Study of Intensive Chemotherapy (MOPP/AVBD) + 1-Low-Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, IIIA2, IIIB, IV Hodgkin's Disease in Pediatric Patients

Location: NNMC, Bethesda

Date: February, 1991 - January, 1993

Primary

Researchers: CAPT B. Duval-Arnoud, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Patients ≤ 21 years of age with histologically proven Hodgkin's disease, previously untreated with the exception of radiation therapy for airway obstruction or spinal cord compression. Informed consent obtained.

Purpose: Protocol: 91-055

1. Determine, in a randomized study, whether the addition of low dose total nodal radiation therapy in pediatric patients with Hodgkin's disease who have achieved a complete remission after receiving 4 courses of MOPP alternating with 4 courses of AVBD will improve the duration of complete remission and survival when compared to patients who have received chemotherapy alone.

2. Determine whether TNRT will significantly increase either acute toxicity or long-term morbidity when compared to MOPP/ABVD alone.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-81: A Phase III Study of Indium III Labeled Granulocytes for Detection of Inflammation Process in Humans

Location: NNMC, Bethesda

Date: May, 1987

Primary

Researchers: CDR Eugene D. Silverman, MC USN, LT Walter E. Drane, MC USNR and LCDR Kastytis Karvelis, MC USNR

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: No patients. Project was terminated.

Purpose: Protocol: 85-06-2108-00

Evaluate inflammatory process with In-111 oxine labeled granulocytes.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-82: Glucose Metabolism by Position Emission Tomography

Location: NNMC, Bethesda

Date: March, 1989 - July, 1993

Primary

Researchers: LT E. Cheney, MC USN and Dr. Robert M. Cohen, M. D., Ph. D.

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Number unknown. Study called for 375 total participants including patients with schizophrenia, affective disorders, or neuropsychiatric disorders and normal volunteers.

Purpose: Protocol: 88-06-2453

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-83: The Sensitivity and Specificity of MRI CT Arthrography and MRI Arthrography for the Evaluation of the Shoulder

Location: NNMC, Bethesda

Date: April, 1992

Primary

Researchers: LT K. Pryor, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: *Approximately 40 patients with shoulder instability over a 24 month period were to be recruited. Informed consent obtained.*

Purpose: Protocol: 91-078

Evaluate the effectiveness of multiple imaging modalities in diagnosis of shoulder injuries.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NNMC-84: Phase I Evaluation of Intravenously Administered ¹³¹I-Col-1 Monoclonal Antibody in Patients with Advanced Carcinoma

Location: NNMC, Bethesda

Date: August, 1992 - November, 1993

Primary

Researchers: CDR James N. Frame, MC USN

Sponsors: Clinical Investigation Program, NNMC

Human

Subjects: Patients ≥ 18 years of age with unresectable or metastatic histologically confirmed adenocarcinoma, and failed standard therapy. Informed consent obtained.

Purpose: Protocol: 92-039

Further develop therapies for patients with gastrointestinal adenocarcinomas following fluorouracil containing treatment regimens.

Category: Treatment use of Radiation

Records: NNMC, Bethesda

Classification: Unclassified

#

Study #NHCHL-01: Blood Volume Studies (51-Cr and 125-I)

Location: Naval Hospital Chelsea/Blood Lab

Date: 1964

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-02: Red Blood Cell Survival Studies (51-Cr and 125-I)

Location: Naval Hospital Chelsea/Blood Lab

Date: 1964

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NHCHEL-03: Platelet Survival Studies (51-Cr and 125-I)

Location: Naval Hospital Chelsea/Blood Lab

Date: 1964

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NHCHEL-04: Blood Volume Studies (51-Cr and 125-I)

Location: Naval Hospital Chelsea/Blood Lab

Date: 1964-1978

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-05: A Study of Carbon Monoxide Production During Anesthesia as Method of Determining Red Blood Cell Survival.

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: S. Vescera

Sponsors: NA

Human

Subjects: 21 patients

Purpose: To evaluate the red cell mass and turnover in patients subjected to surgical stress. Exposure to radiation was incidental to being a part of the study.

Category: Other research, diagnostic.

Records: NH Chelsea

Classification: Unclassified

#

Study #NHCHL-06: Pathophysiological Adaptations in Pregnancy: A Study of Oxygen Transport Mechanisms in Normal Abnormal Pregnancy of Fetal Manifestations of Intrauterine Hypoxia, of Dysfunctional Labor and of Trace Metal Cadmium as Possible Factors in Hypertensive Syndrome

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: S. Barchet

Sponsors: N/A

Human

Subjects: unknown

Purpose: To improve clinical technological approaches to improve maternal care

Category: Other research, diagnostic.

Records: NH Chelsea

Classification: Unclassified

#

Study #NHCHEL-07: Treatment of Ankle Fractures by Anatomic Reduction and Internal Fixation with Early Motion

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: M. A. Maginnis

Sponsors

Human

Subjects: unknown

Purpose: To assess the principle of rigid internal fixation and early motion for fresh ankle fractures .

Category:

Records:

Classification: Unclassified

#

Study #NHCHEL-08: The Clinical Effects of Beta-Blockade on Thyrotoxicosis

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: T. J. Lapine

Sponsors:

Human

Subjects: 10

Purpose: To use beta-blockade to suppress the overt clinical effects of thyrotoxicosis.

Category:

Records:

Classification: Unclassified

#

Study #NHCHEL-09: Evaluation of the Vectorcardiogram on Early Detection of Increased Right Heart Work in Asthma in Children

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: J. W. Thomas

Sponsors:

Human

Subjects: 11 children with asthma

Purpose: To determine if VCG can be used for the early detection of increased right heart work in patients with asthma.

Category:

Records:

Classification: Unclassified

#

Study #NHCHEL-10: A Correctional Compression Osteotomy of the Distal Tibia

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: M. A. Maginnis

Sponsors:

Human

Subjects: unknown

Purpose: To assess a relatively new method of correctional osteotomy for the residual deformities following fractures of the tibial shaft.

Category:

Records:

Classification: Unclassified

#

Study #NHCHEL-11: The Effects of Estrogen Therapy on Parameters of Thyroid Function in the Post-Menopausal Patient

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: M. Birnbaum

Sponsors:

Human

Subjects: unknown

Purpose: To ascertain the effect of estrogen therapy on parameters of thyroid function in post menopausal women.

Category:

Records:

Classification: Unclassified

#

Study #NHCHEL-12: Effects of Position on Results of Gastric Analysis

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: C. I. Giaser

Sponsors:

Human

Subjects: 20

Purpose: To evaluate gastric acidity under rigid controls by the method of Kay in several positions with fluoroscopic placement of the collection to be in the same patient and then to repeat the study without regard for placement and position.

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-13: Clinical Cancer Research in Association with the ECOG

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: E. Braun

Sponsors:

Human

Subjects: unknown

Purpose: Treat patients with advanced cancer, when appropriate studies are available, under drug treatment protocols of the Eastern Co-operative Oncology Group.

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-14: Detection of Occult, Venous Thrombosis by "Impedence Meter" and II25 Fibrinogen

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: R. L. Mullin

Sponsors:

Human

Subjects: 100-201

Purpose: To evaluate the Codman Impedance Phlebograph machine in detecting occult venous thrombosis.

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-15: Treatment of Acute and Chronic Edema Secondary to Lymphatic or Venous Insufficiency

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: R. L. Mullin

Sponsors:

Human

Subjects: Over 50

Purpose: To evaluate the use of the Jobst Intermittent Compression Unit on patients with acute and chronic edema.

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-16: Nitroblue Tetrazolium Test, its Use in (a) Diagnosis of Postoperative Fever, (b) Appendicitis

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: P. J. Kovalcik

Sponsors:

Human

Subjects: 28

Purpose: To aid in the diagnosis of postoperative fever.

Category:

Records:

Classification: Unclassified

#

**Study #NHCHL-17: Evaluation of Hypophosphatemia and Blood Volume Changes
Induced by Parenteral Hyperalimentation**

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: R. L. Schloemer

Sponsors:

Human

Subjects: 10

Purpose: To determine the degree of phosphate depletion and the changes in blood volume in patients undergoing prolonged intravenous hyperalimentation.

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-18: Evaluation of the Cast Brace in Treatment of Femoral Shaft Fractures

Location: Naval Hospital Chelsea/Blood Lab

Date:

Primary

Researchers: J. C. Brothers

Sponsors:

Human

Subjects: 19

Purpose: To improve the care of patients with femoral shaft fractures by allowing ambulation throughout the period of fracture healing.

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-19: Heparin Anticoagulation by Continuous Intravenous Infusion

Location: Naval Hospital Chelsea/Blood Lab

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NHCHL-20: Gallium-67 Scanning for Staging of Carcinoma of the Breast.

Location: Naval Hospital Chelsea/Blood Lab

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**STUDY #NMCS-01: CLINICAL EVALUATION OF GA-76 SCANNING IN THE
DIAGNOSIS OF ANAPLASTIC CARCINOMA AND MALIGNANT LYMPHOMA IN
THE THYROID GLAND.**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : UNKNOWN

PRIMARY RESEARCHERS: UNKNOWN

SPONSOR: UNKNOWN

SUBJECTS: UNKNOWN

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☒ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

**STUDY #NMCSD-02: THE SIGNIFICANCE OF POSITIVE IPSILATERAL NODES
IN RESECTIONS OF LUNG**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1972

PRIMARY RESEARCHERS: CAPT R. G. FOSBURG

SPONSOR: BUMED

SUBJECTS: 75

PURPOSE: To study the significance of positive ipsilateral nodes in resections of lungs.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-03: CHEMOTHERAPEUTIC AGENTS IN THE
TREATMENT OF LUNG TUMORS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1972

PRIMARY RESEARCHERS: CAPT R. G. FOSBURG

SPONSOR: BUMED

HUMAN SUBJECTS: 41

PURPOSE: To treat patients who have advanced carcinoma of the lung with chemotherapeutic agents.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-04: EXTRACRANIAL SUSPENSION VS INTER- OR
INTRAOSSEUS SUPPORT IN TREATMENT OF FACIAL FRACTURE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1972

PRIMARY RESEARCHERS: CAPT W. E. SUGG

SPONSOR: BUMED

HUMAN SUBJECTS: 14

PURPOSE: To Study the comparative analysis of extracranial fixation in the treatment and management of facial fractures.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-05: PANCREATO-CHOLANGIOGRAPHY AND MANOMETRY
OF THE SPHINCTER OF ODI**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1973

PRIMARY RESEARCHERS: LCDR O. T. NEBEL

SPONSOR: BUMED

HUMAN SUBJECTS: 60

PURPOSE: Sphincter of oddi pressure was measured for evaluation of acute and recurrent pancreatitis and post-cholecystectomy syndrome.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-06: RESULTS OF CLUBFOOT TREATMENT

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1973

PRIMARY RESEARCHERS: LCDR A. M. MARTINSON

SPONSOR: BUMED

HUMAN SUBJECTS: 72

PURPOSE: To evaluate patients with a history of clubfeet by investigating their history, giving physical exams, and by taking x-rays and photographs.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-07: COLONOSCOPY IN THE DIFFERENTIAL DIAGNOSIS OF
INFLAMMATORY BOWEL DISEASE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1973

PRIMARY RESEARCHERS: CDR M. F. FORNES

SPONSOR: BUMED

HUMAN SUBJECTS: 20

PURPOSE: Patients with hematochezia were evaluated by colonoscopy to determine the diagnostic efficacy of this procedure in rectal bleeding.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-08: STRESS FRACTURES OF THE FEMUR

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1973

PRIMARY RESEARCHERS: LCDR J. M. LaPOINT

SPONSOR: BUMED

HUMAN SUBJECTS: 50

PURPOSE: To Study fatigue fractures of the femoral neck.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-09: KETAMINE ANESTHESIA IN MINOR OTOLOGIC PROCEDURES

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1974

PRIMARY RESEARCHERS: LCDR ROPER/LCDR KRAMER

SPONSOR: BUMED

HUMAN SUBJECTS: 78

PURPOSE: To evaluate effectiveness of Ketamine anesthesia in minor otologic procedures. Chest x-rays were part of the evaluation.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY#NMCSD-10 IMMUNOCYTOADHERENCE TESTING IN
LYMPHOPROLIFERATIVE DISORDERS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1974

PRIMARY RESEARCHERS: LCDR R. F. GRANATIR

SPONSOR: BUMED

HUMAN SUBJECTS: 112

PURPOSE: To Study and identify circulating lymphocytes in patients with lymphomas and to Study the effect of subsequent therapy on circulating lymphocytes.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-11: TREATMENT OF TIBIAL FRACTURES WITH ELECTRIC MICROCURRENT

LOCATION :NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1974

PRIMARY RESEARCHERS: CAPT G. W. CADY

SPONSOR: BUMED

HUMAN SUBJECTS: 4

PURPOSE: To evaluate the feasibility of accelerating the healing of tibial fractures by local administration of electric microcurrent.

CATEGORIES

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-12: EARLY DIAGNOSIS OF ASEPTIC NECROSIS OF THE
FEMORAL HEAD FOLLOWING TRAUMATIC DISLOCATION OF THE HIP**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1974

PRIMARY RESEARCHERS: LCDR R. L. NUTT

SPONSOR: BUMED

HUMAN SUBJECTS: 17

PURPOSE: To Study the validity of radioisotopic scanning in the early diagnosis of aseptic necrosis following traumatic hip dislocation and femoral neck fractures, including stress fractures.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-13: ACROMIO-CLAVICULAR SEPARATIONS

LOCATION :NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1974

PRIMARY RESEARCHERS: LCDR R. J. IMATAMI

SPONSOR: BUMED

HUMAN SUBJECTS: 23

PURPOSE: To Study the significance between operative and non operative treatment of complete dislocations of the acromio-clavicular joint.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-14: USE OF NON-INVASIVE MONITORING TECHNIQUE TO
EVALUATE THE PRE-AND POST-OPERATIVE ARTERIAL BLOOD FLOW A-S-O**

LOCATION :NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1974

PRIMARY RESEARCHERS: CAPT D. R. JAMES

SPONSOR: BUMED

HUMAN SUBJECTS: 126

PURPOSE: To evaluate the role of profunda femoris arterial reconstruction in the treatment of femoropopliteal atherosclerotic occlusive disease.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-15: ENDOSCOPIC ELECTROSURGICAL POLYPECTOMY

LOCATION :NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1974

PRIMARY RESEARCHERS: LCDR O. T. NEBEL

SPONSOR: BUMED

HUMAN SUBJECTS: 15

PURPOSE: To evaluate duodenoscopy and the diagnosis of upper gastrointestinal bleeding.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

STUDY #NMCSD-16: RECURRENT LOWER URINARY TRACT INFECTIONS IN WOMAN: THE EFFECT OF URETHRAL DILATION

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1975

PRIMARY RESEARCHERS: CDR J. P. SANDS JR.

SPONSOR: BUMED

HUMAN SUBJECTS: 25

PURPOSE: The effect of urethral dilation on recurrent lower urinary tract infections in woman.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-17: ANGIOGRAPHIC ANALYSIS OF LEFT VENTRICULAR MECHANICS IN YOUNG PATIENTS WITH ATYPICAL CHEST PAIN AND ISCHEMIC HEART DISEASE

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1975

PRIMARY RESEARCHERS: CAPT A. D. HAGAN

SPONSOR: BUMED

HUMAN SUBJECTS: 26

PURPOSE: To investigate left ventricular mechanics in young men and women with suspected or proven ischemic heart disease.

CATEGORY:

- ☒ **EXPERIMENTAL DIAGNOSTIC**
- ☐ **INCIDENTAL DIAGNOSTIC**
- ☐ **EXPERIMENTAL THERAPEUTIC**
- ☐ **THERAPEUTIC TREATMENT**
- ☐ **OTHER**
- ☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-18: FRACTURE OF THE ANKLE IN A MILITARY POPULATION

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1975

PRIMARY RESEARCHERS: LCDR J. S. SARKISIAN

SPONSOR: BUMED

HUMAN SUBJECTS: 250

PURPOSE: To evaluate the functional radiographic results of treatment of ankle fractures.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-19: ABNORMALITIES INVOLVING THE ALTERNATE
PATHWAY IN URTICARIA OR ANGIOEDEMA**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1975

PRIMARY RESEARCHERS: LCDR D. S. HUREWITZ

SPONSOR: BUMED

HUMAN SUBJECTS: 10

PURPOSE: To Study the alteration of the complement system in chronic idiopathic urticaria.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-20: A Clinical Trial to Compare Combination Chemotherapy with and without C. Parvum in the Management of Patients with Surgically Curable Breast Cancer Who Have One or More Axillary Nodes

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1976

PRINCIPAL INVESTIGATOR: CAPT J. Ragland

SPONSOR: NSABP

HUMAN SUBJECTS: 22

PURPOSE: To compare combination Chemotherapy in the management of patients with surgically curable breast cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-21: DETECTION OF A PERICARDIAL EFFUSION BY
ECHOCARDIOGRAPHY IN HYPOTHYROID PATIENTS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1976

PRIMARY RESEARCHERS: LCDR D. M. DAVIDSON

SPONSOR: BUMED

HUMAN SUBJECTS: 25+

PURPOSE: To determine the presence of and quantitate pericardial fluid accumulation in patients with hypothyroidism, both before and after treatment.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-22: THE USE OF ^{99m}Tc-PYROPHOSPHATE BONE SCANNING IN THE EARLY DETECTION OF STRESS FRACTURES

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1976

PRIMARY RESEARCHERS: LT J. W. WILCOX

SPONSOR: BUMED

HUMAN SUBJECTS: 34

PURPOSE: To evaluate the usefulness of bone scanning in the early diagnosis of exercise-related stress injuries of the lower extremities.

CATEGORY:

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-23: BONE AND GALLIUM SCANNING IN THE EVALUATION
OF DISSEMINATED COCCIDIOIDMYCOSIS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1976

PRIMARY RESEARCHERS: LCDR J. H. BODDICKER

SPONSOR: BUMED

HUMAN SUBJECTS: 34

PURPOSE: To determine the presence and extent of disseminated coccidioidmycosis
through bone and gallium scans.

CATEGORY

- ☒ **EXPERIMENTAL DIAGNOSTIC**
- ☐ **INCIDENTAL DIAGNOSTIC**
- ☐ **EXPERIMENTAL THERAPEUTIC**
- ☐ **THERAPEUTIC TREATMENT**
- ☐ **OTHER**
- ☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-24: NSABP# 4

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1986

PRIMARY RESEARCHERS: CDR T. J. GUZIK

SPONSOR: BUMED/NCI

HUMAN SUBJECTS: 52

PURPOSE: To compare radical mastectomy vs total with radiation vs total mastectomy with radiation for stage A (ONE) and radical mastectomy vs total mastectomy with radiation for stage B (TWO) breast cancer.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-25: THE DISTRIBUTION OF VENTILATION/PERFUSION RATIOS IN ACUTE AND CHRONIC CARDIOPULMONARY DISEASE

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1976

PRIMARY RESEARCHERS: CAPT R. F. SCHILLACI

SPONSOR: BUMED

HUMAN SUBJECTS: 16

PURPOSE: To Study the distributions of ventilation and blood flow in patients with several different types of acute and chronic lung disease.

CATEGORY:

- ☒ **EXPERIMENTAL DIAGNOSTIC**
- ☐ **INCIDENTAL DIAGNOSTIC**
- ☐ **EXPERIMENTAL THERAPEUTIC**
- ☐ **THERAPEUTIC TREATMENT**
- ☐ **OTHER**
- ☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-26: EFFECT OF HYPERTHYROIDISM ON SERUM GASTRIN
AND GASTRIC ACID PRODUCTION BEFORE AND AFTER TREATMENT**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1976

PRIMARY RESEARCHERS: LCDR D. S. ANDERSON

SPONSOR: BUMED

HUMAN SUBJECTS: 4

PURPOSE: To Study the acid secretory rates in patients with Grave's disease both before and after treatment for thyrotoxicosis. Also Study of acid secretory rate with serum gastrin production after a protein meal, and again both before and after treatment for hyperthyroidism.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-27: VASODILATED EXCRETORY UROGRAPHY - A
DIAGNOSTIC APPROACH TO RENOVASCULAR HYPERTENSION**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1977

PRIMARY RESEARCHERS: LCDR C. W. EMARINE

SPONSOR: NONE

HUMAN SUBJECTS: UNCERTAIN

PURPOSE: To Study the alterations in Renal Vasodilatory Reserve as estimated from renal size changes and changes in renal silhouette area size before and after intravenous injection of Lasix.

CATEGORY

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-28: CONTRAST MEDIA REACTIONS - THE ROLE OF HISTAMINE, COMPLEMENT, AND DILUTIONAL SKIN TESTS

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1977

PRIMARY RESEARCHERS: LCDR SCHATZ

SPONSOR: NRMCS

HUMAN SUBJECTS: 25-50

PURPOSE: To Study the effect of intravascular RCM administration on plasma complement levels and on plasma histamine levels. Also to define the significance of cutaneous responses to diluted contrast media injections.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-29: PILOT STUDY FOR THE TREATMENT OF PREVIOUSLY
UNTREATED BRAIN TUMOR IN CHILDREN**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1977

PRIMARY RESEARCHERS: CDR KOENIG

SPONSOR: BUMED

HUMAN SUBJECTS: 8

PURPOSE: To examine the feasibility of using chemotherapy at the time of diagnosis of brain tumors in children in combination with standard surgical and radiation approaches.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-30: COMBINATION CHEMOTHERAPY OF DISSEMINATED
TESTICULAR CARCINOMA W/CIS DIAMINODICHLOROPLATINUM
W/DIURESIS, BLEOMYCIN**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1977

PRIMARY RESEARCHERS: P.M. DAINER MC/USNR

SPONSOR: BUMED

HUMAN SUBJECTS: 30

PURPOSE: To Study a regimen of Cis-Diaminodichloroplatinum (DDP), Bleomycin, and Vinblastine with respect to response rate, duration disease free interval and survival in patients with testicular carcinomas. Participants were initially given chest x-rays

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-31: NSABP R-01: A Clinical Trial to Evaluate Postoperative Radiation and Postoperative Systemic Chemotherapy in the Management of Resectable Rectal Carcinoma

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1978

PRINCIPAL INVESTIGATOR:CAPT J. Ragland

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:11

:Cancer Patients

SUMMARY: To evaluate Postoperative Radiation and Postoperative Chemotherapy in the management of respectable Rectal Carcinoma.

☐ **EXPERIMENTAL DIAGNOSTIC**
☐ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☒ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-32: NSABP C-01: A Clinical Trial to Evaluate Postoperative Immunotherapy and Postoperative Systemic Chemotherapy in the Management of Resectable Colon Cancer

**LOCATION OF STUDY: NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY: 1978

PRINCIPAL INVESTIGATOR: CAPT J. Ragland

SPONSOR: NSABP

NUMBER OF HUMAN SUBJECTS: 20

SUMMARY: To evaluate Postoperative Immunotherapy and Postoperative Chemotherapy in the management of resectable Colon Cancer.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

#

STUDY #NMCSD-33: A COMPARISON OF THREE IODINATED CONTRAST MEDIA FOR EXCRETORY UROGRAPHY

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1978

PRIMARY RESEARCHERS: F.H. GERBER CDR/MC/USNR

SPONSOR: BUMED

HUMAN SUBJECTS: 30

PURPOSE: to compare three iodinated contrast media for excretory urography.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-34: THE EFFICACY OF CORTICOSTEROID IN THE
TREATMENT OF ACUTE ASTHMA**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1978

PRIMARY RESEARCHERS: R.A. PICK LT/MC/USNR

SPONSOR: BUMED

HUMAN SUBJECTS: 24

PURPOSE: To Study the role of corticosteroid in the treatment of acute asthma.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSO-35: THE USEFULNESS OF COMPUTERIZED AXIAL
TOMOGRAPHY IN EVALUATION OF PULMONARY METASTASES**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1978

PRIMARY RESEARCHERS: CAPT J. A. GIBBONS

SPONSOR: NMCSO

HUMAN SUBJECTS: 6

PURPOSE: To assess the usefulness of computerized axial tomography of the chest in evaluation of possible metastatic pulmonary disease as compared to conventional investigation.

CATEGORY:

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-36: ADJUVANT IMMUNOTHERAPY IN STAGE I NON-OAT
CELL LUNG CARCINOMA**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1978

PRIMARY RESEARCHERS: H.J. LONG CDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 59

PURPOSE: To determine whether adjuvant BCG by the intrapleural route of administration prolongs duration of disease free survival in patients with surgically resected Stage I non-oat cell carcinoma of the lung and whether it prolongs the duration of disease free survival in patients receiving postoperative irradiation for Stage II non-oat cell carcinoma of the lung.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-37: BONE SCANNING IN THE EVALUATION OF STRESS FRACTURES

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1979

PRIMARY RESEARCHERS: F.H. GERBER CAPT/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 409

PURPOSE: To evaluate stress fractures of the lower extremity through the use of bone scanning.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-38: TREATMENT OF LOWER RESPIRATORY TRACT
INFECTION WITH CEFORANIDE VS CEFAZOLIN**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1979

PRIMARY RESEARCHERS: CDR W. O. HARRISON

SPONSOR: BUMED

HUMAN SUBJECTS: 30

PURPOSE: To Study the treatment of lower respiratory tract infection with ceforanide vs cefazolin.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-39: EVALUATION OF A NEW CEPHALOSPORIN, HR-756, IN THE TREATMENT OF INFECTIONS CAUSED BY SUSCEPTIBLE BACTERIA

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1979

PRIMARY RESEARCHERS: CAPT W. O. HARRISON

SPONSOR: BUMED

HUMAN SUBJECTS: 332

PURPOSE: To evaluate the efficacy, safety, tolerance and optimal therapeutic dosages of HR-756, a new cephalosporin, in the treatment of adult patients with infections due to susceptible microorganisms.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-40: PHASE III CLINICAL INVESTIGATION OF INDIUM DTPA
FOR CISTERNOGRAPHY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: CDR B. R. RAO

SPONSOR: NMCS/UCSD

HUMAN SUBJECTS: 8

PURPOSE: Phase III clinical investigation of indium DTPA for Cisternography.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-41: EVALUATION OF KETOCONAZOLE IN THE TREATMENT OF SYSTEMIC MYCOSES

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: CAPT R. F. SCHILLACI

SPONSOR: JANSSEN PHARMACEUTICA

HUMAN SUBJECTS: 20

PURPOSE: To evaluate the clinical usefulness of ketoconazole in the treatment of systemic mycoses. All participants had initial chest x-rays.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

**STUDY #NMCS-42: CONTROLLED STUDY ON THE USE OF DOPAMINE IN
NEONATAL ASPHYXIA**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: LCDR R. M. McNEAL

SPONSOR: NMCS

HUMAN SUBJECTS: 20

PURPOSE: To observe if Dopamine will prevent complications in neonates who are born asphyxiated.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-43: AN EVALUATION OF PROFILE CHANGES FOLLOWING VESTIBULOPLASTY TECHNIQUES

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: D.L. PFEIFER CAPT/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 409

PURPOSE: To determine the difference between pre-surgical and post-surgical facial profiles. Radiographic profiles were required.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

STUDY #NMCSD-44: NATIONAL STUDY OF CONTRAST MEDIA REACTIONS

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: F.H. GERBER CAPT/MC/USN

SPONSOR: NATIONAL INSTITUTE OF HEALTH

HUMAN SUBJECTS: 600

PURPOSE: To determine whether patients pretreated with adrenalcorticosteroids will have a significantly lesser incidence of reactions to the IV injection of x-ray contrast media.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-45: A QUANTITATIVE ASSESSMENT OF FACIAL SOFT
TISSUE RESPONSE FOLLOWING THE USE OF METHYLPRENDISOLONE
AFTER SINGULAR ORTHOGNATHIC SURGICAL PROCEDURES**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: C.B. STULLER CDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 35

PURPOSE: To quantify facial soft tissue response following the use of Methylprednisolone after singular orthognathic surgical procedures.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-46: VENTILATORY FUNCTION AFTER FLAIL CHEST INJURY

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: S.R. SHACHFORD LCDR/MC/USN

SPONSOR: NMCS

HUMAN SUBJECTS: 62

PURPOSE: To Study ventilory function after flail chest injury. Chest x-rays were given.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

#

STUDY #NMCSD-47: COMBINATION CHEMOTHERAPY OF DIFFUSE MALIGNANT PLEURAL MESOTHELIOMA WITH EITHER ADRIAMYCIN AND CYTOXAN OR CYTOXAN, ONCOVIN, METHOTREXATE AND 5-FLUOROURACIL

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: R.W. HAERR LT/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To Study the use of combination chemotherapy of diffuse malignant pleural mesothelioma with either adriamycin and cytoxan or cytoxan, oncovin, methotrexate and 5-fluorouracil. A CAT scan was obtained after delivery.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-48: RADIONUCLIDE BILIARY IMAGING UTILIZING ^{99m}Tc - PIPIDA

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: J.R. WILCOX LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 128

PURPOSE: Report that 99 Tc m PIPIDA is no longer used by the Radiology Department due to the use of a new FDA approved radiopharmaceutical called 99 mTc-DISIDA.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-49: VENTILATION CHANGES RESULTING FROM DRAINAGE
AND PLEURODESIS FOR MALIGNANT PLEURAL EFFUSION**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: CAPT J. A. GIBBONS

SPONSOR: NMCS/BUMED

HUMAN SUBJECTS: 20

PURPOSE: To quantitate the ventilation changes of patients undergoing pleural drainage and pleurodesis for malignant pleural effusions.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-50: TERMINAL DEOXYNUCLEOTIDYL TRANSFERASE (TdT)
IMMUNOFLUORESCENCE OF BONE MARROW SMEARS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1980

PRIMARY RESEARCHERS: CAPT W. J. THOMAS

SPONSOR: BUMED

HUMAN SUBJECTS: 15

PURPOSE: To determine bone marrow conditions and the value of performing terminal deoxynucleotidyl transferase (TdT) immunofluorescence on patients with lymphoid malignancies. Participants had chest x-ray studies completed.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-51: SURGICAL ADJUVANT CHEMOTHERAPY OF STAGE II
BREAST CANCER: TWO CMFVP REGIMENS WITH OR WITHOUT A
SUBSEQUENT ADRIAMYCIN COMBINATION**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA
92134-5000

DATE : 1981

PRIMARY RESEARCHERS: CDR F. MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS: 20

PURPOSE: To determine Surgical Adjuvant Chemotherapy of Stage II Breast Cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-52: NSABP B-06: A Protocol to Compare Segmental Mastectomy and Axillary Dissection with and without Radiation of the Breast and Total Mastectomy and Axillary Dissection

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1981

PRINCIPAL INVESTIGATOR:CAPT J. RAGLAND

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:13

SUMMARY: To compare Segmental Mastectomy and Axillary Dissection with and without Radiation of the breast and total Mastectomy and Axillary Dissection

☐ EXPERIMENTAL DIAGNOSTIC
☐ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☒ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-53: NSABP B-11: A Protocol to Compare Alkeran (L-PAM) + 5-Fluorouracil (5-FU) with and without Adriamycin in the Management of Patients with Primary Breast Cancer and Positive Axillary Nodes Whose Tumors Are Negative For Estrogen Receptors

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1981

PRINCIPAL INVESTIGATOR:CAPT J. RAGLAND

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:8

:Breast Cancer Patients

SUMMARY: To determine whether the addition of Adriamycin to L-PAM + 5-FU will result in decreasing the change of tumor recurrence and prolong survival.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-54: NSABP B-12: A Protocol to Compare Alkeran (L-PAM) and 5-Fluorouracil (5-FU) + Tamoxifen with and without Adriamycin in the Management of Patients with Primary Breast Cancer and Positive Axillary Nodes Whose Tumors Are Positive for Estrogen Receptors

LOCATION OF STUDY: NAVAL HOSPITAL/NAVAL MEDICAL CENTER, SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1981

PRINCIPAL INVESTIGATOR: CAPT J. RAGLAND

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:6

:Breast Cancer Patients

SUMMARY: Compare Alkeran (L-PAM) + 5-Fluorouracil (5-FU) + Tamoxifen with or without Adriamycin in the management of patient with Primary Breast Cancer and positive Axillary Nodes whose tumors are positive for Estrogen Receptors.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-55: A RANDOMIZED CONTROLLED TRIAL OF
INDOMETHACIN, PGI₂, AND HEPARIN IN THE ACUTE PHASE OF CEREBRAL
ISCHEMIA**

LOCATION :NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: LCDR A. J. DUTKA

SPONSOR: BUMED/UPJOHN

HUMAN SUBJECTS: UNCERTAIN

PURPOSE: A randomized controlled trial of indomethacin, PGI 2, and heparin in the acute phase of cerebral ischemia.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-56: RADIONUCLIDE BILIARY IMAGING UTILIZING ^{99m}Tc-P-BUTYL-IDA

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: CAPT B. R. RAO

SPONSOR: BUMED

HUMAN SUBJECTS: 90

PURPOSE: To evaluate radionuclide biliary imaging utilizing ^{99m}Tc-py-buty1-IDA.

CATEGORY:

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-57: A DOUBLE-BLIND CONTROLLED STUDY COMPARING
INDOMETHACIN AND PLACEBO IN PREVENTION OF RADIATION
ESOPHAGITIS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: LCDR P. K. MEYERS

SPONSOR: BUMED

HUMAN SUBJECTS: 7

PURPOSE: A double-blind controlled study comparing indomethacin and placebo in prevention of radiation esophagitis.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-58: COMBINATION CHEMOTHERAPY, WHOLE-BODY
RADIOTHERAPY AND NON-CROSS RESISTANT CHEMOTHERAPY FOR SMALL
CELL CARCINOMA OF THE LUNG, EXTENSIVE DISEASE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: CAPT LEA

SPONSOR: BUMED

HUMAN SUBJECTS: 4

PURPOSE: Used combined chemotherapy, whole-body radiotherapy and non-cross resistant chemotherapy for small cell carcinoma of the lung having extensive disease.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-59: A COMPARATIVE STUDY OF CEFADROXIL VS
CEPHALEXIN IN THE TREATMENT OF BACTERIAL PNEUMONIA IN
AMBULATORY PATIENTS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: CAPT W. O. HARRISON

SPONSOR: BUMED

HUMAN SUBJECTS: 132

PURPOSE: To compare the use of cefadroxil vs cephalixin in the treatment of bacterial pneumonia in ambulatory patients. Chest x-rays were given.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-60: SERIAL ANGIOGRAPHIC ASSESSMENT OF THE EFFECT OF RISK FACTOR MODIFICATION IN YOUNG ACTIVE DUTY NAVY MEN

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: CAPT R. A. PICK

SPONSOR: BUMED

HUMAN SUBJECTS: 30

PURPOSE: Perform angiograms to assess the effect of risk factor modification in young active duty men.

CATEGORY:

- ☒ **EXPERIMENTAL DIAGNOSTIC**
- ☐ **INCIDENTAL DIAGNOSTIC**
- ☐ **EXPERIMENTAL THERAPEUTIC**
- ☐ **THERAPEUTIC TREATMENT**
- ☐ **OTHER**
- ☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

**STUDY #NMCSO-61: ESTABLISHMENT OF RADIOIMMUNOASSAY FOR
MEASURING HUMAN IMMUNOGLOBULIN**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: CDR W. J. THOMAS

SPONSOR: BUMED

HUMAN SUBJECTS: 80

PURPOSE: To establish a reproducible sensitive assay to measure small quantities of human immunoglobulin G.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-62: THE COMPARATIVE EFFECTIVENESS OF COMBINATION CHEMOTHERAPY ALONE OR WITH RADIATION THERAPY TO INVOLVED FIELD OR EXTENDED FIELD, IN POOR RISK PATIENTS WITH STAGE I AND II HODGKIN'S DISEASE

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: LCDR M. R. SHEA

SPONSOR: BUMED

HUMAN SUBJECTS: 2

PURPOSE: To test if combination Chemotherapy alone is as effective as extended field Radiotherapy in poor prognosis Hodgkins's disease patients with Stages I and II.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-63: CALGB 7761: COMBINATION CHEMOTHERAPY OF MULTIPLE MYELOMA

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: LCDR M. R. SHEA

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To test the hypothesis of combination Chemotherapy of multiple Myeloma.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-64: PROTOCOL FOR CLINICAL EVALUATION OF
PERCUTANEOUS CORONARY ANGIOPLASTY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1981

PRIMARY RESEARCHERS: LCDR R. PICK

SPONSOR: BUMED

HUMAN SUBJECTS: 24

PURPOSE: To provide to proper atmosphere for the continued study of the technique of percutaneous coronary angioplasty.

CATEGORY

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

STUDY #NMCSD-65: USE OF VP16-213 IN COMBINATION WITH CISPLATIN FOR TREATMENT OF RECURRENT TESTICULAR CANCER IN A SINGLE PATIENT.

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: G. DANNISH LCDR/MC/USNR

SPONSOR: NRMCMC

HUMAN SUBJECTS: 1

PURPOSE: Determine the effectiveness of a combination of antineoplastic agents for treatment of recurrent testicular carcinoma in a single patient.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-66: EMERGENCY USE OF INVESTIGATIONAL DRUG VM-26
MONO-OCTNOIN IN THE CASE OF R. NEVILLS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: D.S. ANDERSON CDR/MC/USNR

SPONSOR: NRMCMC

HUMAN SUBJECTS: 1

PURPOSE: Emergency use of an investigational drug on a single patient.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-67 CHEMOTHERAPY OF ADVANCED PANCREATIC CANCER-
A COMPARATIVE PHASE II STUDY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR D. R. MASYS

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To establish the activity of two combination chemotherapeutic regimens against pancreatic carcinoma.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

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**STUDY #NMCSD-68: A STUDY OF THE EFFECTIVENESS OF
INTENSIFICATION WITH TWO COURSES OF CYTOSIN ARABINOSIDE AND
DAUNORUBICIN FOLLOWING REMISSION INDUCTION WITH ACUTE
LYMPHOCYTIC LEUKEMIA**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR W. L. ROBINSON

SPONSOR: BUMED

HUMAN SUBJECTS: 2

PURPOSE: To study the effectiveness of intensification with two courses of Cytosin Arabinoside and Daunorubicin following remission induction with Actue Lymphocytic Leukemia.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-69: A RANDOMIZED STUDY COMPARING THE
COMBINATION OF HORMONAL THERAPY AND CHEMOTHERAPY WITH
CHEMOTHERAPY ALONE FOR THE TREATMENT OF ADVANCED BREAST
CANCER IN WOMEN**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER
DATE : 1982

PRIMARY RESEARCHERS: LCDR D. R. MASYS

SPONSOR: BUMED

HUMAN SUBJECTS: 7

PURPOSE: To test whether the combination of hormonal manipulation and chemotherapy changes the response and survival in postmenopausal patients with advanced breast cancer, as compared to chemotherapy alone.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSO-70: SURGICAL ADJUVANT CHEMOTHERAPY OF STAGE II
BREAST CANCER; TWO CMFVP REGIMENS WITH OR WITHOUT A
SUBSEQUENT ADRIAMYCIN COMBINATION**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR R. M. SHEA

SPONSOR: BUMED

HUMAN SUBJECTS: 9

PURPOSE: To study the possibility of use of chemotherapy for patients with Stage II breast cancer, after surgery.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

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**STUDY #NMCSD-71: LOCALIZED SMALL CELL CARCINOMA OF THE LUNG -
A PHASE II STUDY OF SIMULTANEOUS CHEMOTHERAPY AND
RADIOTHERAPY VS SEQUENTIAL THERAPY VS CHEMOTHERAPY ALONE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR R. M. SHEA

SPONSOR: BUMED

HUMAN SUBJECTS: 2

PURPOSE: Test whether chemotherapy plus radiation are superior to chemotherapy alone in the treatment of lung cancer. Also it would evaluate the intermediate and delayed effects of CNS radiation on the cognitive functions of the patients

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-72: A COMPARATIVE STUDY OF HIGH DOSE ARA-C ALONE OR GIVEN SEQUENTIALLY WITH L-ASPARAGINASE FOR REMISSION INDUCTION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA AFTER FAILURE OF INITIAL INDUCTION OR IN RELAPSE

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR D. R. MASYS

SPONSOR: NMCS

HUMAN SUBJECTS: 2

PURPOSE: To test the drug araabinofuranosyl cytosine (ara-C) in the treatment of leukemia. A part of the test included a chest x-ray.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-73: VINBLASTINE, DTIC, AND CIS-PLATINUM (DDP) IN THE TREATMENT OF ADVANCED OR RECURRENT METASTATIC MALIGNANT MELANOMA

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR D. R. MASYS

SPONSOR: NMCS

HUMAN SUBJECTS: 2

PURPOSE: To test the drug VDP in the treatment of recurrent malignant melanoma. During the study whole brain irradiation was authorized and would not interfere with the chemotherapy study.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-74: THERAPY OF CHRONIC MYELOGENOUS LEUKEMIA IN
BLAST CRISIS WITH 5-AZACYTIDINE PLUS VP-16-213**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR D. R. MASYS

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To determine the effectiveness of azacytidine therapy in the treatment of leukemia. A routine chest x-ray is required.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-75: NSABP B-13: A Clinical Trial to Assess Sequential Methotrexate + 5-Fluorouracil in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Negative for Estrogen Receptors

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1982

PRINCIPAL INVESTIGATOR:CAPT J. RAGLAND

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:7

:Breast Cancer Patients

PURPOSE: A clinical trail to test methotrexate in the treatment of breat cancer. There was *no mention of the use of radiation in this study.*

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-76: NSABP B-14: A Clinical Trial to Assess Tamoxifen in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Positive for Estrogen Receptors

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1982

PRINCIPAL INVESTIGATOR:CAPT J. RAGLAND

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:16

:Breast Cancer Patients

PURPOSE: A clinical trial to test Tamoxifen in the treatment of breast cancer.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-77: COMBINATION CHEMOTHERAPY WITH MASTECTOMY
OR RADIOTHERAPY FOR STAGE III BREAST CARCINOMAS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR D. R. MASYS

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To test the relative efficacy of surgery versus radiotherapy when either is performed following chemotherapy. The secondary object was to determine patterns of relapse sites following mastectomy or radiotherapy.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-78: CONTINUOUS INFUSION VINBLASTINE WITH
BLEOMYCIN AND CISPLATIN FOR TREATMENT OF CANCERS OF THE UPPER
DIGESTIVE TRACT AND LUNG**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR M. R. SHEA

SPONSOR: BUMED

HUMAN SUBJECTS: 2

PURPOSE: To determine rate and duration of response to this combination of antineoplastic agents in patients with non-oat cell carcinoma of the lung. The standard treatment for this form of cancer was surgery, radiation therapy or a combination of both.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-79: EVALUATION OF LIGHT SCANNING AS A NEW MODALITY FOR SCREENING WOMEN FOR BREAST CANCER

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: V. G. MARSHALL

SPONSOR: BUMED

HUMAN SUBJECTS: ~5000

PURPOSE: To demonstrate the efficacy of the use of lightscanning as a screening procedure for cancer of the breast. (Lightscanning is a name used for simple transillumination of the breasts.) The benefit of using this procedure is that there is no radiation or known risks associated with this procedure.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-80: A PHASE II TRIAL OF A THREE DRUG REGIMEN
CONSISTING OF CYTOXAN, 5-FU, AND CIS-PLATINUM IN STAGE D
ADENOCARCINOMA OF THE PROSTATE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR J. MANFRO

SPONSOR: BUMED

HUMAN SUBJECTS: 75

PURPOSE: The purpose of the study was to test the effectiveness of the stated drugs in the treatment of prostate cancer. Radiation therapy or P-32 were used to alleviate bone pain in patients.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-81:INTERGROUP RHABDOMYOSARCOMA (RMS) STUDY II
(IRS 2)

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: CDR A. L. LIGHTSEY JR.

SPONSOR: NMCSD

HUMAN SUBJECTS: 1

PURPOSE: RMS represents between 5-15% of all malignant solid tumors. It was shown that RMS could be controlled or ablated when doses of radiation were delivered to the site in the range of 5,000 to 6,000 rads.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-82: A-COP PLUS FOR NON-HODGKIN'S LYMPHOMA IN CHILDREN

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1979

PRIMARY RESEARCHERS: CDR W. J. THOMAS

SPONSOR: NMCS

HUMAN SUBJECTS: 2

PURPOSE: To test whether a combination of drugs and radiotherapy would be effective in the treatment of non-hodgkin's lymphomas. Radiotherapy 3,000 Rads tumor dose would be administered during the first sign of remission.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-83: INTERMITTENT HIGH DOSE CYTARABINE FOR
TREATMENT OF COLORECTAL ADENOCARCINOMA: A PHASE II STUDY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LCDR M. R. SHEA

SPONSOR: BUMED

HUMAN SUBJECTS: 5

PURPOSE: The objective of this study was to determine whether Cytarabine given in high doses intermittently is an effective single agent treatment of patients with colon or rectum carcinoma. Prior to entry into this study the patient would have to under go a number of prescreening tests to include:chest x-ray, radionuclide scans of liver, brain and bones, and a IV urogram.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-84: STRESS FRACTURE AS THE ETIOLOGY OF ACUTE CHONDROMALACIA, PATELLA (CMP)

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1982

PRIMARY RESEARCHERS: LT D. O. HOLMES/LT M. J. BOSSE

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: The ability to differentiate between CMP and a common stress fracture. The patient would receive a standard x-ray of the knee. Bone scanning would be accomplished using Tc-99 (The average dose in routine scanning is 20 mCu per patient study.) Patients with an abnormal bone scan would undergo a diagnostic arthroscopy to confirm the diagnosis.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

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Study #NMCSD-85:CALGB 8321: A Comparative Study of Two Remission Induction Regimens of ARA-C for Acute Myelogenous Leukemia: A Phase III Study

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1983

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:4

:Cancer Patients

PURPOSE: *A comparative drug test. for the treatment of Acute Myelogenous Leukemia.*

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

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Study #NMCS-86:CALGB 8251: Treatment of Advanced Hodgkin's Disease: A Randomized Phase III Trial Comparing MOPP vs. ABVD vs. MOPP Alternating with ABVD

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1983

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:4

:LEUKEMIA

PURPOSE: To compair the group B treatment protocol for cancer and leukemia.

☐ **EXPERIMENTAL DIAGNOSTIC**
☒ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☐ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-87: EMERGENCY USE OF CIS-PLATINUM (DDP), VINDESINE (DVA), AND BLEOMYCIN IN THE TREATMENT OF ESOPHAGEAL CARCINOMA

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: LCDR G. J. GUZLEY

SPONSOR: ELI LILLY CO

HUMAN SUBJECTS: 1

PURPOSE: ..The purpose test was for the emergency use of an investigational drug for a single patient. The drug that was to be used was Vindesine Sulfate and the sponsor of the drug was Eli Lilly. The patient had been treated with a full dose irradiation and still had progression of the disease. This was a test of a new drug.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSO-88: THERAPY OF CML IN BLAST CRISIS WITH 5 -
AZACYTIDINE PLUS VP-16-213**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: D.R. MASYS LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To determine the activity of intensive chemotherapy with continuous infusion 5-azacytidine and etoposide in patients with CML blast crisis.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-89: COMBINATION CHEMOTHERAPY FOR METASTATIC
RECURRENT CANCER OF THE BREAST. A RANDOMIZED PHASE III TRIAL
COMPARING CAF VATH VS. VATH ALTERNATING WITH CMFVP**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: D.R. MASYS LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 3

PURPOSE: To compare the complete remission frequency, disease-free survival and survival for the three combination chemotherapy regimens. The patients will be required to have either a scan or x-ray.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-90: A RANDOMIZED PHASE II TRIAL OF CYTOSINE ARABINOSIDE (ARA-C) AND PLATINUM (CDDP) VS VINBLASTINE (VLG) AND PLATINUM (CDDP) IN ADVANCED NON-SMALL CELL LUNG CARCINOMA

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: LCDR D. R. MASYS

SPONSOR: BUMED

HUMAN SUBJECTS: 2

PURPOSE: Unknown (Abstract not available)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-91: THE EFFECT OF VERAPAMIL ON PATIENTS WITH IRRITABLE BOWEL SYNDROME (IBS) WHO HAVE DIARRHEA WITH OR WITHOUT ABDOMINAL PAIN

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: LCDR L. D. FREEMAN

SPONSOR: BUMED

HUMAN SUBJECTS: 6

PURPOSE: To evaluate the clinical effects of Verapamil on patients with symptomatic IBS and compare the results to a group that was given a placebo. Verapamil is a drug that produces its effect by acting as calcium blockers. One of the routine tests required for this study was a barium enema.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-92: COMPUTED TOMOGRAPHY AND PERITONEAL LAVAGE
IN DETERMINING THE SEVERITY OF VISCERAL INJURY AFTER BLUNT
ABDOMINAL TRAUMA**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: CDR P. W. SOBALLE

SPONSOR: NMCS

HUMAN SUBJECTS: 3

PURPOSE: To determine the efficacy of computer tomography and peritoneal lavage in the diagnosis of significant visceral injury after blunt abdominal trauma. (BAT). The purpose was to reduce the number of unnecessary laparotomy procedures.

CATEGORY:

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-93: PHASE I STUDY OF INDIUM-111 LABELED MURINE
MONOCLONAL ANTIBODY FOR EXTERNAL PHOTOSCANNING OF
MELANOMA AND OTHER TUMORS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: LCDR J. SHEGA

SPONSOR: BUMED

HUMAN SUBJECTS: 4

PURPOSE: To administer Indium-111 for radioimmunodetection of (imagining) melanoma and to evaluate its toxicity.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-94: NONALCOHOLIC LIVER DISEASE IN THE ALCOHOLIC

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: LCDR R. A. BROWER

SPONSOR: BUMED

HUMAN SUBJECTS: 76

PURPOSE: To determine the frequency of nonalcoholic liver disease in a patient population with heavy alcohol intake and evidence of hepatic dysfunction.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-95: INDIUM-111 OXINE LABELED GRANULOCYTES FOR
DETECTION OF INFLAMMATORY PROCESS IN HUMANS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: CAPT B. R. RAO

SPONSOR: NMCS

HUMAN SUBJECTS: 18

PURPOSE: The best test available for intra-abdominal infection. In labeled leukocytes have provided useful information in the detection or exclusion of inflammatory processes.

CATEGORY:

- ☒ **EXPERIMENTAL DIAGNOSTIC**
- ☐ **INCIDENTAL DIAGNOSTIC**
- ☐ **EXPERIMENTAL THERAPEUTIC**
- ☐ **THERAPEUTIC TREATMENT**
- ☐ **OTHER**
- ☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-96: THE USE OF ISOTRETINOIN IN PREVENTION OF BASAL CELL CARCINOMA

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1983

PRIMARY RESEARCHERS: LCDR H. T. GREENWAY

SPONSOR: BUMED

HUMAN SUBJECTS: 90

PURPOSE: This was a test of isotretinoin as a treatment for skin cancer. It helps to link the role of vitamin A intake in the prevention of human malignancies.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study # NMCS-97: NSABP B-04: PROTOCOL FOR THE EVALUATION OF
RADICAL MASTECTOMY AND TOTAL MASTECTOMY WITH AND WITHOUT
RADIATION IN THE PRIMARY TREATMENT OF CANCER OF THE FEMALE
BREAST**

Location: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

Date: 1984

Primary Researchers: CAPT J. RADLAND

Sponsors: NSABP

Human Subjects: 63

Purpose: To determine the amount of surgery required in the primary treatment of breast cancer.

Category:

-[] EXPERIMENTAL DIAGNOSTIC
-[X] INCIDENTAL DIAGNOSTIC
-[] EXPERIMENTAL THERAPEUTIC
-[] THERAPEUTIC TREATMENT
-[] OTHER
- [] UNKNOWN/UNCERTAIN

Records: NAVAL MEDICAL CENTER SAN DIEGO

Classification: Unclassified

#

**Study # NMCS-98: A CLINICAL TRIAL TO COMPARE L-PAM WITH L-PAM
AND 5-FU IN THE MANAGEMENT OF PRIMARY BREAST CANCER WHO HAVE
ONE OR MORE POSITIVE NODES**

Location: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

Date: 1984

Primary Researchers: CAPT J. RAGLAND

Sponsors: NSABP

Human Subjects: 7

Purpose: Test chemotherapy combinations in stage II breast cancer women

Category:

.....[] EXPERIMENTAL DIAGNOSTIC
.....[X] INCIDENTAL DIAGNOSTIC
.....[] EXPERIMENTAL THERAPEUTIC
 [] THERAPEUTIC TREATMENT
.....[] OTHER
.....[] UNKNOWN/UNCERTAIN

Records: NAVAL MEDICAL CENTER SAN DIEGO

Classification: Unclassified

#

Study #NMCS-99 NSABP B-08: A Clinical Trial to Compare L-PAM and 5-FU vs. L-PAM and 5-FU and Methotrexate in the Management of Patients with Primary Breast Cancer Who Have One or More Positive Axillary Nodes

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1984

PRINCIPAL INVESTIGATOR:CAPT J. RAGLAND

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:21

:BREAST CANCER

PURPOSE To test varied chemotherapy regimes on women with positive nodes in primary breast cancer.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-100: EMERGENCY DRUG USE OF INVESTIGATIONAL DRUG
AZQ** ICO THERESA FOUSEL

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1984

PRIMARY RESEARCHERS: CDR W. J. THOMAS

SPONSOR: NMCS

HUMAN SUBJECTS: 1

PURPOSE: To treat a patient that was resistant to standard therapy. AZQ offered the best chance for long term control of the disease. Patient diagnosis: Glioblastoma, multiforme.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-101: APPROVAL OF THE FINAL CASE REPORT ON THE
EMERGENCY USE OF INVESTIGATIONAL DRUGS METHYL-GAG AND
IFOSPHAMIDE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1984

PRIMARY RESEARCHERS: W.J. THOMAS/MC/USNR

SPONSOR: NMCSD/UCSF

HUMAN SUBJECTS: 1

PURPOSE: To treat a patient with AIDS.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-102: CARBOPLATIN (CBDCA) VS IPROPLATIN (CHIP) IN
ADVANCED NON-SMALL CELL LUNG CARCINOMA, PHASE II**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1984

PRIMARY RESEARCHERS: LCDR W. M. SHEA

SPONSOR: BUMED

HUMAN SUBJECTS: 3

PURPOSE: To screen single-agent or combination chemotherapy programs for significant activity in metastatic NSCLC because of a malignant pleural effusion. The secondary objective was to measure the toxicity of the single or combination chemotherapy program. Prior to the study the patient would receive: chest x-ray; bone scan; and a liver scan.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-103: REGIONAL STAGE III NSCLC CHEMOTHERAPY
AND RADIATION THERAPY VS. RADIATION THERAPY ALONE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1987

PRIMARY RESEARCHERS: LCDR W. L. ROBINSON

SPONSOR: BUMED

HUMAN SUBJECTS: 3

PURPOSE: To look at whether adding chemotherapy to conventional radiotherapy would improve overall or disease free survival in patients with non-small cell lung cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-104: MITOMYCIN C AND CISPLATIN VS. ADRIAMYCIN AND CISPLATIN FOR MALIGNANT MESOTHELIOMA PHASE II

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1984

PRIMARY RESEARCHERS: W.L. ROBINSON LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To outline the procedure for Phase II studies to evaluate the efficacy of intensive treatment of patients with histologically proven malignant mesothelioma.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-105: CYTOSINE ARABINOSIDE AND CISPLATIN FOR
ADVANCED STAGE BREAST CANCER**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1984

PRIMARY RESEARCHERS: W.L. ROBINSON LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: This was a protocol that outlined the procedure for Phase II studies to evaluate single or multiple agents for significant anti-tumor activity in the treatment of inoperable, advanced or recurrent carcinoma of the breast. A chest x-ray, liver scan and bone scan are part of the routine studies which will be performed.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-106: COLD CARDIOPLEGIA - EFFECTS ON PHRENIC NERVE CONDUCTION, DIAPHRAGM MOTION, AND LUNG VOLUMES

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1984

PRIMARY RESEARCHERS: LCDR M. T. KUBAR

SPONSOR: BUMED

HUMAN SUBJECTS: 15

PURPOSE: The purpose of the study was three fold: (1) Determine the incidence of phrenic nerve injury after topical cold cardioplegia during cardio-pulmonary bypass; (2) Assess the duration and severity of injury to phrenic nerve; (3) Determine if patients who will develop phrenic nerve injury can be identified by high-risk profile.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study # -NMCSD-108: ADJUVANT CDF FOR PATHOLOGIC STAGE II BREAST
CANCER: RANDOMIZATION AMONG INTENSIVE CDF FOR FOUR MONTHS
VS. STANDARD DOSE CDR FOR SIX MONTHS**

Location: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

Date: 1985

Primary Researchers: CDR F. MILLARD

Sponsors: CALGB

Human Subjects: . 15

Purpose: Follow on study for CDR in the treatment of breast cancer.

Category:

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSITC
.....| ☐ EXPERIMENTAL THERAPEUTIC
.....| ☐ THERAPEUTIC TREATMENT
.....| ☐ OTHER
☐ UNKNOWN/UNCERTAIN

Records: NAVAL MEDICAL CENTER SAN DIEGO

Classification: Unclassified

#

Study #NMCSD-109: NSABP B-15: Three Arm Clinical Trial Comparing Short Intensive Adriamycin-Cyclophosphamide with or without Interval Reinduction Chemotherapy (CMF) to Conventional Chemotherapy (CMF) in Positive Node Patients Who are Ages 49 or Younger Six Months

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1985

PRINCIPAL INVESTIGATOR:CAPT J. RAGLAND

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:6

PURPOSE:To compare short intensive asriamycin cyclophosphamide with or without interval reinduction chemotherapy to conventional chemotherapy in positive node patients who are ages 49 or younger.

☐ **EXPERIMENTAL DIAGNOSTIC**
☒ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☐ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-110: NSABP B-16: Three Arm Clinical Trial Comparing Tamoxifen Alone with Short Intensive Adriamycin-Cyclophosphamide + Tamoxifen in Node Positive Patients with Positive Progesterone Assays Who Are Aged 50 to 59 or Greater than 59 Regardless of PR Status

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1985

PRINCIPAL INVESTIGATOR:CAPT J. RAGLAND

SPONSOR:NSABP

NUMBER OF HUMAN SUBJECTS:6

PURPOSE: To test varied chemotherapy hormonal therapies on postmenopausal node positive patients who are PRA positive.

☐ **EXPERIMENTAL DIAGNOSTIC**
☒ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☐ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study # -NMCS-111: NATIONAL INTERGROUP PROTOCOL FOR
INTERMEDIATE THICKNESS MELANOMAS 1.0 TO 4.0 MM**

Location: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

Date: 1985

Primary Researchers: CAPT J. RAGLAND

Sponsors: NATIONAL INTERGROUP

Human Subjects: 1

Purpose: Study to determine the size of surgical excision in intermediate melanomas

Category:

☐ EXPERIMENTAL DIAGNOSTIC
.....☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ OTHER
☐ UNKNOWN/UNCERTAIN

Records: NAVAL MEDICAL CENTER SAN DIEGO

Classification: Unclassified

#

**STUDY #NMCS-112: APPROVAL OF THE FINAL REPORT ON THE
EMERGENCY USE OF INVESTIGATIONAL DRUG CYANOACRYLATE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1985

PRIMARY RESEARCHERS: C.E. LEY LCDR/MC/USNR

SPONSOR: NMCS/UCSF

HUMAN SUBJECTS: 1

PURPOSE: The benefits that this drug would produce include: it would allow the palliation of an otherwise inoperable lesion with such benefits as improved blood flow to normal brain with possible improvement of neurological deficit.; also it facilitation of surgical removal of large malformations or fistulae. In all it leads to improved treatment for intracrnial lesions.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

**STUDY #NMCSO-113: ONE TIME EMERGENCY USE OF INVESTIGATIONAL
AGENT CISPLATIN/THIOSULFATE ICO T. ARY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1985

PRIMARY RESEARCHERS: LCDR M. A. KOSMO

SPONSOR: NMCSO

HUMAN SUBJECTS: 1

PURPOSE: A one time use of an investigational drug in the treatment of a patient with malignant pleural effusion. The patient underwent a CT scan and a chest x-ray

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-114: FORWARDING HSETC INFORMATION RE EMERGENCY
USE OF VM-26 ICO Y. BORJAS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1985

PRIMARY RESEARCHERS: CDR G. P. GROSS

SPONSOR: NMCS

HUMAN SUBJECTS: 1

PURPOSE: To treat a patient that had a large cystic tumor in her abdomen. The drug which was selected was VM-26 which was obtained from the NCI.. X-rays, bone scans and liver scans were conducted.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSO-115: NON-EMERGENCY USE OF AN INVESTIGATIONAL
PROCEDURE ICO MCKINLEY WRIGHT**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1985

PRIMARY RESEARCHERS: LCDR J. P. GREEN

SPONSOR: NMCSO

HUMAN SUBJECTS: 1

PURPOSE: To evaluate the blood loss of a patient through a heparinization process.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSO-116: COMPARISON OF FOUR METHODS OF MEASURING
EXTENSION OF THE LUMBAR SPINE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1985

PRIMARY RESEARCHERS: LT R. A. SELLIN

SPONSOR: USC

HUMAN SUBJECTS: 20

PURPOSE: To study and compare both clinical and radiographic methods of measuring lumbar extension in various postures. Two lumbar spine x-rays were required.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSO-117: TREATMENT OF CALCINOSIS CIRCUMSCRIPTA WITH
PROBECID - A PILOT STUDY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1985

PRIMARY RESEARCHERS: CAPT R. W. KLOFKORN

SPONSOR: NMCSO

HUMAN SUBJECTS: 10

PURPOSE: To investigate the effect of probenecid on the dystrophic calcification present in the connective tissue disorders of progressive systemic sclerosis.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-118: ONE TIME USE OF INVESTIGATIONAL DRUG,
ABSOLUTE ALCOHOL, ON A SINGLE PATIENT ICO BRENDA L. FERRIN**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1985

PRIMARY RESEARCHERS: LCDR M. D. NICOL

SPONSOR: NMCS

HUMAN SUBJECTS: 1

PURPOSE: To assist in the evaluation of a patient that had a complicated liver disease.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

**STUDY #NMCS-119: FEVER AND BACTEREMIA FOLLOWING
BRONCHOSCOPY: A PROSPECTIVE STUDY TO DETERMINE FREQUENCY,
SOURCE OF BACTERIA, AND IMPLICATIONS FOR ENDOCARDITIS
PROPHYLAXIS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1985

PRIMARY RESEARCHERS: LCDR L. S. SMITH

SPONSOR: BUMED

HUMAN SUBJECTS: 200

PURPOSE: To establish the incidence of fever, bacteremia and pneumonia following flexible fiberoptic bronchoscopy.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-120: INVESTIGATIONAL AGENT STATUS REPORT
(IFOSPHAMIDE, VP-16)

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1986

PRIMARY RESEARCHERS: CDR W. J. THOMAS

SPONSOR: NCI

HUMAN SUBJECTS: 1

PURPOSE: To treat a patient that had a recurrent tumor of the right hip and lungs that had not responded to treatment. VP-16 was started because of severe right hip pain and enlarging pulmonary metastases.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study # -NMCSD-121: NSABP B-17: A CLINICAL TRIAL TO EVALUATE
NATURAL HISTORY AND TREATMENT OF PATIENTS WITH NON-INVASIVE
INTRADUCTAL ADENOCARCINOMA**

Location: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

Date: 1986

Primary Researchers: CAPT J. RAGLAND

Sponsors: NSABP

Human Subjects: 1

Purpose: To determine the optimal therapy for intraductal adenocarcinoma of the breast.

Category:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

Records: NAVAL MEDICAL CENTER SAN DIEGO

Classification: Unclassified

#

STUDY #NMCS-122: PHASE III TRIAL OF INTENSIVE TREATMENT FOR ADULT ACUTE LL A COMPARISON OF COMBINATION CHEMOTHERAPY PLUS ALTERNATING MITOXANTRONE AND DAUNORUBICIN VS. COMBINATION CHEMOTHERAPY PLUS DAUNORUBICIN

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1986

PRIMARY RESEARCHERS: W.L. ROBINSON LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 2

PURPOSE: To evaluate CNS leukemia development during hematologic remission while receiving or completed the treatment protocol. A radiotherapy treatment was initiated if the disease persisted.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-123: ECHINOMYCIN FOR ADVANCED BREAST CANCER: A
PHASE II STUDY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1986

PRIMARY RESEARCHERS: W.L. ROBINSON LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: To evaluate the efficacy and side effects of the investigational agent echinomycin in the treatment of breast cancer.

PURPOSE:

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-124: COMBINATION CHEMOTHERAPY FOR REMISSION INDUCTION AND MAINTENANCE FOR 1) RECURRENT CLL OCCURRING SIX MONTHS OR GREATER AFTER ELECTIVE CESSATION OF THERAPY- HODGKIN'S LYMPHOMA AND 2) CHILDREN WITH OCCULT TESTICULAR LL AFTER 3 YEARS OF CONTINUOUS COMPLETE REMISSION

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1986

PRIMARY RESEARCHERS: CDR H. E. BEVAN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To test treatment methods for recurrent childhood lymphocytic leukemia and children with occult testicular lymphocytic leukemia. The treatment tested for testicular leukemia included radiation therapy with a total dosage of 2600cGy in 13 treatments. Radiation therapy for patients with CNC relapse would receive 2400 cGy in 12 treatments

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-125: UTILITY OF ENDOSCOPY FOR X-RAY NEGATIVE
DYSPHAGIA: A PROSPECTIVE ANALYSIS**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1986

PRIMARY RESEARCHERS: J.M. LAWSON, LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 113

PURPOSE: To evaluate the need for endoscopy and manometry in patients with x-ray negative dysphagia. It addressed how frequent are significant lesions found by UGI endoscopy and what is the cost of finding a significant lesion with x-ray negative dysphagia.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study # NMCSD-126: MANAGEMENT STRATEGIES ON RISK AFTER ACUTE MYOCARDIAL INFARCTION

Location: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

Date: 1986

Primary Researchers: RITTELMAYER

SONSORS: Unknown

HUMAN SUBJECTS: 102

PURPOSE: To investigate patients that had myocardial infarctions to demonstrate the value of risk multivariate statistical techniques. Part of the test would include the injection of radionuclides for imaging purposes.

Category:

.....☐ EXPERIMENTAL DIAGNOSTIC
 ☒ INCIDENTAL DIAGNOSTIC
 ☐ EXPERIMENTAL THERAPEUTIC
 ☐ THERAPEUTIC TREATMENT
 ☐ UNKNOWN/UNCERTAIN

Records: NAVAL MEDICAL CENTER SAN DIEGO

Classification: Unclassified

#

Study #NMCS-127:CALGB 8651: Trimetrexate (NSC # 352122) For Non-Hodgkin's Lymphoma: Phase II

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1986

PRINCIPAL INVESTIGATOR:LCDR W. L. ROBINSON

SPONSOR:BUMED

NUMBER OF HUMAN SUBJECTS: 2

SPECIAL CLASS OF SUBJECTS:Cancer Patients

PURPOSE: To evaluate the treatment of advanced stage Non-Hodgkin's lymphoma with combination chemotherapy regiments.using Trimetrexate.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

Study #NMCS-128: CALGB 8534: Combination Chemotherapy with Intensive ACE/PCE and Radiation Therapy to the Primary Tumor and Prophylactic Whole-Brain Radiation Therapy with or without Warfarin in Limited Small Cell Carcinoma of the Lung: Phase III

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1987

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:3

:LUNG CANCER

PURPOSE: To evaluate the effectiveness of various combination of chemotherapy and whole brain radiation therapy in the treatment of carcinoma of the lung.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-129: CALGB 8661: The Epidemiology of Acute Leukemias in Adults with Special Reference to Cytogenetically Determined Subgroups

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1987

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:17

:Leukemia

PURPOSE: The study attempted to systematically assess the occupational (including radiation), environmental and family histories of patients with acute leukemia.

☐ **EXPERIMENTAL DIAGNOSTIC**
☐ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☐ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-130:CALGB 8695: Combination Chemotherapy for Advanced Hodgkin's Disease

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1987

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:6

: CANCER

PURPOSE: To compare the effectiveness of the MOPP/ABV hybrid with sequential MOPP, for patients with advanced or recurrent Hodgkin's Diseases.

☐ **EXPERIMENTAL DIAGNOSTIC**
☒ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☐ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-131:CALGB 8691: Cyclophosphamide vs. Cyclophosphamide Plus Alpha-2 Interferon in the Treatment of Follicular, Low Grade Lymphomas: Phase III

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1987

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:3

: CANCER

PURPOSE: To test the use of cyclophosphamide plus interferon in the treatment of low grade Non-Hodgkins Diseases.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study # NMCS-132:CALGB 8642: A Master Protocol to Study Single Agent Induction
Chemotherapy vs. Standard Chemotherapy for Stage IV Breast Carcinoma - Phase III**

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1987

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:2

:BREAST CANCER

PURPOSE: Unknown abstract not available.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-133:CALGB 8653: Recombinant Interleukin-2 and B-interferon for Relapsed or Refractory Lymphoma - A Limited Access Phase II Study

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1987

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:

: CANCER

PURPOSE: Unknown (Abstract Not Available)

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-134:CALGB 8741: A Dose Response Trial of Megestrol Acetate in Advanced Breast Cancer: A Phase III Study

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1987

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:

:BREAST CANCER

PURPOSE: UNKNOWN (Abstract not available)

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study # -NMCSD-135: AN EPIDEMIOLOGIC STUDY OF THE ETIOLOGIC AGNES OF PNEUMONIA AMONG RECRUITS AT RECRUT TRAINING CENTER, SAN DIEGO AND THE UTILITY OF RAPID DIAGNOSTIC

Location: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

Date: UNKNOWN

Primary Researchers: UNKNOWN

Sponsors: UNKNOWN

Human Subjects: UNKNOWN

Purpose: UNKNOWN (ABSTRACT NOT AVAILABLE)

Category:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ OTHER
- ☒ UNKNOWN/UNCERTAIN

Records: NAVAL MEDICAL CENTER SAN DIEGO

Classification: Unclassified

#

**Study # -NMCS-136: PULMONARY FUNCTION TEST IN NORMAL FILIPINO
MALES**

Location: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

Date: UNKNOWN

Primary Researchers: UNKNOWN

Sponsors: UNKNOWN

Human Subjects: UNKNOWN

Purpose: UNKNOWN (ABSTRACT NOT AVAILABLE)

Category:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ OTHER
- ☒ UNKNOWN/UNCERTAIN

Records: NAVAL MEDICAL CENTER SAN DIEGO

Classification: Unclassified

#

STUDY #NMCSO-137: 5-AXACYTIDINE TO INDUCE DIFFERENTIATION IN MYELOYDYSPLASTIC SYNDROMES, A PHASE I-II STUDY

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1987

PRIMARY RESEARCHERS: LCDR M. P. KOSTY

SPONSOR: NMCSO

HUMAN SUBJECTS: 1

PURPOSE: Unknown (Abstract not available)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-138: CARBOPLATIN FOR MALIGNANT MESOTHELIOMA
PHASE II

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1987

PRIMARY RESEARCHERS: M.P. KOSTY LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: Unknown (Abstract not available)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-139: RANDOMIZED COMPARISON OF M-BACOD AND CHOP
COMBINATION CHEMOTHERAPY IN ADVANCED STAGE DIFFUSE LARGE
CELL (HISTIOCYTIC) AND DIFFUSE MIXED NON-HODGKIN'S LYMPHOMA**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1987

PRIMARY RESEARCHERS: LCDR M. P. KOSTY

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: Unknown (Abstract not available)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-140: A DOSE RANGE STUDY OF RECOMBINANT GAMMA INTERFERON IN THE TREATMENT OF NSCLC ASSESSING DISEASE RESPONSE AND SERIAL MEASUREMENTS OF IMMUNOMODULATORY EFFECTS: PHASE II

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1987

PRIMARY RESEARCHERS: M.P. KOSTY LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 4

PURPOSE: Unknown (Abstract not available)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-141: RECOMBINANT BETA-INTERFERON IN ADVANCED NSCLC: A PHASE II STUDY

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1987

PRIMARY RESEARCHERS: M.P. KOSTY LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-142: COMPREHENSIVE THERAPY TO EWING'S SARCOMA:
TAILORED VS. STANDARD RADIATION THERAPY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1987

PRIMARY RESEARCHERS: HEROMAN LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-143: EMERGENCY ONE TIME USE OF RIFAMPIN ON A SINGLE PATIENT

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1988

PRIMARY RESEARCHERS: STEVE CRIDER

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-144: PACE AND GAMMA INTERFERON FOR EXTENSIVE
SMALL CELL CARCINOMA OF THE LUNG**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1988

PRIMARY RESEARCHERS: M.P. KOSTY LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-145: NSABP C-03: A Clinical Trial to compare Adjuvant Leucovorin and 5-FU (LV+5-FU) with Adjuvant MeCCNU Vincristine and 5-FU (MOF) in Patients with Dukes' B and C Colon Cancer

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1988

PRINCIPAL INVESTIGATOR: CAPT J. RAGLAND

SPONSOR:

HUMAN SUBJECTS: 3

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

STUDY #NMCSD-146: INCIDENCE OF DEEP VENOUS THROMBOSIS IN MAJOR ORAL AND MAXILLOFACIAL SURGICAL PATIENTS.

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : UNKNOWN

PRIMARY RESEARCHERS: UNKNOWN

SPONSOR: UNKNOWN

HUMAN SUBJECTS: UNKNOWN

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☒ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-147: Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia A Multicenter Cooperative Study

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1988

PRINCIPLE INVESTIGATOR:Norman Waecker, CDR, MC, USN

SPONSOR:

HUMAN SUBJECTS:12

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-148: TREATMENT OF CHILDREN WITH NEWLY DIAGNOSED
ANLL USING HIGH DOSE CYTOSINE ARABINOSIDE AND ETOPOSIDE + 5-
AZACYTIDINE FOR INTENSIFICATION OF EARLY THERAPY**

LOCATION :NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1988

PRIMARY RESEARCHERS: CAPT W. J. THOMAS

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To determine the effects of high dose cytosine arabinoside and etoposide +5
azacytidine administered to one patient with Acute Nonlymphoblastic Leukemia.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCS-149: MANAGEMENT OF STRESS FRACTURES WITH A
PNEUMATIC LEG BRACE**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1988

PRIMARY RESEARCHERS: Z.N. BALSARA LCDR/MC/USNR

SPONSOR: NMCS

HUMAN SUBJECTS: 95

PURPOSE: Use pneumatic leg braces to accelerate the healing of stress fractures in the leg.
Correlate bone scan findings in control patients and patients wearing the splint.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

##

Study #NMCSD-150:The Utility of Urinalysis in Screening for Occult Renal Injury in Patients with Minor Trauma

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1988

PRINCIPLE INVESTIGATOR:Robert Buckley, LT, MC, USN

SPONSOR:

HUMAN SUBJECTS:Not Defined

PURPOSE: Evaluate the presence of blood in the urine , and kidney damage following a low impact accident.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

**STUDY #NMCSO-151: THE TREATMENT OF ADVANCED HODGKINS DISEASE
WITH MODEL C FOLLOWED BY MVPP: A LIMITED ACCESS PILOT STUDY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1988

PRIMARY RESEARCHERS: M.P. KOSTY LCDR/MC/USN

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: To assess the effectiveness of a combination of medications to prevent relapse in a Hodgkin's disease patient.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-152: PACE AND GAMMA INTERFERON RECOMBINANT BETA INTERFERON IN ADVANCED NON-SMALL CELL LUNG CANCER: A PHASE II STUDY

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1988

PRIMARY RESEARCHERS: M.P. KOSTY LCDR/MC/USN

SPONSOR: BUMED/NCI

HUMAN SUBJECTS: 5

PURPOSE: Evaluate the effectiveness of a combination of PACE and recombinant gamma interferon in carcinoma of the lung.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-153: EVALUATION OF UGI BLEEDING IN MILITARY
PERSONNEL UTILIZING DUODENOSCOPY**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1973

PRIMARY RESEARCHERS: LCDR O. T. NEBEL

SPONSOR: BUMED

HUMAN SUBJECTS: 50

PURPOSE: To diagnose patients with UGI bleeding using both barium contrast media and duodenoscopy. Using both processes would increase the accuracy in detecting upper gastrointestinal bleeding.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study #NMCSD-154:CALGB 8852: A Pilot Study of Cyclophosphamide,
Doxorubicin,Vincristine, Prednisone,Etoposide (CHOPE) in Diffuse Lymphomas**

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1989

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR:

HUMAN SUBJECTS:3

PURPOSE: Investigate the effect of dose intensity on the relapse free survival and overall survival rate in patients with diffuse lymphomas.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-155: TRIAL OF CYSTECTOMY ALONE VS
NEOADJUVANT M-VAD + CYSTECTOMY IN PATIENTS WITH LOCALLY
ADVANCED BLADDER CANCER**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : UNKNOWN

PRIMARY RESEARCHERS: UNKNOWN

SPONSOR: UNKNOWN

HUMAN SUBJECTS: UNKNOWN

PURPOSE: UNKNOWN (ABSTRACT NOT AVAILABLE)

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☒ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

Study #NMCSD-156: CALGB 8811: Phase II Trial of a 5 Drug Induction Regimen with Intensive Consolidation in Adult Lymphoblastic Leukemia

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1989

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:3

PURPOSE: A five drug treatment, which included cyclophosphamide and L-asparaginase was administered to patients with Adult Lymphoblastic Leukemia.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-157:CALGB 8856: CHOPE/ABVD for Advanced Hodgkin's Disease: A Limited Access Phase II Study

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1989

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:7

PURPOSE: The study uses a combination of the two drugs which have been used singularly. This is also a pilot for a Phase III study with the same drugs.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-158: NSABP B-20: Clinical Trial to Determine the Worth of Chemotherapy and Tamoxifen over Tamoxifen Alone in the Management of Patients with Primary Invasive Breast Cancer, Negative Nodes and Estrogen Positive.

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1989

PRINCIPAL INVESTIGATOR: CAPT J. RAGLAND

SPONSOR: NSABP

HUMAN SUBJECTS:

PURPOSE: Test various chemotherapies with Tamoxifen against Tamoxifen alone in Stage I ER positive breast carcinoma.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-159: NSABP B-19: A Clinical Trial to Compare Secuential Methotrexate 5-FU (M-F) with Conventional CMF in Primary Cancer Patients with Negative Nodes and Estrogen Receptor Negative Tumors

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1989

PRINCIPAL INVESTIGATOR: CAPT J. RAGLAND

SPONSOR: NSABP

HUMAN SUBJECTS: 2

PURPOSE: Compare chemotherapy regimens in the treatment of Stage I ER negative breast cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-160: NSABP B-18: A Unified Trial to Compare Short Intensive Pre-Operative Systemic Adriamycin Cyclophosphamide Therapy with Similar Therapy Administered in Conventional Post Operative Fashion

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1989

PRINCIPAL INVESTIGATOR: CAPT J. RAGLAND

SPONSOR: NSABP

HUMAN SUBJECTS: 1

PURPOSE: Test pre-operative Vs. post operative chemotherapy in the treatment of breast cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-161: NSABP B-21: A Clinical Trial to Determine the Worth of Tamoxifen and the Worth of Breast Radiation in the Management of Patients with Node-Negative, Clinically Occult, Invasive Breast Cancer Treated by Lumpectomy

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1989

PRINCIPAL INVESTIGATOR: CAPT J. RAGLAND

SPONSOR: NSABP

HUMAN SUBJECTS: 0

PURPOSE: Determine the worth of Tamoxifen and the worth of breast radiation in the management of patients with node-negative, clinically occult, invasive breast cancer treated by lumpectomy.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-162: STUDIES OF THROMBOCYTOPOIESIS IN PATIENTS WITH MYELOPROLIFERATIVE DISORDERS

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1988

PRIMARY RESEARCHERS: LCDR CHRISTINE HUNTER

SPONSOR: BUMED

HUMAN SUBJECTS: 9

PURPOSE: Assess the formatio and destruction of platelets in patients with Myeloproliferative disorders by using Indium-111 labeled platelets.

CATEGORY

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCS-163: GRPC PROTOCOL - FUNDARABINE PHOSPHATE IN PATIENTS WITH REFRACTORY CLL (NCI PROTOCOL# I89-0018)

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1989

PRIMARY RESEARCHERS: LCDR F. E. MILLARD

SPONSOR: BUMED

HUMAN SUBJECTS: 1

PURPOSE: Administer FAMP to patients with refractory chronic lymphocytic leukemia and determine the response rate, response duration and toxicity of this regimen.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-164: ABROGATION OF DRUG RESISTANCE TO CISPLATIN
AND 5-FU IN PATIENTS WITH METASTATIC COLORECTAL CANCER
THROUGH THE USE OF DILTIAZEM
LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER**

DATE : 1989

PRIMARY RESEARCHERS: LCDR F. E. MILLARD

SPONSOR: BUMED

HUMAN SUBJECTS: 5

PURPOSE: Treat patients with advanced colorectal cancer that is incurable by surgery, radiation, or chemotherapy with Diltiazem .

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**STUDY #NMCSD-165: PROTOCOL FOR PROSPECTIVE CORRELATIVE
CLINICAL TRIAL OF THE ANTI-CANCER DRUG RESPONSE ASSAY -
RECURRENT BREAST CANCER TREATED WITH ADRIAMYCIN**

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1989

PRIMARY RESEARCHERS: LCDR M. J. EDELMAN

SPONSOR: BUMED/UCSD

HUMAN SUBJECTS: 15

PURPOSE: To utilize an in vitro technique to culture biopsy specimens from patients with recurrent breast cancer who will be receiving chemotherapy with single agent Adriamycin.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

Study #NMCSD-166: The Effects of Terfenadine Alone and in Combination with Ipratropium Bromide on Pulmonary, Cardiovascular and Cognitive Function in Military Personnel with Mild or Moderate Asthma

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1988

PRINCIPLE INVESTIGATOR:R. Reynolds, CAPT, MC, USN

SPONSOR:Merrell Dow

HUMAN SUBJECTS:0

PURPOSE: To assess the effects of Terfenadine in various treatments in Asthmatics, to test the effects on the cardiovascular system.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

Study #NMCSD-167: Treatment of Acute Infectious Arthritis in Adults: A Prospective Comparison of Drainage Methods

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1989

PRINCIPLE INVESTIGATOR:Anthony Melillo, LT, MC, USN

SPONSOR:

HUMAN SUBJECTS:4

PURPOSE: Compare different methods for drainage of infected joints in arthritis patients.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-168:CALGB 8897: Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1990

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:5

PURPOSE: Random study to compare adjuvant chemotherapy with and without endocrine therapy in high risk, node negative breast cancer patients. The patients will be followed up with either observation or 5 additional years of Tamoxifen.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-169:CALGB 8991: Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin Plus Etoposide with either Lbleomycin or Ifosfamide

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1990

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:6

PURPOSE: Randomize various chemotherapy treatments for administration in patients with disseminated advanced stage testicular cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-170:CALGB 8984: Phase II - Conservative Treatment of Adenocarcinoma of the Distal Rectum: Local Resection Plus Adjuvant 5-FU/Radiation Therapy

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1990

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:2

PURPOSE: To test the ability of local surgery combined with chemotherapy and radiation therapy to provide local control of rectal cancers without radical, sphincter - removing surgery.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-171:CALGB 9051: Phase II Study of Etoposide, Vinblastine, Doxorubicin (EVA)and Subtotal Nodal Radiation in Poor Risk, Early Stage Hodgkin's Disease

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1990

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:5

PURPOSE: Assess the effectiveness of various drugs in the treatment of early stage Hodgkin's disease. The combinations being tested in this study are thought to be equally effective but less toxic than other more commonly used regimens.

CATEGORY:

- ☐ **EXPERIMENTAL DIAGNOSTIC**
- ☒ **INCIDENTAL DIAGNOSTIC**
- ☒ **EXPERIMENTAL THERAPEUTIC**
- ☐ **THERAPEUTIC TREATMENT**
- ☐ **OTHER**
- ☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-172: NSABP B-22: PA Clinical Trial to Evaluate the Effect of Dose Intensification and Increased Cumulative Dose of Postoperative Adriamycin-Cyclophosphamide (AC) Therapy on Disease-Free Survival

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1990

PRINCIPAL INVESTIGATOR: CAPT J. RAGLAND

SPONSOR: NSABP

HUMAN SUBJECTS: 7

PURPOSE: To test the efficacy of dose intensification and increased cumulative dose of AC in breast cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-173: NSABP C-04: A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin, 5-FU + Levamisole, and 5-FU + Leucovorin + Levamisole in Patients with Dukes' B and C Carcinoma of the Colon

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1990

PRINCIPAL INVESTIGATOR: CAPT J. RAGLAND

SPONSOR: NSABP

HUMAN SUBJECTS: 2

PURPOSE: Assess the efficacy of various treatments in postoperative patients with Dukes' B and C carcinoma of the colon.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-174:POG 8650: National Wilms' Tumor Study

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1990

PRINCIPAL INVESTIGATOR:CDR W. LANDE

SPONSOR: POG

HUMAN SUBJECTS:4

PURPOSE: Determine the relapse free and overall survival percentages of patients with Stage I and II favorable histology, and stage I anaplastic Wilms' tumor treated with various therapies; compare the rates in patients with sarcoma of the kidney.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-175:Utility of Endoscopy for X-Ray Negative Dysphagia: A Prospective Analysis

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1989

PRINCIPLE INVESTIGATOR:William Schindler, CDR, MC, USN

SPONSOR:

HUMAN SUBJECTS:9

PURPOSE: Endoscope study for patients with dyspyhagia, including ingestion of a barium tablet.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-176:Single-Dose Cefotetan or Cefoxitin vs. Multiple Dose Cefoxitin as Prophylaxis in Patients Undergoing Appendectomy for Non-Perforated Appendicitis

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1990

PRINCIPAL INVESTIGATOR:LCDR M. LIEBERMAN

SPONSOR: NA

HUMAN SUBJECTS:92

PURPOSE: Administer one dosage of antibiotics preoperatively to patients undergoing appendectomy, to prevent post-appendectomy sepsis and wound infection.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-177: Method of Diagnosis of Cartilaginous and Ligamentous Knee Injuries Associated with Lower Extremity Fractures Using Physical Exam, Stress Radiographs and Magnetic Resonance Imaging

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1990

PRINCIPLE INVESTIGATOR:Joseph Jankiewicz, LT, MC, USN

SPONSOR: NA

HUMAN SUBJECTS:0

PURPOSE: Use of physical examination, stress radiographs and magnetic resonance imaging to diagnose knee injury.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-178:Use of Magnetic Resonance Imaging to Prospectively Evaluate the Healing Ability of Scaphoid Fractures

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1990

PRINCIPLE INVESTIGATOR:*Jeffrey Zilberfarb, LT, MC, USN*

SPONSOR: NA

HUMAN SUBJECTS:11

PURPOSE: Use MRI to evaluate the healing of scaphoid fractures.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study #NMCSD-179:CALGB 8837: Hyperfractionaton Radiotherapy and
Chemotherapy in Limited Stage Small Cell Lung Carcinoma**

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:CDR F. MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:1

PURPOSE: Test the tolerance to and effectiveness of hyperfractionated radiation when combined with standard chemotherapy for small cell lung cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSO-180:POG 9000/9005: Dose Intensification of Methotrexate and 6-Mecapopurine for Acute Lymphocytic Leukemia in Children (ALINC #15)

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:CAPT W. THOMAS

SPONSOR: POG

HUMAN SUBJECTS:3

PURPOSE: Compare two treatment medications for treatment of Leukemia in children.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☒ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-181:POG 9000/9005: Up-Front Alternating 6-MP/MTX vs. Up-front Alternating Chemotherapy for Active Lymphocytic Leukemia in Children (ALINC #15)

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:CAPT W. THOMAS

SPONSOR: POG

HUMAN SUBJECTS:0

PURPOSE: Alternate two treatment drug therapies in patients with active lymphocytic Leukemia.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-182: Underlying Metabolic Bone Disease in Femoral Neck Stress Fractures

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1991

PRINCIPLE INVESTIGATOR: Michael Muldoon, LT, MC, USN

SPONSOR: NA

HUMAN SUBJECTS: 18

PURPOSE: Comparison of histomorphometric, radiographic, and biochemical methods for treating femoral neck stress fractures.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-183: The Efficacy of Arthroscopic Bankart Repair in Acute First Time Anterior Shoulder Dislocation

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPLE INVESTIGATOR:T. Cullison, CDR, MC, USN

SPONSOR:

HUMAN SUBJECTS:0 (This Study is a Retrospective Chart Review)

PURPOSE: Establish a registry to evaluate the efficacy of arthroscopic repair in initial, acute anterior shoulder dislocations and to determine if the high recurrence rate and associated instability are significantly affected.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-184:CALGB 9033: Oral vs. Intravenous Etoposide in Combination with Intravenous Cisplatin in Extensive Small Cell Lung Cancer: Phase III

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:CDR F.MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:7

PURPOSE: Evaluate the difference in bioavailability, toxicity and efficacy between oral and intravenous etoposide when combined with another effective drug in small cell lung cancer, cisplatin.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-185:CALGB 9091: A Phase III Intergroup Trial: A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery versus Surgery Alone for Patients with Local Regional Disease

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:CDR F.MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:2

PURPOSE: Test whether the addition of chemotherapy preoperatively will improve survival and decrease the likelihood of relapse.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-186:CALGB 8944: Intensive Doxorubicin, Surgery, CMF and Radiation Therapy for Stage III Breast Cancer - A Study of Efficacy with Pharmacokinetic and Antigenic Monitoring

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:CDR F.MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:3

PURPOSE: Test the use of intensive up front doxorubicin followed by surgery, additional chemotherapy and radiation.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-187:CALGB 9193: Phase III Comparison of Cyclophosphamide, Doxorubicin and 5-FU CAF) and Chemohormonal Therapy (CAF + Zoladex + Tamoxifen) in Premenopausal Women with Axillary Node Positive, Receptor Positive Breast Cancer

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:CDR F.MILLARD

SPONSOR: CALGB

HUMAN SUBJECTS:1

PURPOSE: Test increased frequency and increased dosage of treatment drugs against a standard regimen of chemotherapy in patients with axillary node positive receptor positive breast cancer.

CATEGORY:

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#Study #NMCS-188: CALGB 9192: Phase III Comparison of Combination Chemotherapy (CAF) and Chemo-Hormonal Therapy (CAF + Zolodex or CAF + Tamoxifen) in Premenopausal Women with Axillary Node Positive, Receptor Positive Breast Cancer

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:Mark D. Browning

SPONSOR:CALGB

HUMAN SUBJECTS:3

SPECIAL CLASS OF SUBJECTS:Breast Cancer Patients

PURPOSE: Compare three different strategies with respect to their impact on recurrence rates, and overall survival in women with node positive breast cancer.

CATEGORY:

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-189: CALGB 9194: Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Premenopausal Women with Involved Axillary Lymph Nodes and Positive Receptors

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1991

PRINCIPAL INVESTIGATOR: Mark D. Browning

SPONSOR: CALGB

HUMAN SUBJECTS: 0

SPECIAL CLASS OF SUBJECTS: Breast Cancer Patients

PURPOSE: Compare two different sequences of chemohormonal therapy to hormonal therapy alone. Patients will be randomized to tamoxifen alone, or chemotherapy followed by tamoxifen or the two given simultaneously.

CATEGORY:

- ☒ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-190: Phase III Trial of G-CSF Vs. Placebo During Remission Induction and Consolidation Chemotherapy for Adult Acute Lymphoblastic Leukemia.

LOCATION : NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE : 1991

PRIMARY RESEARCHERS: Fred Millard

SPONSOR: CALGB

HUMAN SUBJECTS: 2

PURPOSE: Randomize treatment between G-CSF and placebo, in an attempt to see if hematologic and other organ toxicity, infection and number of days of hospitalization can be reduced.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

STUDY#NMCS-191:CALGB 9130: Phase III Trial of Vinblastine/Cisplatin/Radiation Therapy with or without Carboplatin (NSC# 241240) for Inoperable Stage IIIA and Stage IIIB non-small Cell Lung Cancer

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:Fred Millard

SPONSOR:CALGB

HUMAN SUBJECTS:1

PURPOSE: Compare treatments of patients with inoperable Stage IIIA and Stage IIIB non small cell lung cancer.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

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STUDY#NMCSD-192:NSABP C-05: A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin with or without Interferon Alpha-2a in Patients with Dukes' B and Carcinoma of the Rectum

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:Jerry Ragland, CAPT, MC, USN

SPONSOR:NSABP

HUMAN SUBJECTS:3

PURPOSE: Assess the efficacy of two postoperative treatments in patients with Dukes' B abd C carcinoma of the colon.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCS-193:CALGB 9041: Subcutaneously Administered Recombinant Human Interleukin-2 and Interferon Alpha-2a for Advanced Breast Cancer

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:0

PURPOSE: Study the toxicity and efficacy of combining two biologic response modifiers, interleukin-2 and interferon alfa-2a in the treatment of advanced breast cancer.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCS-194:CALGB 9140: A Phase III Study of CAF-Leucovorin Vs. CAF for Visceral Crisis Breast

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:0

PURPOSE: Study the effectiveness of adding leucovorin to CAF in patients with metastatic breast cancer who have visceral crisis.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

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STUDY#NMCS-195:CALGB 9190: Intergroup Post-Operative Adjuvant Interferon Alpha-2b in Resected High-Risk Primary and Regionally Metastatic Melanoma

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:0

PURPOSE: Evaluate treatment of high risk metastatic melanoma patients with Interferon Alpha-2B.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

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STUDY#NMCSD-196;CALGB 9195: Trial of Adjuvant Chemoradiation After Gastric Resection for Adenocarcinoma

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:0

PURPOSE: Compare surgery alone with surgery combined with chemotherapy using 5-FU and leucorvin in the treatment of patients with Gastric cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

Study #NMCSD-197: Bone Structure Analysis: Tibial Bone Mineral Density (BMD) as a Predictive Factor for Tibial Stress Fractures in Navy SEAL Trainees

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1991

PRINCIPLE INVESTIGATOR:LT Bruce Thomas

SPONSOR: NA

HUMAN SUBJECTS:162

PURPOSE: Compare the bone mineral density in Navy SEAL trainees who have suffered tibial stress fractures with those who have not experienced stress fractures.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

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STUDY#NMCS-198:CALGB 9191: Phase III Randomized Study of ALL-Trans Retinoic Acid Vs. Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients with Previously Untreated Acute Promyelocytic Leukemia

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:I

PURPOSE: Assess the ability of TRA to induce complete remissions in acute promyelocytic leukemia.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCS-199:CALGB 9181: A Randomized Study Comparing Standard Vs. Moderately High Megestrol Acetate in Advanced Prostate Cancer

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:1

PURPOSE: Evaluate Megestrol in the treatment of prostate cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-200:Cryovalve Heart Valve Allografts

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPLE INVESTIGATOR:Dr. R. Moreno

SPONSOR: NA

HUMAN SUBJECTS:1

PURPOSE: Assess the efficacy of the Cryovalve allograft heart valve as a replacement or treatment for disease, damaged, malformed or malfunctioning aortic or pulmonary heart valve.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCSD-201:NSABP B-25: A Clinical Trial to Evaluate the Effect Dose Intensification and Increased Cumulative Dose of Postoperative Adriamycin-Cyclophosphamide (AC) Therapy with G-CSF on the Disease-Free Survival and Survival of Patients with Primary Breast Cancer and Positive Axillary Nodes

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:Jerry Ragland, CAPT, MC, USN

SPONSOR:NSABP

HUMAN SUBJECTS:2

PURPOSE: Evaluate the effect of dose intensification and increased doses of various drugs in breast cancer patients.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCSD-202:CALGB 9251: High Intensity, Brief Duration Chemotherapy for Diffuse Small Noncleaved Cell Lymphoma and the L-3 Subtype of ALL: A Pilot Study of a Multidrug Regimen

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:1

PURPOSE: Evaluate a high intensity brief duration chemotherapy for diffuse small noncleaved cell lymphoma.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCS-203:CALGB 9131: Edatrexate (20-ethyl-deaza-aminopterin) for Malignant Mesothelioma: A Phase II Study

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:1

PURPOSE: Evaluation for the investigational agent in the treatment of patients with lung cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCS-204:Color Doppler Ultrasound Finding in Transitional Cell Carcinoma of the Bladder and Kidney

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:W. G. Horstman, LCDR, MC, USN

SPONSOR:CID

HUMAN SUBJECTS:18

PURPOSE: Evaluate the efficacy of using color doppler ultrasound findings in transitional cell carcinoma of the bladder and kidney.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCS-205:CALGB 9150: Phase II Study of High-Dose Cyclophosphamide Plus Recombinant Granulocyte-Colony Stimulating Factor in the Treatment of Follicular, Low Grade Non-Hodgkin's Lymphoma

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:Unknown at this time

PURPOSE: Evaluate different therapies in the treatment of follicular low grade non Hodgkin's lymphoma.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-206:CALGB 9092: Phase III Protocol for the Evaluation of 5-Fluorouracil Vs. 5-Fluorouracil + PALA or 5-Fluorouracil + Oral Leucovorin or 5-Fluorouracil + Intravenous Leucovorin or 5-Fluorouracil + rIFN Alpha-2a in Patients with Advanced Colorectal Cancer

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:0

PURPOSE: Evaluate various treatments in patients with advanced colorectal cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY #NMCSD-207:CALGB 9134: A Comparison of "Best Local-Regional Therapy" with or without Chemotherapy for Stage IIIA (N2) Non-Small Cell Lung Cancer: A Randomized Phase III Study

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:0

PURPOSE: Compare different therapies in the treatment of non small cell lung cancer.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-208: Impact of Stellate Ganglion Blockade on Diaphragmatic Function

LOCATION: NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE: 1992

PRINCIPLE INVESTIGATOR: John Vassar, LCDR, MC, USN

SPONSOR: NA

HUMAN SUBJECTS: Unknown at this time

PURPOSE: Assess the impact of stellate ganglion blockade on diaphragmatic function.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-209:Randomized Treatment of Jones' Fractures

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1992

PRINCIPLE INVESTIGATOR:Mark F. Clapper, CDR, MC, USN

SPONSOR: NA

HUMAN SUBJECTS:18

PURPOSE: Assess different treatments in patients with Jones' fractures.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-210:Recombinant Urokinase (RUK, Abbott-76120) Versus Operative Intervention as Initial Therapy for Acute Lower-Limb Arterial Occlusion

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1993

PRINCIPLE INVESTIGATOR:Jerry T. Light, LCDR, MC, USN

SPONSOR:Abbott Labs

HUMAN SUBJECTS:2

PURPOSE: Evaluation of drug therapy Vs. operative intervention as initial therapy for Lower Limb Arterial Occlusion.

CATEGORY:

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCS-211:CALGB 9155: Treatment of AIDS Associated Non-Hodgkin's Lymphoma with Cyclophosphamide/ Doxorubicin/ Vincristine/ Prednisone/ Etoposide(Chope), Zidovudine, Granulocyte-Colony Stimulating Factor (G-CSF), and Erythropoietin (rhEPO)

LOCATION:NAVAL HOSPITAL/NAVAL MEDICAL CENTER

DATE:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

HUMAN SUBJECTS:0

PURPOSE: Evaluation of drug therapy for tolerance in HIV patients.

CATEGORY

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

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STUDY#NMCS-212:CALGB 9153: A Phase II Trial of 2-Chlorodeoxyadenosine in Advanced-Stage, Previously Untreated Low-Grade Lymphomas

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Lymphoma Patients

PURPOSE: This phase II trial administered 2-CdA by a daily 2 hour infusion for 5 days every 4 weeks. (CHEMOTHERAPY)

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT

☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

STUDY#NMCS-213:CALGB 9211: A Phase II Trial of 2-Chlorodeoxyadenosine (2-CdA) in B-Cell Chronic Lymphocytic Leukemia Patients who have Previously Failed Therapy with Fludarabine Phosphate

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:>18 y/o Leukemia Patients

PURPOSE: The purpose of this study was to determine whether cross-resistance exists between fludarabine and 2-CdA. (CHEMOTHERAPY)

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

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STUDY#NMCSD-214:CALGB 9281: A Phase II Trial of Induction Chemotherapy Followed by Radiation Therapy Plus Concurrent Chemotherapy for Poor Prognosis, Locally Advanced, Previously Untreated Carcinomas of the Anal Canal

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:>18 y/o Anal CA Patients

PURPOSE: To treat patients with high-risk tumors with combined cisplatin/5-FU/mitomycin-C and radiation.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCS-215:Hip Arthrodesis: A New Technique

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Thomas J. O'Brien, LCDR, MC, USN

SPONSOR:CID

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Hip Fusion Patients

PURPOSE: Hip fusion using total joint arthroplasty instrumentation and a dynamic hip compression screw. Exposure to ionizing radiation was incidental to being a part of the study.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

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STUDY#NMCSD-216:CALGB 9256: Phase II Study of Taxotere (NSC# 628503) in Previously Treated Non-Hodgkin's Lymphoma: IWF Grades A-H

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:>18 y/o Lymphoma Patients

PURPOSE: To investigate the use of Taxotere in patients with relapsed non-Hodgkins lymphomas, both low and intermediate grades.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

STUDY#NMCS-217:CALGB 9362: Phase I Study of Topotecan and Taxol

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0 Patients at this time

SPECIAL CLASS OF SUBJECTS:Cancer Patients with solid tumors refractory to standard therapy or for which no standard effective therapy exists.

PURPOSE: Chemotherapy study. Exposure to ionizing radiation was incidental to being a part of the study.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

STUDY#NMCS-218:CALGB 9294: Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil Vs. 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0 Patients at this time

SPECIAL CLASS OF SUBJECTS:Colon Cancer Patients

PURPOSE: Previous cooperative studies have demonstrated a survival advantage for adjuvant therapy of node-positive colon cancer with 1 year of 5-FU and levamisole drug therapy. Local recurrence continues to be a clinical problem, however. The current study addresses the issue of adjuvant radiotherapy to help reduce this problem.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

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STUDY#NMCS-219:CALGB 9242: Topotecan for Advanced Breast Cancer: A Phase II Study

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0 Patients at this time

SPECIAL CLASS OF SUBJECTS:Breast Cancer Patients

PURPOSE: To administer Topotecan to women with metastatic breast cancer who have failed 1 prior treatment.

☐ **EXPERIMENTAL DIAGNOSTIC**
☒ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☐ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCSD-220:CALGB 9236: Dose Intensive Multi-Modality Therapy in Limited Small Cell Lung Cancer: A Phase II Study-Limited Access

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0 Patients at this time

SPECIAL CLASS OF SUBJECTS:Lung Cancer Patients

PURPOSE: Combination chemotherapy and radiotherapy treatment of limited stage small cell lung cancer.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

STUDY#NMCSD-221:CALGB 9141: A Feasibility Study of Adjuvant Chemotherapy with Dose-Intensified Cyclophosphamide/Doxorubicin (CA) + G-CSF in Patients with Operable Breast Cancer and Histologically Involved Axillary Lymph Nodes

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0 Patients at this time

SPECIAL CLASS OF SUBJECTS:Breast Cancer Patients

PURPOSE: Phase II feasibility study to determine the effectiveness and toxicities of further dose escalation beyond the high-dose arm of 8541.

☐ **EXPERIMENTAL DIAGNOSTIC**
☒ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☐ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

Study #NMCS-222:CALGB 8952: Treatment of Advanced Hodgkin's Disease: A Randomized Phase III Trial Comparing ABVD Vs. MOPP/ABV Hybrid

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Hodgkin's Patients

PURPOSE: A comparison study of two types of chemotherapy used in the treatment of advanced Hodgkins disease. Exposure to ionizing radiation was incidental to being a part of the study.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-223:CALGB 9391: Randomized Trial of Subtotal Nodal Irradiation Vs. Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Hodgkin's Patients

PURPOSE: To study the benefit of adding 3 cycles of doxorubicin and vinblastine to subtotal nodal irradiation for patients with clinically staged, good prognosis disease.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

Study #NMCSD-224:Evaluation of the Biliary Tree During Laparoscopic Cholecystectomy: Ultrasonography Vs. Intraoperative Cholangiography

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Johnny B. Green, CDR, MC, USN

SPONSOR:CID

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Cholecystitis Patients

PURPOSE: To examine the hypothesis that intraoperative ultrasound (IOUS) is equally effective as IOC for the diagnosis of extra-hepatic biliary pathology.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

Study #NMCS-225:Angiographic Antioxidant Atherosclerosis Trial

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPLE INVESTIGATOR:Peter Casterella, LT, MC, USN

SPONSOR:UCSD

NUMBER OF HUMAN SUBJECTS:0-(New)

SPECIAL CLASS OF SUBJECTS:Coronary Artery Disease Patients

PURPOSE: To use the quantitative angiography as a primary endpoint to determine whether antioxidant therapy influences the progression and/or regression of coronary artery disease in humans.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

Study #NMCS-226:CALGB 9255: Phase II Study of Cyclophosphamide, Prednisone, and Infusional Doxorubicin, Vincristine, and Etoposide (i-Chope) in Diffuse Lymphoma's Relapsed/Refractory to Bolus Therapy

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Non-Hodgkin's Lymphomas

PURPOSE: No Abstract Provided

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSO-227:CALGB 9235: Etoposide, Cisplatin and Radiation Therapy with or without Tamoxifen in Limited Stage Small Cell Lung Cancer: A Randomized Phase III Study

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Lung Cancer Patients

PURPOSE: Patients were randomly assigned to standard therapy with cisplatin/etoposide/radiation or the same plus oral tamoxifen in an effort to ascertain if this benefit extends to other cisplatin-sensitive tumors.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-228:CALGB 9311: A Phase II Trial of Lineage-Specific Consolidation Therapy for Adult Acute Lymphoblastic Leukemia (ALL): Anti-B4-Blocked Ricin (NSC #639185) for B-Lineage ALL and High-Dose Cytarabine for Non-B-Lineage ALL

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPAL INVESTIGATOR:Fred Millard, CDR, MC, USNR

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Leukemia Patients

PURPOSE: Treatment of adult acute lymphoblastic leukemia (ALL) .

☐ EXPERIMENTAL DIAGNOSTIC
☐ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-229: Comparison of Central Venous Pressures in the Superior and Inferior Vena Cavas in Children

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPLE INVESTIGATOR:Abhik Biswas, LT, MC, USNR

SPONSOR:

NUMBER OF HUMAN SUBJECTS:0-(New)

SPECIAL CLASS OF SUBJECTS:Pediatric Cardiology

PURPOSE: To test the hypothesis that end-expiratory central venous pressure in the superior vena cava correlates with that in the abdominal inferior vena cava.

☒ **EXPERIMENTAL DIAGNOSTIC**
☐ **INCIDENTAL DIAGNOSTIC**
☐ **EXPERIMENTAL THERAPEUTIC**
☐ **THERAPEUTIC TREATMENT**
☐ **OTHER**
☐ **UNKNOWN/UNCERTAIN**

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCSD-230:Hip Arthrodesis: Allergic Fungal Sinusitis, Immunotherapy

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTERSAN
DIEGO, CA 92134-5000

START DATE OF STUDY:1993

PRINCIPLE INVESTIGATOR:Darrell H. Hunsaker, CAPT, MC, USN

SPONSOR:

NUMBER OF HUMAN SUBJECTS:0 (New)

SPECIAL CLASS OF SUBJECTS:Sinusitis Patients

PURPOSE: Prospectively study all patients with nasal or sinus polyps prior to undergoing
endoscopic sinus surgery in order to identify historical and immunologic evidence of allergy.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMCS-231: CALGB 9232: Hematopoietic Growth Factor Vs. Prophylactic Antibiotic Support in Advanced Non-Small Cell Lung Cancer: A Prospective Double-Blind Randomized Control Trial: A Phase III Study

LOCATION OF STUDY: NAVAL HOSPITAL/NAVAL MEDICAL CENTER SAN DIEGO, CA 92134-5000

START DATE OF STUDY: 1993

PRINCIPAL INVESTIGATOR: Fred Millard, CDR, MC, USNR

SPONSOR: CALGB

NUMBER OF HUMAN SUBJECTS: 0

SPECIAL CLASS OF SUBJECTS: Lung Cancer Patients

PURPOSE: To use cisplatin/etoposide chemotherapy in NSCLC as a model to assess the effect of prophylactic ciprofloxacin and/or granulocyte-colony stimulating factor (G-CSF) on 3 endpoints:

- 1) the incidence of infectious complications
- 2) quality of life
- 3) expense

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☒ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

☒ UNCLASSIFIED

#

Study #NMSCD-232:CALGB 8971: A Dose Response Trial of Megestrol Acetate for the Treatment of Cachexia in Patients with Advanced Lung or Colorectal Cancer

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1990

PRINCIPAL INVESTIGATOR:CDR Fred Millard

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Lung, Colo-Rectal Patients

PURPOSE: To correlate dose of megestrol acetate with efficacy and toxicity, and to employ fairly sophisticated quality of life measurements, and assessments of nutritional status.

☐ EXPERIMENTAL DIAGNOSTIC
☒ INCIDENTAL DIAGNOSTIC
☐ EXPERIMENTAL THERAPEUTIC
☐ THERAPEUTIC TREATMENT
☐ OTHER
☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMSCD-233:POG 8719: TRIAL OF SHORTENED THERAPY WITHOUT MAINTENANCE FOR THE TREATMENT OF LOCALIZED NON-HODGKIN'S LYMPHOMA, A PHASE III STUDY

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1989

PRINCIPAL INVESTIGATOR:LCDR William M. Lande

SPONSOR:POG

NUMBER OF HUMAN SUBJECTS:1 Child

SPECIAL CLASS OF SUBJECTS:Hodgkin's Patients

PURPOSE:

- 1) To determine if 24 weeks of maintenance chemotherapy with daily oral 6-MP and weekly methotrexate contributes to relapse-free survival and survival for patients with localized non-Hodgkins lymphoma when added to a 9 week induction and consolidation regimen as administered in POG8314.
- 2) To maintain a high cure rate with minimum toxicity for children with localized non-Hodgkins lymphoma favorable sites.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study #NMSCD-234:CALGB 8765: ANALYSIS OF PROTO-ONCOGENE EXPRESSION
IN ACUTE NONLYMPHOCYTIC LEUKEMIA**

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1986

PRINCIPAL INVESTIGATOR:CAPT William Thomas

SPONSOR:POG

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Leukemia Patients

PURPOSE: To study the degree of proto-oncogene activation in the leukemic cells of patients and correlate that information with the response to standard chemotherapy.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☒ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMSCD-235:T-CELL #3 PILOT STUDY: POG 8691

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1986

PRINCIPAL INVESTIGATOR:CAPT William Thomas

SPONSOR:POG

NUMBER OF HUMAN SUBJECTS:6

SPECIAL CLASS OF SUBJECTS:Children with Cancer

PURPOSE:

- 1) To determine the toxicity and complications associated with the administration of an intensive chemotherapy regimen to children with T-cell leukemia and advanced stage T-cell lymphoma.
- 2) To determine the feasibility of using this chemotherapy regimen as the backbone of a randomized groupwide T-cell study evaluating intensive L-asparaginase therapy.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMSCD-236:EVALUATION OF TREATMENT REGIMENS IN ACUTE LYMPHOID LEUKEMIA OF CHILDHOOD: POG 8602

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1986

PRINCIPAL INVESTIGATOR:CAPT William Thomas

SPONSOR:POG

NUMBER OF HUMAN SUBJECTS:3

SPECIAL CLASS OF SUBJECTS:Children with Leukemia

PURPOSE: To test the concept that intensive asparagine (ASP) therapy, designed to maintain low asparagine levels for the first 6 months of maintenance will improve the outcome for patients with standard risk ALL when added to pulses of intermediate dose methotrexate, as compared to intensification with IDM alone.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

**Study #NMSCD-237:ETOPOSIDE, VINBLASTINE, DOXORUBICIN (EVA) AS THE
PRIMARY TREATMENT OF ADVANCED HODGKIN'S DISEASE IN RELAPSE FROM
MoPP OR MOPP VARIANTS: PHASE II: CALGB 8751**

**LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

START DATE OF STUDY:1987

PRINCIPAL INVESTIGATOR:LCDR M. P. Kosty

SPONSOR:CALGB

NUMBER OF HUMAN SUBJECTS:3

SPECIAL CLASS OF SUBJECTS:Hodgkin's Patients

PURPOSE: *To evaluate the toxicity and efficacy of etoposide, vinblastine, and doxorubicin (EVA) as the primary treatment of advanced Hodgkin's disease.*

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☒ INCIDENTAL DIAGNOSTIC
- ☐ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NMSCD-238:CALGB 8525: A PHASE III COMPARATIVE STUDY OF POST REMISSION INTENSIVE ARA-C IN PATIENTS WITH ACUTE NON-LYMPHOCYTIC LEUKEMIA IN FIRST REMISSION

LOCATION OF STUDY:NAVAL HOSPITAL/NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

START DATE OF STUDY:1986

PRINCIPAL INVESTIGATOR:CDR Fred Millard

SPONSOR:

NUMBER OF HUMAN SUBJECTS:0

SPECIAL CLASS OF SUBJECTS:Leukemia Patients

PURPOSE: Chemotherapy.

- ☐ EXPERIMENTAL DIAGNOSTIC
- ☐ INCIDENTAL DIAGNOSTIC
- ☒ EXPERIMENTAL THERAPEUTIC
- ☐ THERAPEUTIC TREATMENT
- ☐ OTHER
- ☐ UNKNOWN/UNCERTAIN

LOCATION OF RECORDS: NAVAL MEDICAL CENTER SAN DIEGO

[X] UNCLASSIFIED

#

Study #NHOAK-01: Localization of Ga-67 Citrate in Plasma Cell Granuloma of the Lung

Location: Naval Hospital Oakland

Date:

Primary

Researchers: W. H. Wong, B. R. Rao, T. P. Dresser and J. M. Winebright

Sponsors: NH Oakland and BUMED(CR48-9-14)

Human

Subjects: One 60 y/o female

Purpose: A linear tomography chest x-ray and Ga-67 citrate scintiscans were used to diagnose and evaluate a plasma cell granuloma in a 60 y/o patient.

Category:

Records: NH Oakland

Classification: Unclassified

Category: Other research, diagnostic.

Records: NH Oakland

Classification: Unclassified

#

Study #NHOAK-02: Supernumary Toe Arising from the Medial Cuneiform

Location: Naval Hospital Oakland

Date: 1979

Primary

Researchers: B. R. Rao,

Sponsors: NH Oakland and BUMED (CR-9-C5)

Human

Subjects: One 17 y/o male with an accessory right big toe.

Purpose: A weight bearing roentgenogram of the patient's right foot revealed an accessory right big toe.

Category: Other research, diagnostic.

Records: NH Oakland

Classification: Unclassified

#

Study #NHOAK-03: Splenic Artifact Caused by Barium in the Colon

Location: Naval Hospital Oakland

Date:

Primary

Researchers: B. R. Rao, J. W. Winebright and T. P. Dresser

Sponsors: NH Oakland

Human

Subjects: 54 y/o female with a history of alcohol abuse.

Purpose: A routine Tc-99m-sulfur colloid liver-spleen scan yielded conflicting results relating to a splenic focal defect. An abdominal roentgenogram obtained immediately after the scan revealed residual barium within the colon from an upper GI tract series performed the previous day.

Category: Other research, diagnostic

Records: NH Oakland

Classification: Unclassified

#

Study #NHOAK-04: Functional Asplenia after Thorotrast Administration

Location: Naval Hospital Oakland

Date:

Primary

Researchers: B. R. Rao, J. W. Winebright and T. P. Dresser

Sponsors: NH Oakland and BUMED (CR 48-9-15)

Human

Subjects: 68 y/o female

Purpose: X-ray of the upper abdomen of a 68 y/o patient revealed a radiopaque density in the region of the spleen. This was followed by a Tc-99m-sulfur colloid scan and reversed chest radiograph which revealed functional asplenia.

Category: Other research, diagnostic.

Records: NH Oakland

Classification: Unclassified

#

Study #NHOAK-05: Gallium-67 Uptake in a Benign Thymic Cyst

Location: Naval Hospital Oakland

Date:

Primary

Researchers: S. R. Jensen, B. R. Rao, J. W. Winebright and R. O'Reilly

Sponsors: NH Oakland and BUMED (CR 7-48-1023)

Human

Subjects: 46 y/o male

Purpose: A routine chest x-ray of a 46 y/o male patient revealed an anterior mediastinal mass. A follow-up chest radiograph revealed enlargement of the mass and a Ga-67 scan demonstrated uptake in the mass. The mass was removed surgically.

Category: Other research, diagnostic

Records: NH Oakland

Classification: Unclassified

#

Study #NHOAK-06: Soft-tissue Uptake of Tc-99m MCP in Secondary Scrotal Lymphodema

Location: Naval Hospital San Diego

Date:

Primary

Researchers: B. R. Rao and D. W. Hodgins

Sponsors: NH San Diego and BUMED (Protocol # 81-16-1487)

Human

Subjects: A 77 y/o male with a history of Stage C adenocarcinoma of the prostate.

Purpose: The patient received a Tc-99m MDP bone scan which revealed a large scrotum. The patient then underwent radiation therapy and surgery.

Category: Other research, diagnostic followed by therapeutic.

Records: NH San Diego

Classification: Unclassified

#

Study #NHOAK-07: The Early Determination of the Incidence and Healing of Aseptic Necrosis of the Femoral Head Following Trauma Utilizing Radioisotope Scan

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: I.J. Woodstein

Sponsors: Oakland

Human

Subjects: 8 Patients

Purpose: The early determination of the incidence and healing of aseptic necrosis of the femoral head following trauma utilizing radioisotope scan.

Procedure: Patient with neck fractures, traumatic hip dislocations or fractures of the acetabulum received a scan six weeks after injury. Follow-up scans were received at three-month intervals until equilibrium is reached or until twenty-four months have elapsed from the date of injury if aseptic necrosis does not develop during the interim.

- SMA-12 and Hematocrit were obtained prior to radioisotope injection.
- One quart of liquid provided to patient in the hour following injection.
- Patient received up to 10mCi of a 99mTc bone scanning agent.
- Scanning commenced 2.5 to 2.75 hours after injection.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-08: The Hepatic Abnormalities of Diabetes Mellitus. The Abnormalities of Radionuclide Scan in Relation to Diabetic Control

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: Charles R. Rost

Sponsors: Oakland

Human

Subjects: 18 Patients

Purpose: The hepatic abnormalities of diabetes mellitus. The abnormalities of radionuclide scan in relation to diabetic control.

Procedure: Diabetic patients were asked to participate in this study. Informed consent was obtained. Subjects were divided into groups based on body weight, age, and presence of abnormal liver enzyme levels on routine serum testing. Technecium sulfacolloid liver scan was obtained from the patient while under moderate to poor control and again after good metabolic control was achieved. Control was judged on the basis of fasting blood sugar, two hour post-prandial blood sugar, hemoglobin A1C concentration and twenty-four hour urine glucose excretion. Interpretation of liver scan patterns was accomplished by a single physician who had no knowledge of the metabolic state of the patient at the time of the scan.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-09: Xenon-127 Gas for Inhalation

Location: Naval Regional Medical Center, Oakland, CA 94627

Date: 22 July 1978

Primary

Researchers: CAPT James Winebright MC USN

Sponsors: Oakland

Human

Subjects: 40 Patients

Purpose: To provide the Nuclear Medicine Service with a lung ventilation study for use following a perfusion study.

Procedure: Xenon-133 was routinely used in nuclear medicine for lung ventilation studies. The low energy output of this radiopharmaceutical gas requires the study be performed prior to a technetium 99m perfusion study. From a practicality standpoint, the study was conducted following the technetium study since a normal perfusion study would be reason not to conduct a ventilation study. Xenon-127 due to its high energy output, allows the ventilation study to follow the perfusion study. Consent was requested from participants of this study.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-10 Indium Oxine Indium-111 Labeled Cellular Blood Components

Location: Naval Regional Medical Center, Oakland, CA 94627

Date: During 1981. Specific date not stated.

Primary

Researchers: CAPT James Winebright MC USN

Sponsors: Oakland

Human

Subjects: 296 Patients

Purpose: Indium-111 labeled cellular blood components. To provide a diagnostic procedure for abscess localization, vascular injuries associated with platelet accumulation and platelet survival studies.

Procedure: Not stated.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-11: Technetium-99m Sulfur Colloid of Oral Use

Location: Naval Regional Medical Center, Oakland, CA 94627

Date: During 1981. Specific date not stated.

Primary

Researchers: CAPT James Winebright MC USN

Sponsors: 12 Patients

Purpose: Technetium 99m sulfur colloid for oral use. To provide a diagnostic procedure for the detection and quantification of esophageal reflux using a radionuclide. This procedure offers improved sensitivity and reduced patient discomfort as compared to previously practiced procedures.

Procedure: Patients with chronic heartburn regurgitation and epigastric pain were referred for this study. Involves the oral administration of the gamma emitting radionuclide Technetium 99m sulfur colloid. If reflux is present then the radionuclide would reappear in the esophagus when pressure was applied to the stomach. By use of a gamma camera, the presence of the radionuclide in the esophagus was recorded. 300 microcuries of technetium 99m sulfur colloid in orange juice was administered orally. The dose was adjusted for children using Clarke's Rule. Patients were required to sign an informed consent form prior to each procedure.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-12: NCOG OR81 All Sites, Phase I & II Protocol of Heavy Charged Particle Radiotherapy for Locally Advanced and or Recurrent Cancers of Multiple Sites and Types

Location: Naval Regional Medical Center, Oakland, CA 94627

Date: During 1981. Specific date not stated.

Primary

Researchers: Michael A. Crucitt

Sponsors: Oakland

Human

Subjects: 18 Patients

Purpose: NCOG OR81 all sites, Phase I & II protocol of heavy charged particle radiotherapy for locally advanced and or recurrent cancers of multiple sites and types. Objectives included evaluation of normal tissue tolerance to large field multi-fraction heavy charged-particle radiotherapy; to evaluate local tumor responses and establish the dose range required for tumor control; evaluate and refine the CT based computerized treatment planning, patient immobilization and large field, charged particle radiotherapeutic treatment techniques; and make initial evaluations as to which heavy charged particles are suitable for prospective randomized clinical trials.

Procedure: Patient selection for this investigation required the following:

Biopsy proven, locally advanced and/or recurrent and/or metastatic malignancy of any anatomic site and any histologic type. Patients with deepseated gliomas were accepted without biopsies.

Poor chance of control with conventional radiotherapy, surgery or chemotherapy because of tumor site, stage or histology.

Reasonable expectation of completing the treatment and required follow-up examinations. Life expectancy is greater than three months.

Karnofsky score greater than or equal to 50%.

Able to travel to Lawrence Berkeley Laboratory where the treatment and follow-up visits were accomplished.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-13: NCOF 3L91 Liver

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: M. A. Crucitt

Sponsors: NCOG

Human

Subjects: 2 patients

Purpose:

- (1) To compare objective response rate of I.A. chemotherapy plus hepatic radiation with I.V. chemotherapy plus hepatic radiation with hepatic radiation only.
- (2) To compare survival from date of onset of therapy of the three approaches.
- (3) To compare duration of response from date of onset of best response in the three arms.
- (4) To compare toxicities of each therapy.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-14: NCOG 7H61, A Randomized Phase III Study Of Radiation Therapy with or Without Chemotherapy for Remission Induction and Multidrug Chemotherapy Program for Remission Consolidation and Maintenance in Inoperable Squamous Cell Carcinoma of the Head and Neck

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: M. A. Crucitt

Sponsors: NCOG

Human

Subjects: 3 patients

Purpose: To determine the effect of radiation therapy with and without chemotherapy used during induction, consolidation, and maintenance on:

- (1) overall survival time
- (2) Complete response and 3-y control of the primary site.
- (3) Complete response and 3-y control of regional lymph nodes.
- (4) duration of disease-free survival in patients with advanced inoperable squamous cell carcinoma of the head and neck.
- (5) Prevention of metastatic disease in distant sites
- (6) Normal tissue in patients with the combination radiotherapy and chemotherapy program.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-15: NCOG 6G61 A Phase III Study of Radiotherapy plus Hydroxyurea and BCNU vs. Radiotherapy plus Hydroxyurea and Procarbazine, BCNU, Vincristine (PCV) for the Treatment of Primary Malignant Brain Tumors

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: M. A. Crucitt

Sponsors: NCOG

Human

Subjects: 6 patients

Purpose: To compare the results in two treatment groups (radiotherapy + HU BCNU vs. radiotherapy + HU PCV) with regard to:

- (1) Time to disease recurrence or progression, measured from the date of randomization.
- (2) Response rates and duration of response
- (3) Survival time, measured from the date of randomization.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-16: NCOG 9M91 A Phase I-II Study of Combination Chemotherapy and Sequential Hemibody Radiation Therapy in the Treatment of High Tumor Burden Multiple Myeloma

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: M. A. Crucitt

Sponsors: NCOG

Human

Subjects: 2 patients

Purpose:

(1) To determine whether systemic radiation therapy effects an additional reduction in paraprotein production after induction with VMCP in patients with high tumor burden myeloma.

(2) To determine whether radiation therapy allows subsequent chemotherapy (with same regimen) to achieve a still further reduction in paraprotein production.

(3) To evaluate the toxicities (hematologic, pulmonary, cardiac and renal) of the combined modalities.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-17: Tumor Burden Multiple Myeloma

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Procedure:

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

**Study #NHOAK-18: NCOG 13L-80-1 Treatment of Adult Lymphoblastic Lymphoma,
A Phase II Study using Intrathecal Methotrexate with Whole Brain Radiotherapy
Combined with Systemic Methotrexate**

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: M. A. Crucitt

Sponsors: NCOG

Human

Subjects: 1 patient

Purpose:

(1) To test the effectiveness of an intensive chemotherapeutic regimen on the induction and maintenance of remission in adult lymphoblastic lymphoma with respect to:

- objective response (remission) rates
- duration of response (remission)

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-19: NCOG 50-82-1 A Phase II Study of Pelvic and Abdominal Radiotherapy vs. Cisplatin Adriamycin, and Cyclophosphamide

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: M. A. Crucitt

Sponsors: NCOG

Human

Subjects: 1 patient

Purpose:

(1) To provide rigorous operative staging and optimal cytoreduction for patients with epithelial ovarian carcinoma and to prospectively evaluate their effect on progression-free interval and survival.

(2) To compare whole abdominal and pelvic irradiation to PAC chemotherapy with regard to toxicity, overall rates of response, percent of complete clinical response, progression-free interval, and survival.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-20: NCOG 20-83-1, A Phase III Trial of Seven-drug Versus Three-drug Chemotherapy Regimens with or without Cranial Irradiation (PCI) for Undifferentiated Small Cell Anaplastic Lung Cancer

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: M. A. Crucitt

Sponsors: NCOG

Human

Subjects: 19 patients

Purpose:

- (1) To test the good results of NCOG Protocol 2091 in extensive disease (Arm A).
- (2) To test the value of intense exposure to three drugs (Arm B) vs. alteration of seven drugs (Arm A).
- (3) To test the value of prophylactic cranial irradiation in complete responders.
- (4) Principal endpoints of disease response will be time to response, disease-free survival, and survival. Groups will be monitored for performance status, weight, and for specific toxicities.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-21: Scintigraphic Arthrography Using 99m Technetium Sulfur Colloid

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: G. B. Batten

Sponsors: Oakland

Human

Subjects: 24 patients

Purpose: This was a prospective study using the relatively new technique of intra-articular injection of Tc-99m sulfur colloid to assess its usefulness in evaluating patients with symptomatic total joint arthroplasties. Following the traditional work-up with plain radiographs and nuclear scans, the radionuclide was injected into the joint at the completion of the standard aspiration and contrast arthrogram. Twenty-six nuclear arthrograms in 24 patients were carried out.

Category: Therapeutic research involving radiation

Records: St. Louis, MO

Classification: Unclassified

#

Study #NHOAK-22: Early Determination of Femoral Head Vascularity Using Technetium 99m Sulfur Colloid and Quantitative Technique

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: A. H. Alexander

Sponsors: Oakland

Human

Subjects: 75 patients >7 y/o.

Purpose: Tc-99m sulfur collodi reflects activity in bone marrow. It was reported that this agent could detect early avascular necrosis following femoral neck fracture or hip fracture dislocation using qualitative methods for assessing uptake. The purpose of this study is to confirm and reproduce these findings and to refine this method by using quantitative rather than qualitative methods of assessing sulfur colloid uptake.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-23: Use of Quantitative Computed Tomography (QCT) in Assessing Bone Mass Changes in Diabetic Patients

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: C. B. Sainten

Sponsors: Oakland

Human

Subjects: 20 patients (premenopausal diabetics)

Purpose: Peripheral cortical bone mineral content has been reported to be reduced in insulin-dependent diabetics, but other studies have shown no increase in vertebral fracture incidence in this population. In this study, QCT was used to measure mineral content in Type I and Type II diabetics.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-24: 99m Tc-HMPAO Labeled Leukocytes and Platelets: Basic and Clinical Studies

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: T. P. Dresser

Sponsors: Oakland

Human

Subjects: 8 patients

Purpose:

(1) Achieve optimum labeling efficiency for leukocytes and platelets with Tc-99m-HM-PAO in both *in vitro* and *in vivo* environments.

(2) Compare the diagnostic accuracy of leukocytes labeled with In-111 vs. Tc-99m-HM-PAO.

(3) Compare the diagnostic accuracy of platelets labeled with In-111 vs. Tc-99m-HM-PAO.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-25: Comparison of Thallium Scintigraphic Images after Transesophageal Atrial Pacing (TAP) and Dipyridamole for the Detection of Atherosclerotic Coronary Artery Disease

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: A. Wales, L. Balagurchik, D. Hill, K. Tucker, J. Maher and T. Dresser

Sponsors: Oakland

Human

Subjects: 25 patients

Purpose: To determine the differences in sensitivity and specificity between transeophageal atrial pacing (TAP) with handgrip (HG) exercise and oral dipyridamole with HG in conjunction with thallium scintigraphic imaging for the detection of atherosclerotic coronary artery disease, this study evaluated 25 patients undergoing coronary angiography in a prospective, comparative study of alternative diagnostic modalities done using a cross-over design.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-26: Evaluation of Subcutaneous Gallium-Citrate Injection for the Imaging of Malignant Abdominal Adenopathy

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: R. A. Olshaker

Sponsors: Oakland

Human

Subjects: 1 patient

Purpose: Evaluation of the utility of subcutaneous Ga-67 citrate scanning in the detection of amalignant involvement of abdominal lymph nodes.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-27: Radiographic Correlation of Leg Length Inequality in Patients with Total Hip Arthroplasty (THA)

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: J. Edeen

Sponsors: Oakland

Human

Subjects: 53 patients

Purpose: To use standing orthoroentgenograms to accurately measure the functional leg length in patients with THA

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-28: Radionuclide Imaging of Chronic Anterior Cruciate Ligament Deficient Knees

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: J. D. Main

Sponsors: Oakland

Human

Subjects: 24 patients

Purpose: To determine if bone imaging can be used to detect changes in osseous homeostasis prior to the appearance of radiographic degenerative changes.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-29: . A Prospective Comparison of Air-Contrast Barium Enema Plus Procto-Sigmoidoscopy with Colonoscopy in the Screening of Asymptomatic Persons with a History of Colorectal Cancer in First Degree Relatives

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: R. H. Koehler

Sponsors: Oakland

Human

Subjects: 34 patients

Purpose: To determine which screening modality, air-contrast barium enema/rigid sigmoidoscopy or full colonoscopy, is the more accurate and more cost-effective means of detecting and removing, when possible, neoplastic polyps in asymptomatic patients who are first-degree relatives of persons with a history of colorectal cancer.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-30: CALGB 9130, A Phase II Trial of Vinblastine/Cisplatin/Radiation Therapy with or without Carboplatin for Inoperable Stage IIIA and Stage IIB Non-small Cell Lung Cancer

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: J. T. Ganey

Sponsors: CALGB

Human

Subjects: 1 patient

Purpose:

(1) To determine if the concurrent addition of CBDCA during radiation therapy for Stage IIIA and IIB inoperable non-small cell lung cancer will prolong survival and improve local disease control.

(2) To determine if the improvement in survival, if any, is related to disease stage; tumor (T) status and nodal status.

(3) To determine if the improvement in survival, if any, is related to tumor size.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-31: Acromion Morphology in the Active Duty Population: Plain Roentgenogram Analysis

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: D. P. Adkison

Sponsors: Oakland

Human

Subjects: 60 patients

Purpose: The subacromial outlet radiograph will be used to evaluate acromion morphology for shape and size of hook and to:

(1) To document the distribution of acromion types in a population of patients without shoulder complaints.

(2) To document the distribution of acromion types in patients presenting with shoulder impingement.

(3) To determine the relative risk of acromion type in painful shoulders for surgical treatment during the study period.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-32: NSAP C-01, A Clinical Trial to Evaluate Post-operative Immunotherapy and Postoperative Systemic Chemotherapy in the Management of Resectable Colon Cancer

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 5 patients

Purpose: To investigate various treatment modalities for colon cancer.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-33: NSABP B-11, A Clinical Trial to Compare PF with and without Adriamycin in the Management of Patients with Primary Breast Cancer and Positive Axillary Nodes Whose Tumors are Negative for Estrogen Receptors

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 3 patients

Purpose: To evaluate the addition of Adriamycin to PF in patients with one or more positive axillary nodes whose tumor estrogen receptors have been quantitatively assayed and found to be < 10 fmol/mg cytosol proteins.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-34: NSABP B-14, A Clinical Trial to Assess Tamoxifen in Patients with Primary Breast Cancer and Negative Axillary Nodes whose Tumors are Positive for Estrogen Receptors

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 13 patients

Purpose: Cancer treatment protocol, and the exposure to radiation was incidental to being a part of the protocol.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-35: NSABP B-12, A Clinical Trial to Compare PFT with and without Adriamycin in the Management of Patients with Primary Breast Cancer and Positive Axillary Nodes whose Tumors are Positive for Estrogen Receptors

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 5 patients

Purpose: To evaluate the addition of Adriamycin to PFT in patients with one or more positive axillary nodes whose tumor estrogen receptors have been quantitatively assayed and found to be < 10 fmol/mg cytosol proteins.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-36: NSABP B-13, A Clinical Trial to Assess Sequential Methotrexate 5 Fluorouracil in Patients with Primary Breast Cancer and Negative Axillary Nodes whose Tumors are Negative for Estrogen Receptors

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 1 patient

Purpose: Cancer treatment protocol, and the exposure to radiation was incidental to being a part of the protocol.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-37: NSABP B-16, A Three-Arm Clinical Trial Comparing Tamoxifen Alone with L-PAM, 5-FU, and Tamoxifen or Short Intensive Adriamycin-Cyclophosphamide and Tamoxifen in Positive Node Patients

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 3 patients

Purpose: Cancer treatment protocol, and the exposure to radiation was incidental to being a part of the protocol.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-38: NSABP B-18, A Unified Trial to Compare Short Intensive Preoperative Systemic Adriamycin Cyclophosphamide Therapy with Similiar Therapy Administered in Conventional Postoperative Fashion

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 2 patients

Purpose: Patients with palpable operable breast cancer were placed into two study groups. Group I received a total or segmental mastectomy plus axillary dissection followed by four cycles of Adriamycin and cyclophosphamide given every 21 days. Group II received four cycles of Adriamycin and cyclophosphamide followed by a total or segmental mastectomy plus axillary dissection within 4 weeks of the fourth course of chemotherapy. For patients undergoing segmental mastectomy, breast radiation was to be given after the completion of chemotherapy.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-39: NSABP B-20, A Clinical Trial to Determine the Worth of Chemotherapy and Tamoxifen over Tamoxifen Alone in the Management of Patients with Primary Invasive Breast Cancer, Negative Axillary Nodes, and Estrogen Receptor Positive Tumors

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 1 patient

Purpose: All patients who had a lumpectomy as part of this study were to receive breast irradiation.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-40: NSABP C-04, A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin, 5-FU + Levamisole, and 5-FU + Leucovorin + Levamisole in Patients with Dukes' B and C Carcinoma of the Colon

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 1 patient

Purpose: To evaluate the relative efficacy of the following postoperative treatment regimens in patients with Dukes' B and C carcinoma of the colon:

- (1) 5-FU + leucovorin, as employed in NSABP Protocol C-03.
- (2) 5-FU plus levamisole, used by other investigators.
- (3) 5-FU plus leucovorin (as used in Protocol C-03) with levamisole.

Cancer treatment protocol, and the exposure to radiation was incidental to being a part of the protocol.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-41: CALGB 9033, Oral Versus Intravenous Etoposide in Combination with Intravenous Cisplatin in Extensive Small Cell Lung Cancer: Phase III

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: J. T. Ganey

Sponsors: Cancer and Leukemia - Group B

Human

Subjects: 1 patient

Purpose: Phase III trial to compare the standard therapy which involves a combination of IV cisplatin and etoposide given on the first three days of each 21-day cycle with an experimental therapy in which IV cisplatin is combined with a daily low dose of oral etoposide. Cancer treatment protocol, and the exposure to radiation was incidental to being a part of the protocol.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-42: NSABP B-23, A Clinical Trial Comparing Short, Intensive AC + Tamoxifen with Conventional CMF + Tamoxifen in Node-Negative Breast Cancer Patients with ER-Negative Tumors

Location: Naval Regional Medical Center, Oakland, CA 94627

Date:

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 2 patients

Purpose:

(1) Whether 4 cycles of Adriamycin and cyclophosphamide are superior to 6 cycles of cyclophosphamide, mehtotrexate and fluorouracil.

(2) whether tamoxifen added to one of the above is more effective than the cytotoxic chemotherapy alone.

Cancer treatment protocol, and the exposure to radiation was incidental to being a part of the protocol.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

#

Study #NHOAK-43: NSABP C-05, A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin with or without Interferon ALFA-2A

Location: Naval Hospital, Oakland

Date: 1991

Primary

Researchers: H. L. Russell

Sponsors: NSABP

Human

Subjects: 4 patients

Purpose: Evaluate the efficacy of two postoperative treatment regimens in patients with Dukes' B and C carcinoma. Cancer treatment protocol, and the exposure to radiation was incidental to being a part of the protocol.

Category: Therapeutic research involving radiation

Records:

Classification: Unclassified

Study # NHPTS-01: "Postpartum Chest X-Ray Studies of 1,000 Patients to determine Incidence of Pneumopericardium and Pneumomediastinum."

Location: Clinical Investigative and Research Department, NH Portsmouth

Date: FY72

**Primary
Researchers:**

Sponsors: NH Portsmouth

Human

Subjects: 2 females within 48 hours of delivery

Purpose: Postpartum Chest X-ray studies to determine incidence of Pneumopericardium and Pneumomediastinum 48 hours of delivery.

Category: Other

Records:

Classification: Unclassified

#

Study NHPTS-02: "Closed Internal Fixation of Fractures Using Image Intensifier Control."

Location: Clinical Investigative and Research Department, NH Portsmouth

Date: FY75

**Primary
Researchers:**

Sponsors: NH Portsmouth

Human

Subjects: 6 patients - no special class of patients

Purpose: The Human Use Committee specifically noted that the orthopedic fluoroscopic imaging that occurred during this study was clinically indicated based on published literature at that time

Category: Other

Records:

Classification: Unclassified

#

Study # NHPTS-03: "Evaluation of Post-Due Obstetric Patients."

Location: Clinical Investigative and Research Department, NH Portsmouth

Date: FY73

**Primary
Researchers:**

Sponsors: NH Portsmouth

Human

Subjects: 56 patients - special class of patients is females

Purpose: These females received a fetogram during their forty-second week of pregnancy. The fetogram was an x-ray of the pelvis to determine the position of the fetus.

Category: Other

Records:

Classification: Unclassified

#

Study #NHPTS -04: "The Management of Cervical Intraepithelial Neoplasia with CO2 Laser."

Location: NH Portsmouth

Date: 1972-1979

Primary

Researchers: R. T. Upton

Sponsors: NH Portsmouth

Human

Subjects: 25 patients - special class of patients is females

Purpose:

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-05: "Diagnosis and Presurgical Evaluation of Biliary and Pancreatic Disorders Utilizing a Fiberisfunoscope."

Location: NH Portsmouth

Date: 1972-1774

Primary

Researchers: E. L. Burke

Sponsors: NH Portsmouth

Human

Subjects: 13 - no special class of patients

Purpose: To attempt ampullary cannulation

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-06: "Evaluation of Inferior Esophageal Sphincter Competence by Esophagoscopy."

Location: NH Portsmouth

Date: 1972-1974

Primary

Researchers: E. L. Burke

Sponsors: NH Portsmouth

Human

Subjects: Not available

Purpose: To relate the amount of "open time" of the inferior esophageal sphincter during examination with the fiber optic esophagoscope to the degree of competence of the inferior esophageal sphincter. A secondary aim is to correlate if possible the extent and severity of esophagitis and the demonstration of presence or absence of histal hernia and reflux by x-ray.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study #NHPTS -07: "Evaluation to Post-Due Obstetric Patients."

Location: NH Portsmouth

Date: 1973-1973

Primary

Researchers: E. T. Upton, J. Sebastian, and J. O. Goodwin

Sponsors: NH Portsmouth

Human

Subjects: 56 patients - special class of patients is pregnant females

Purpose: To achieve more uniform care of the post-due patient to detect patients at risk with post mature fetuses. Patients in their 42nd week were evaluated with fetogram.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-08: "Ambulatory Treatment of Legg-Calve-Perthes' Disease."

Location: Portsmouth

Date: 1972-1975

Primary

Researchers: J. M. Casey

Sponsors: NH Portsmouth

Human

Subjects: 40 patients - special classes of patients is children with the above disease

Purpose: To evaluate a treatment of patients with Legg-Calve-Perthes disease with a newer modification of traditional therapy with abduction casts, namely the maintenance of abduction with the use of braces. During their treatment, patients must be seen and given clinical and radiological examinations at 2 to 3 months intervals

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-9: "Participation in Acute Leukemia Group B."

Location: NH Portsmouth

Date: 1975-1979

Primary

Researchers: J. W. Reid

Sponsors: NH Portsmouth; ALGB

Human

Subjects: 15-30 patients a year with the above disease.

Purpose: To improve care of the patient with advanced malignancy. To have access to the use of the newer and improved drugs and methods for treatment of advanced malignancies. There is mention of 12 different drugs in the study but no radiation treatment.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-10: "Closed Internal Fixation of Fractures Using the Image Intensifier."

Location: NH Portsmouth

Date: 1975-1978

Primary

Researchers: J. C. P. Collier

Sponsors: NH Portsmouth

Human

Subjects: 6 patients - no special classes of patients

Purpose: To study the advantages of image intensifier fluoroscopy over standard methods of x-ray control in closed internal fixation of certain bone fractures. To determine the radiation exposure of the patient and the surgical team during these procedures using the image intensifier fluoroscope

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-11: "Protocol for the Treatment of Acute Myelocytic Leukemia and Related Disorders. Number PWH 001."

Location: NH Portsmouth

Date: 1975-1977

Primary

Researchers: J. W. Reid

Sponsors: NH Portsmouth; ALGB

Human

Subjects: 8 patients annually - no special classes of patients

Purpose: To accumulate additional data on the use of Daunomycin in acute leukemia. Prior to this drug therapy, a chest x-ray among other tests will be given.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

**Study #NHPTS -12: "Protocol for the Use of Adriamycin in Certain
Metastatic Malignant Tumors**

Location: NH Portsmouth

Date: 1975-1976

Primary

Researchers: J. E. Kostinas

Sponsors: NH Portsmouth

Human

Subjects: 48 patients - no special classes of patients

Purpose: To gain additional information on the toxicity and efficacy of adriamycin in therapy of certain metastatic malignant tumors. A chest x-ray , if appropriate, will be given at the beginning of the study.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-13: "Immunologic Evaluation and Therapy of Patients with Carcinoma of the Lung."

Location: NH Portsmouth

Date: 1975-1981

Primary

Researchers: J. W. Reid

Sponsors: NH Portsmouth; NNMC Bethesda; NCI

Human

Subjects: 150 patients - no special class of patients

Purpose: To gain information regarding efficacy of immunotherapy (BCG and killed allogeneic tumor cells) as an adjunct to standard methods in treatment of carcinoma of the lung. No radiation treatment is mentioned. Possibly x-rays were performed

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-14: "Clinical Use of a Hypothalamic Releasing Hormone: Conadotropin Releasing Hormone ."

Location: NH Portsmouth

Date: 1976

Primary

Researchers: A. T. Guav

Sponsors: Not listed

Human

Subjects: 30-50 patients - special class of patients is adults

Purpose: To determine LH, FSH and testosterone (in males) response after the hypothalamic hormone, LRF in patients with suspected pituitary insufficiency. To evaluated more fully patients with suspected hypogonadism. X-rays were probably used but were not listed in the report

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-15: Evaluation of Freeze-Dried Bone in the Treatment of Periodontal Osseous Defects

Location: NH Portsmouth

Date: 1976-1977

Primary

Researchers: R. J. Steunick

Sponsors: NH Portsmouth; NNMC Bethesda

Human

Subjects: 6 patients - no special class of patients

Purpose: The primary objective of this study is to conduct a carefully controlled clinical evaluation of human freeze dried bone as a therapeutic modality for treating periodontal bony defects. A comparison will be accomplished by grafting certain defects with freeze-dried bone alone and similar defects with a composite graft of freeze-dried human allograft combined with fresh autologous marrow, fresh cancellous or cortical bone from the oral cavity. Preoperative and postoperative radiographs will be taken.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-16: "Classification and Treatment of Fractures of the Base of the Fifth Metacarpal."

Location: NH Portsmouth

Date: 1977-1980

Primary

Researchers: S. B. Pledger

Sponsors: NH Portsmouth

Human

Subjects: 38 patients - no special class of patients

Purpose: To establish a classification for fractures of the base of the fifth metacarpal. To correlate the type of fracture and mode of treatment necessary. To evaluate the degree of disability secondary to fractures of the base of the fifth metacarpal. X-rays were used in this study.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study NHPTS-17: Study of Gastric Ulcers

Location: NH Portsmouth

Date: 1977-1978

Primary

Researchers: F. Garcia-Tores

Sponsors: NH Portsmouth

Human

Subjects: Not available - no special class of patients

Purpose: To ascertain the efficacy of the two methods (fiber optic endoscopy and barium contrast studies) of evaluation and sequential follow-up of patients with gastric ulcers, particularly with reference to differentiation between malignant and benign ulcers. Endoscopic rather than x-ray was used.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-18: "Use of CA(OH)₂ to Prevent. Arrest and/or Reverse the External and/or Resorption of Teeth Following Their Luxation or Avulsion."

Location: NH Portsmouth

Date: 1977-1980

Primary

Researchers: G. S. Foster

Sponsors: NH Portsmouth

Human

Subjects: 5 patients - special class of patients is Adults and minors

Purpose: It is the aim of this study to determine the efficacy of CA (OH)₂ used as a temporary root filling material to prevent, arrest and/or reverse the internal and/or external resumption of teeth following their severe luxation or avulsion. No mention of radiation is mentioned in the report. However x-rays may have been used.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-19: "Platinum-Adriamycin Therapy

Location: NH Portsmouth

Date: 1977-1978

Primary

Researchers: J. W. Reid

Sponsors: NH Portsmouth; NCI

Human

Subjects: Not available but patients enrolled - no special class of patients

Purpose: To test the efficacy of DDP-Adriamycin combination in therapy of advanced lung cancer. To determine if DDP and Adriamycin are synergistic in lung cancer. To assess the clinical toxicity of this combination of drugs. Chest x-rays were used in the initial part of the study and may have been used at other times

Category: Others

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-20: "Prospective Study of Ankle Fractures."

Location: NH Portsmouth

Date: 1977

Primary

Researchers: G. Meadows

Sponsors: NH Portsmouth

Human

Subjects: Project never really began. Many patients were being missed

Purpose: To gather clinical data on ankle fractures using x-rays as a diagnostic tool.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

**Study # NHPTS-21: "Minoxidil as an Antihypertensive in Patients
Refractory to Available Medications"**

Location: NH Portsmouth

Date: 1977

Primary

Researchers: G. Meadows

Sponsors: NH Portsmouth

Human

Subjects: Plan to use 10 patients over a two year period

Purpose: To test the hypothesis that Minoxidil is an effective alternative treatment for patients whose blood pressure is refractory to available drugs or who have experienced unacceptable side effects from them and whose situation is life threatening. Skull x-rays performed at the beginning and at 1 year intervals. Recent chest x-rays were used. If not available then a chest x-ray was performed. Chest x-rays were to be performed every 6 months for two years.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-22: "Immunologic Evaluation and Phase One Immunotherapy Trial in Patients with Carcinoma."

Location: NH Portsmouth

Date: 1978

Primary

Researchers: J. W. Reid

Sponsors: NH Portsmouth; NCI

Human

Subjects: 60 patients - no special class of patients

Purpose: To develop an anti-tumor inoculation.

Category: Other

Classification: Unclassified

#

**Study #NHPTS -23: "Extracranial Cerebrovascular Reconstruction-
Cerebral Blood Flow and Neuro psychological Function."**

Location: NH Portsmouth

Date: 1979

Primary

Researchers: R. A. Armstrong

Sponsors: NH Portsmouth

Human

Subjects: 24 patients- no special class of patients

Purpose: To determine whether significant improvement in neuropsychological function, particularly cognitive behavior, following carotid endarterectomy can be

1. objectively documented
2. correlated with alteration in cerebral blood flow

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-24: "ECOG EST 5177. Phase III An Adjuvant Clinical Trial to Compare Cytosan. Methotrexate. 5FO (CMF) Lo CMF. Prednisone (CMFP) With or Without Tamoxifen in Pre-menopausal Women with Stage II Breast Cancer."

Location: NH Portsmouth

Date: 1981-1982

Primary

Researchers: C. W. Caldwell

Sponsors: NH Portsmouth; ECOG

Human

Subjects: 90 to 270 patients will be needed - special class of patients is adults (male & female) with breast cancer

Purpose: To test the concept that combined chemohormonotherapy is superior to chemotherapy in the pre-menopausal adjuvant setting. The effect of CMFP + Tamoxifen will be compared to CMFP and to CMF with respect to:

1. increasing the time from surgery to recurrence
2. decreasing the recurrence rates across time
3. increasing survival across time
4. the impact of pretreatment characteristics on the above parameters

Bone scans and x-rays were used in this study.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

**Study # ~~NHPTS-25~~: GOG 44. Evaluation of Adjuvant Vincristine.
Dactinomycin and Cyclophosphamide Therapy in Malignant Germ Cell
Tumors of the Ovary After Resection of All Gross Tumor**

Location: NH Portsmouth

Date: 1983

Primary

Researchers: D. G. Gallup

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: numbers not available - special class of patients is post menopausal females having had a total mastectomy and either axillary dissection or low axillary sampling and having one or more tumor positive axillary nodes.

Purpose: To evaluate the effects of combined drugs -Vincristine, Dactinomycin, and Cyclophosphamide- in chemotherapy in patients with tumors after all gross tumors have been cut out. Because of surgery, there is the use of x-rays and bone scans.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-26: GOG 45. Evaluation of Vinblastine. Bleomycin and Cisplatin to Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary

Location: NH Portsmouth

Date: 1983-present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females with cancer

Purpose: To evaluate the effect of four cycles of the combined drugs - vinblastine, bleomycin, and cis-platinum - chemotherapy in the management of tumors of the ovary. Though there is no mention of x-rays or bone scans, there was probably some for diagnostic reasons

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-27: GOG 63. A Clinical Pathologic Study of Stages IIB. III and IVA Carcinoma of the Cervix

Location: NH Portsmouth

Date: 1983-1992

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To evaluate the sensitivity and specificity of non-invasive procedures such as sonography, computerized axial tomography (CAT or CT), and lymphangiography in detection of metastases.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-28: GOG 56. A Randomized Comparison of Hydroxyurea vs. Misonidazole as an Adjuvant To Radiation Therapy in Patients with Stages IIB, III, and IVA Carcinoma of the Cervix and Negative Para-aortic Nodes. Phase III

Location: NH Portsmouth

Date: 1983-1986

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine whether hydroxyurea or Misonidazole is superior as a potentiation of radiation therapy in advanced cervical cancer. To compare the toxicity of hydroxyurea versus Misonidazole when given concurrently with radiotherapy. Radiation sources employed in these clinical trials will x-ray generators which produce x-ray beams with a peak photon energy of 1 MEV or more or Cobalt 60 irradiators.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-29: GOG 59. Extended Field Radiation Therapy and Hydroxydrea Followed By a Randomized Comparison of Ciaplatin or no Further Therapy in Patients with Cervical Squamous Cell Carcinoma Metastatic to High Common III ac and/or Para-aortic Lymph Nodes. Phase III

Location: NH Portsmouth

Date: 1983-1986

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth

Human

Subjects: None - special class of subject is females with primary, previously untreated histologically confirmed invasive squamous cell carcinoma of the uterine cervix.

Purpose: To determine if cis-diamminedichloroplatinum, cisplatin, given in an adjuvant setting will decrease the risk of geographic failure or improve the survival rate or progression-free interval in patients who have squamous carcinoma of the cervix with metastases to high common iliac and/or para-aortic lymph nodes proven by either histologic or cytologic means. There is radiation therapy. External beam radiation sources employed in this clinical trial will be x-ray generators which produce x-ray beams with a peak photon energy of 4 Mev or greater or 60 Cobalt teletherapy units

Category: Other

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-30: GOG 37. A Randomized Study of Radiation Therapy vs. Pelvic Node Resection for Patients with Invasive Squamous Cell Carcinoma of the Vulva Having Positive Groin Nodes. Phase III

Location: NH Portsmouth

Date: 1983-1985

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: None - special class of patients is female

Purpose: To determine the benefit and morbidity of adding adjunctive radiation therapy to pelvis and groin for patients found to have positive groin nodes at the time of radical vulvectomy and bilateral groin dissection. Chest x-rays given prior to surgery. Patients are to receive 4500 to 5000 rads midplane of the pelvis intersperse at the rate of 180 to 200 rads per day.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-31: GOG 49. A Surgical Pathologic Study of Women with Invasive Carcinoma of the Cervix and Randomly Assigned Radiation Therapy vs. No Further Therapy in Selected Patients. Phase III

Location: NH Portsmouth

Date: 1983-1992

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 5 patients - special class of patients is females

Purpose: To determine the relation between type of disease and spread with the survival of patients. To determine if the addition of radiation therapy for patients whose disease has spread to the lymph nodes will be more effective treatment than surgery alone. Radiation therapy will be delivered by means of Cobalt-60 teletherapy or other supravoltage treatment which allows treatment at 80 cm. SSD. Patients receiving whole pelvic irradiation will receive a minimum of 4,500 rads, to a maximum of 5,000 rads

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-32: GOG 50. A Study of Adriamycin as Post-operative therapy of Ovarian...

Location: NH Portsmouth

Date: 1983

Primary

Researchers: D. G. Gallup

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: Number of subjects is not available - Special class of patients is female

Purpose: To evaluate the efficacy of adriamycin in the treatment of primary ovarian sarcomas, primary or recurrent, through historic controls. Appropriate radiography given every 6-8 weeks.

Category:

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-33: GOG 14. GOG 7602. All Stage 1C and II (A,B,C) and Selected Stage...

Location: NH Portsmouth

Date: 1983-1986

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: This deals with ovarian carcinoma. The study will controlled and randomized for patients with the cancer spread beyond the ovaries but still confined to the true pelvis and which can be encompassed by a radiation field. Radiation must be of megavoltage quality including (C0-60) and administered by apparatus of not less than 80 cm FSD. A midline dose of 4,000 rads/ 4-5 weeks at the rate of 180-200 rads per day will be given.

Category: Other

Records: M. R. Dudzinski

Classification: Unclassified

#

Study # NHPTS-34: GOG 54. The Treatment of Women with Malignant Tumors of the Ovarian Stroma with Combination...

Location: NH Portsmouth

Date: 1983-1992

Primary

Researchers: R. J. Stock

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of subject is females

Purpose: To treat women with cancer of the ovaries through surgery and chemotherapy. Chest x-ray and CT scan will be given.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-35: GOG 34. A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma Stage I and Occult Stage II

Location: NH Portsmouth

Date: 1983-1987

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To study the differences in morbidity and patient survival as functions of various tumor growth patterns using surgery, chemotherapy, and radiation. Radiation sources employed in these clinical trials will be x-ray generators which produce x-ray beams with a peak energy of 1 MEV or more or Cobalt irradiators. Patients with positive para-aortic nodes will receive a para-aortic dose of 4500 rads and an External pelvic dose of 5000 rads.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-36: CCG-193. Treatment of Previously Untreated Acute Lymphoblastic Leukemia for Pediatric Patients with Unfavorable Prognostic Features

Location: NH Portsmouth

Date: 1984-1985

Primary

Researchers: F. Ellwanger

Sponsors: NH Portsmouth; Children's Hospital; Of the King's Daughters (Children's Cancer Study Group)

Human

Subjects: 1 patient - special class of patients is children

Purpose: To improve outcome in the subset of children with ALL and unfavorable prognostic features utilizing a regimen derived from that of the Berlin-Frankfort-Munster Group. Radiation will include chest x-ray and wrist/hand x-ray. Radiation treatment is to be given with super voltage only, i.e., Co-60, four and six MeV linacs or higher photon energies. Photon energies above MeV are not recommended.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-37: GOG 64. A Randomized Comparison of Rapid vs. prolonged (24 hour) Infusion of Cisplatin in Therapy of Squamous Cell Carcinoma of the Cervix

Location: NH Portsmouth

Date: 1984-1986

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: no patients - special class of patients is females

Purpose: The first objective is to determine whether frequency and duration of objective response of squamous cell carcinoma of the cervix is altered significantly by prolonging to 24 hours the duration of the infusion of a dose of cisplatin as compared to administration at a rate of 1 milligram per minute. The second objective is to determine whether administration of a dose of cisplatin as a continuous 24 hour infusion alters the frequency and/or severity of drug-related nausea and vomiting, as compared to administration of the same dose at a rate of 1 milligram per minute. There is a chest x-ray prior to the study and one very 6-8 weeks with also a CT scan.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-38: GOG 42. Treatment of Recurrent of Advanced Uterine Saracen-A Randomized Comparison of Adriaycin vs. Adriamycin and Cyclophosphemide

Location: NH Portsmouth

Date: 1984-1986

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG(NCI)

Human

Subjects: 0 patients - special class of patients is female

Purpose: To determine if Adriamycin alone is more effective than Adriamycin and cyclophosphamide in producing responses in advanced or recurrent uterine sarcoma. A chest x-ray is given prior to the study.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-39: GOG 73. A Clinicopathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy

Location: NH Portsmouth

Date: 1985- Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine the relationship of histopathologic parameters (including microstaging of primary malignant melanoma of the vulva) to FIGO staging and ultimate prognosis. There will a chest x-ray prior to study and every three months if positive.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-40: GOG 261. A Phase II Trial of Tanoxifen in Patients with Advanced Epithelial Ovarian Carcinoma

Location: NH Portsmouth

Date: 1986-1987

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: Oncology protocol comparing different treatment modalities.

Category:

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-41: GOG 56. Ultrastructural Staging and Therapeutic Considerations in Small Cell Carcinoma of the Cervix. Phase II

Location: NH Portsmouth

Date: 1986- Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - *special class of patients is females*

Purpose: A study of patients with cancer of the cervix using drug treatment after radiation therapy

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-42: GOG 77. A Randomized Study of Carbonlatin vs. CHIP in Advanced Carcinoma of the Cervix

Location: NH Portsmouth

Date: 1986-1987

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine the response rate of cancer of the cervix to two drugs, Carboplatin and CHIP. To determine which of these drugs is superior. No mention of radiation is found in the report on hand.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-43: GOG 75. Postoperative Pelvic Radiation in Stage I and II Mixed Mesodermal Tumors of the Uterus. Phase II

Location: NH Portsmouth

Date: 1986-1991

Primary

Researchers: R. J. Stock

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is female

Purpose: Radiation treatment for cancer after surgery with a minimum dose rate of 40 rads/minute at 80 cm.

Category:

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-44: GOG 20W. A Phase II Trial of Echinomycin in Patients with Advanced Pelvic Malignancies

Location: NH Portsmouth

Date: 1987-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is female

Purpose: To determine the effectiveness of the drug Echinomycin on patients who have a malignant pelvic tumor which is not curable by surgery. Patients receive an initial chest x-ray and one every 4 weeks if it shows pulmonary metastases. A CT scan, sonic scan, bone scan, liver scan or other x-rays are optional and at the discretion of the investigator.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # ~~NHPTS-45~~: GOG 81A. Master Protocol for Hormonal Treatment of Advanced or Recurrent Carcinoma of the Endometrium

Location: NH Portsmouth

Date: 1987- Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is female

Purpose: To determine the effectiveness of an oral drug on advanced or recurrent endometrial carcinoma. Patients will have an x-ray, scan, or ultrasound to determine if they have a measurable disease of the abdominal, pelvic or other masses.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-46: GOG 78. Evaluation of Adjuvant 7P16. Bleomycin and Cisplatin Therapy in Totally Resected Choriocarcinoma. Endodermal Zinus Tumor. Embrvonat Carcinoma and Grade 3 Lanoture Teratoma of the Ovary. Pure and Mixed with Other Elements

Location: NH Portsmouth

Date: 1987-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is female

Purpose: To evaluate the effects of three drugs in chemotherapy in patients with cancer. Radiation treatment is mentioned in the study under background and rationale.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-47: GOG 82. A Phase III Trial Comparing Combination Chemotherapy with Whole Abdominal Radiation Therapy for Stage III Optimal Epithelial Ovarian Cancer with No Gross Residual Disease or Gross Residual Disease Less Than 1 cm.

Location: NH Portsmouth

Date: 1987-1987

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is female

Purpose: To compare survival and progression free interval of patients with epithelial ovarian cancer, treated either with adjuvant whole abdominal and pelvic irradiation or combination chemotherapy. Radiotherapy will be initiated within six weeks following surgery.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-48: GOG 71. Treatment of Patients with Suboptimal (Bulky) Stage 18 Carcinoma of the Cervix

Location: NH Portsmouth

Date: 1987-Present

Primary

Researchers: R. J. Stock

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is female

Purpose: Evaluation of the role of adjunctive extrafascial hysterectomy in the treatment of large volume carcinoma of the cervix. The study of toxicity of a combined radiation and surgical therapeutic program. There is radiotherapy for external and intracavitary. For the external irradiation, patients will receive 4000 RAD external beam therapy delivered homogeneously to the pelvis in 4-5 weeks. Intracavitary irradiation in two or one application. Patients will receive sufficient intracavitary treatment to raise point A doses to 8000 RAD.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-49: GOG 76D. A Phase II Trial of Dibromoducito in Patients with Advanced Squamous Cell Carcinoma of the Cervix

Location: NH Portsmouth

Date: 1987-1991

Primary

Researchers: R. J. Stock

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine identification of a new active drugs in combination of cytotoxic drugs to be formed which might lead to an improved complete remission rate of advanced or recurrent squamous cell carcinoma of the cervix. No radiation therapy is mentioned this report.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-50: GOG 90. Evaluation of Cisplatin. Etoposide and Bleomycin (BEP) Induction Followed by Vincristine. Dactinomycin and Cyclophosphamide (VAC). Consolidation in Advanced Ovarian Germ Cell Tumors

Location: NH Portsmouth

Date: 1987-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine the effectiveness of a set of drugs in chemotherapy in patients with advanced ovarian germ cell tumors. There is mention of chest x-rays , liver and bone scans and abdominal CT in pre-treatment. with more if any are abnormal.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-51: GOG 97. A Phase III Randomized Study of Cyclophosphamide and Cisplatin in Patients with Suboptimal Stage III and Stage IV Epithelial Ovarian Carcinoma Comparing Intensive and Bonintensive Schedules.

Location: NH Portsmouth

Date: 1987-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine the response rate, response duration and survival using a single treatment of two drugs with different schedules, one intense and the other standard on ovarian cancer. Prior to the study, the patient will have to have a CT scan and every 6 weeks when clinically indicated.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-52: GOG 81E. A Phase III Trial of High vs. Intermediate Dose Medroxyprogesterone Acetate (MPA) in Patients with Advanced or Recurrent Endometrial Carcinoma with Unknown Estrogen and Progesterone Levels

Location: NH Portsmouth

Date: 1987-1987

Primary

Researchers: M. R. Dudainski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: Number of subject not available - special class of patients is females

Purpose: To determine the relative effectiveness of two dose schedules of an oral drug in the management of advanced or recurrent endometrial carcinoma. There is no mention of radiation in this report.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-53: GOG 95. Randomized Clinical Trial for the Treatment of Women with Selected Stage IC and II (A, B, C) and Selected Stage Iai. IRi and IRii and IBii Ovarian Cancer

Location: NH Portsmouth

Date: 1987-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 1 patient - special class of patients is females

Purpose: To compare the progression-free interval and overall survival of two treatment regimens. To determine the patterns of relapse for each form of therapy. To define the relative toxicities of the tow treatment approaches. There is no mention of any radiation treatment.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-54: GOG 81C. A Phase I-II Trial of Medroxyprogesterous Acetate (MPA) in Patients with Advanced or Recurrent Endometrial Carcinoma Negative for Estrogen and Progesterone Receptors

Location: NH Portsmouth

Date: 1987-1987

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: Number of patients not available - special class of patients is females

Purpose: To determine the relative effectiveness of two dose schedules of an oral drug in the management of advanced or recurrent endometrial carcinoma. There is no mention of radiation in this report.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # ~~NHPTS-55~~: GOG 85. A Randomized Comparison of Hydroxyurea vs. 5FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stages IIB, III and IV Carcinoma of the Cervix and Negative para-aortic Nodes

Location: NH Portsmouth

Date: 1987-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine whether one drug or the combination of drugs is superior as a potentiator of radiation therapy in advanced cervical carcinoma. To determine the relative toxicities of one drug versus a combination of drugs when given concurrently with radiation therapy. External irradiation will use 4080 RAD external beam therapy delivered homogeneously to the pelvis in 24 fractions. Intracavitary Therapy will receive 4000 RAD to point 'A' by intracavitary implant with radium of its equivalent.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-56: GOG 86E. A Phase II Trial of Vincristine (TCR) Given as a Weekly Intravenous Bolus in Advanced or Recurrent Carcinoma

Location: NH Portsmouth

Date: 1987-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: This study seeks to identify additional active agents by studying single new drugs in patients with advanced or recurrent endometrial carcinoma not previously exposed to chemotherapy. Each patient will have a chest x-ray prior to the study and every 4 weeks if the patients has pulmonary lesions.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-57: GOG 76F. A Phase II Trial of Gallium Nitrate in Patients with Advanced Squamous Cell Carcinoma of the Cervix

Location: NH Portsmouth

Date: 1988-1988

Primary

Researchers: M. R. Dudzinski

Sponsors: none listed

Human

Subjects: Number of patients not available - special class of patients is females

Purpose: To determine if new cytotoxic drugs or other chemotherapeutic agents can be formed which might lead to and improved complete remission rate in advanced or recurrent squamous cell carcinomas of the cervix

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-58: GOG 101. A Phase II Evaluation of Pre-operative Chemoradiation for Advanced Vulvar Cancer

Location: NH Portsmouth

Date: 1987-1989

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: Number of patients not available - special class of patients is females

Purpose: To determine the feasibility of using preoperative chemoradiotherapy to obviate the need for pelvic exenteration for patients with advanced vulvar cancer involving the proximal urethra, ladder, anal canal or rectum. Radiation: External beam therapy will be delivered to the primary tumor to a total dose of 4560 RAD

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

**Study # NHPTS-59 Effect of Radiation Therapy on Serum Angiotensia
Converting Enzyme Levels in Patients with Bronchogenic Carcinoma**

Location: NH Portsmouth

Date: 1988-1990

Primary

Researchers: A. Lazarus

Sponsors: NH Portsmouth

Human

Subjects: 3 patients - no special class of patients

Purpose: To determine if radiation treatments to the lungs of patients with no-small cell bronchogenic carcinoma causes a change in the serum angiotensin converting enzyme level. Patients in the study group will receive therapy as determined by the radiation oncologist with doses of 4000 to 4500 rads and tumor dose fractions of 70 to 76.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-60: Diagnosis of Sarcoidosis: Correlation of Gallium-07 Scanning. Minor Salivary Biopsy. Parotid Gland Biopsy and Trans-bronchial lung Biopsy

Location: NH Portsmouth

Date: 1988-1990

Primary

Researchers: J. F. Wilson

Sponsors: NH Portsmouth

Human

Subjects: Number of patients not available - no special class of patients

Purpose: To compare Gallium-67 scanning, minor salivary gland biopsies, parotid gland biopsies and ACE levels. Patients will be evaluated by a number of tests including chest x-ray

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-61: Lateral Tonograms of the Scaphoid

Location: NH Portsmouth

Date: 1988-1989

Primary

Researchers: *D. L. Engdahl*

Sponsors: NH Portsmouth

Human

Subjects: 10 patients - no special class of patients

Purpose: This is a descriptive study. The only experimental part of this study is the prospective collection of data. This study involves no risk to the patient.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-62: Utility of Endoscopy for X-ray Negative Dysphagia: A Prospective Analysis

Location: NH Portsmouth

Date: 1988-1991

Primary

Researchers: J. M. Lawson

Sponsors: NH Portsmouth

Human

Subjects: 44 patients - no special class of patients

Purpose: To evaluate the need for endoscopy and manometry in patients with x-ray negative dysphagia. Patients with a history of dysphagia and a negative barium swallow (excluding radiographic reflux, hiatal hernias or tertiary contractions as positive findings) are requirements for enrollment.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

**Study # NHPTS-63: Spontaneous Pneumothorax: Treatment Using
Standard Tube Thoracostomy vs. Cook Catheter with a Ueimlich Valve**

Location: NH Portsmouth

Date: 1990-Present

Primary

Researchers: D. Cruff

Sponsors: NH Portsmouth

Human

Subjects: 18 patients - no special class of patients

Purpose: To compare the use of standard tube thoracostomy with suction to small tube thoracostomy using a one way flutter valve in the treatment of a first episode of an idiopathic spontaneous pneumothorax. There will be daily x-rays to help confirm tube placement

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-64: GOG 8901. A Phase I Evaluation of Multiple Daily Fraction Radiation and 5-Fluorouracil Plus Cisplatin in Stage IIB. III and IVA Carcinoma of the Cervix with Negative Par-aortic Nodes

Location: NH Portsmouth

Date: 1991 Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 4 patients - special class of patients is females

Purpose: To determine the toxicity of accelerated hyperfractionated radiation with two drugs in patients with cancer of the cervix. Patients will have a chest x-ray and an abdominopelvic CT scan. Radiation therapy will be started within 6 weeks of surgery. Patients will receive 120 rad b.i.d. Following the completion of external beam therapy, patients will receive 3500 rad by intracavitary therapy using radium or cesium.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-65: GOG 8801. A Phase I Evaluation of Multiple Daily Fraction Radiation and Hydroxyurea in Patients with Stage IIB. III and IVA Carcinoma of the Cervix with Negative Para-aortic Nodes

Location: NH Portsmouth

Date: 1991-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 1 subject - special class of patients is females

Purpose: To determine the toxicity of accelerated hyperfractionated radiation plus hydroxyurea in patients with cancer of the cervix. To determine the optimal tolerated dose of hyperfractionated radiation when combined with hydroxyurea and intracavitary radiation. Radiation therapy will be started within 6 weeks of surgery. Patients will receive 120 rad b.i.d. Following the completion of external beam therapy, patients will receive 3500 rad by intracavitary therapy using radium or cesium.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-66: GOG 99. A Phase III Randomized Study of Surgery Vs. Surgery Plus Adjunctive Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma

Location: NH Portsmouth

Date: 1991-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 3 patients - special class of patients is females

Purpose: To determine if patients with intermediate risk endometrial adenocarcinoma who have no spread of disease to their lymph nodes, benefit from postoperative pelvic radiotherapy. To evaluate how the addition of pelvic radiotherapy will alter the site and rate of cancer recurrence in these intermediate risk patients. A daily tumor dose of 180 rad perday will be given to a total dose of 5040 rad in approximately 6 weeks

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-67: GOG 94. A Phase II Study of the Treatment of Stage II and IT Disease of Advanced Endometrial Carcinoma and All Stages of Papillary Serous Carcinoma and Clear Cell Carcinoma of the Endometrium with Total Abdominal Radiation Therapy

Location: NH Portsmouth

Date: 1991-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine the survival and progression free interval of patients with maximally debulked advanced endometrial carcinoma treated with abdominal radiation therapy. Radiotherapy will be initiated within eight weeks after surgery when the patient has recovered. Dose rates between 30 and 200 rad per minute at the midplane of the patient may be used. The whole abdomen is to irradiated with opposed fields to a total dose of 3000 rad in 20 fractions of 150 rad each

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-68: GOG 125. Extended Field Radiation Therapy with Concomitant 5FU Infusion and Cisplatin Chemotherapy in Patients with Cervical Carcinoma Metastatic Para-Aortic Lymph Nodes

Location: NH Portsmouth

Date: 1992- Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 1 subject - special class of patients is females

Purpose: Patients with uterine cervical carcinoma who have biopsy confirmed para-aortic lymph node metastases will receive combination chemotherapy consisting of cisplatin and 5-FU intravenous infusion concomitantly with pelvic and para-aortic extended field radiation therapy. Two regions will receive 150 rad per fraction, one fraction per day. The para-aortic region will receive 150 rad per fraction to a cumulative dose of 4500 rad.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # ~~NHPTS-69~~: GOG 120. A Randomized Comparison of Hydroxyurea Vs. Hydroxyurea. 5FU Infusion and Bolus Cisplatin Vs. Weekly Cisplatin Adjunct to Radiation Therapy in Patients with Stages IIB, III, IVA Carcinoma of the Cervix and Negative Para-aortic Nodes.

Location: NH Portsmouth

Date: 1992-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 1 subject - special class for patients is females

Purpose: To determine whether a number of drugs is superior as a potentiator of radiation therapy in locally advanced cervical carcinoma. To determine the relative toxicities of drugs given concurrently with radiation therapy. Patients will have a chest x-ray prior to therapy. External radiation of stage II-B patients will be 4080 rad in 24 fractions of 170 rad. Intracavitary therapy patients will receive 4000 rad in one or two applications. External radiation for the rest of the patients will be 5100 rad in 30 fractions of 170 rad. Intracavitary therapy patients will receive 6120 rad in one or two applications

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-70: Treatment of Chronic Osteomyelitis with Hyperbaric Oxygenation

Location: NH Portsmouth

Date: 11/76-3/78

Primary

Researchers: LCDR S. Pledger

Sponsors: NH Portsmouth

Human

Subjects: 3 patients - special class of patients is adults

Purpose: To test the results of treatment of chronic osteomyelitis (inflammation of the bone) with hyperbaric oxygen and concurrent parenteral antibiotics in a treatment series of patients. The patients would receive weekly x-rays of the infected bones to look for any reductions in the inflammation.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-71: Chemolumnotherapy of Carcinoma of the Lung Using High Dose Methotrexate and BCG

Location: NH Portsmouth

Date: 6/77-3/78

Primary

Researchers: J. W. Reid

Sponsors: NH Portsmouth

Human

Subjects: 4 patients - special class of patients is adults

Purpose: To test the effectiveness of methotrexate in the treatment of lung cancer. Methotrexate serum levels will be assayed by the I-125 MIA technique. In addition to this the patient would receive a chest x-ray.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-72: Thallium Chloride for Myocardial Imaging

Location: NH Portsmouth

Date: 1977-1978

Primary

Researchers: CAPT. J. Russotto

Sponsors: NH Portsmouth

Human

Subjects: 0 patients - special class of patients is adults

Purpose: To test the effectiveness of Thallium chloride (TI-201) in its imaging abilities to identify and study ischemic heart disease. Thallium was found to be a safe approach to detect changes in myocardial blood flow. The dosage of TI-201 that was administered was 1.5 millicurie.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

**Study # NHPTS-73: Cardiovascular Dynamics of Toxemia of Pregnancy.
Effects of Magnesium Sulfate Therapy and Epidural Anesthesia**

Location: NH Portsmouth

Date: 11/79-1/81

Primary

Researchers: LCDR D Yurth

Sponsors: NH Portsmouth

Human

Subjects: 10 patients - special class of patients is females

Purpose: To look at 10 severely preeclamptic women who had arterial and Swan-Ganz catheter in place to evaluate for congestive heart failure (CHF). There was no mention in this study of radiation exposure, so one can assume that x-rays were taken to observe the placement of the Swan-Ganz catheter into the heart.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-74: Urinary Tract Evaluation of DES Exposed Progeny

Location: NH Portsmouth

Date: 7/79-5/83

Primary

Researchers: D. Gallup

Sponsors: NH Portsmouth

Human

Subjects: 52 patients - special class of patients is females

Purpose: To determine the side effects that diethylstilbestrol (DES) would have on the urinary tract of DES exposed women during their pregnancy. To help determine the effects that DES actually had on the woman and her offspring. An intravenous pyelogram (IVP) was conducted to detect any urinary tract anomalies

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-75: The Use of Electrosapinal Instrumentation in Idiopathic Scoliosis

Location: NH Portsmouth

Date: 06/82-04/84

Primary

Researchers: LCDR W. Johnson

Sponsors: NH Portsmouth; Medtronic

Human

Subjects: 3 patients - special class of patients is minors

Purpose: To evaluate the effectiveness and reliability of electrosapinal intrustmentation in the treatment of scoliosis. This was accomplished through the implantation of muscle stimulators to help correct he curvature of the spine. There is no mention of radiation exposure in this study but one can assume that it was incidental to x-ray examination of spinal column.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study #NHPTS-76: Computerized Axial Tomography versus Complex Motion Tomography as a Predictor of Surgical Finding to Middle Ear and Mastoid Cholesteotoma

Location: NH Portsmouth

Date: 09/82-08/85

Primary

Researchers: LCDR D. Lewis

Sponsors: NH Portsmouth

Human

Subjects: 58 patients - special class of patients is adults

Purpose: The purpose of this study was to determine the effectiveness of Computerized Axial Tomography (C/T scan) in the diagnosis of inner ear infection. The patient would receive an exposure 0.1 - 0.2 rads to the lens of the eye. From the older diagnostic procedures the patient would have been subjected to 2.1 rads.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-77: GOG 260. A Phase II Trial of Aminothiadiazols in Patients...

Location: NH Portsmouth

Date: 1986- 1991

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - no special class of patients

Purpose: To determine the effectiveness of chemotherapeutic agents in the treatment of recurrent pelvic malignancies. The patient would receive a chest x-ray before the study. If clinically warranted, the patient would receive an additional CT scan and a bone scan if warranted.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-78: Radiation Esophagitis

Location: NH Portsmouth

Date: 1987-1990

Primary

Researchers: E. L. Cattau

Sponsors: NH Portsmouth

Human

Subjects: 0 patients - no special class of patients

Purpose: To determine the minimal and maximum radiation tolerance dose to the esophagus. Patients consenting to the esophageal manometry would be studied prior to the radiation therapy after 2000 rads, 4000 rads and 6000 rads. Any patient that developed esophageal symptoms would be studied at the onset of the symptoms and after the symptoms resolved. If impairment of esophageal function is demonstrated, two drugs would be given to determine the mechanism of impairment (Tensilon and Urecholine).

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

**Study # NHPTS-79: GOG 80. Cytoreductive Surgery and PAC
Chemotherapy...**

Location: NH Portsmouth

Date: 1987-1987

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine the effectiveness of chemotherapy and cytoreductive surgery in the treatment of ovarian cancer. Prior to the study, the patient would receive a routine chest x-ray, IVP, and an abdominal CAT scan.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-80: GOG 79. Single Agent Weekly Methotrexate Therapy in the Treatment...

Location: NH Portsmouth

Date: 1987

Primary

Researchers: R. J. Stock

Sponsors: NH Portsmouth; GOG (NCI)

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine the efficacy of weekly methotrexate therapy in the treatment of gestational trophoblastic disease. Prior to the study, the patient would receive a routine chest x-ray and a liver and brain CAT scan.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-81: C-Reactive Levels in Asthma

Location: NH Portsmouth

Date: 1990-1992

Primary

Researchers: M. Duvall

Sponsors: NH Portsmouth

Human

Subjects: 17 patients - special class of patients is adults

Purpose: To determine if C-Reactive Protein (CRP) levels are elevated in patients with asthma. The patients underwent a standard evaluation test for asthma which included a chest x-ray.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # NHPTS-82: GOG 70. A Randomized Comparison of Single Agent Methotrexate and Methotrexate...

Location: NH Portsmouth

Date: 10/92-11/92

Primary

Researchers: H. Wolcott

Sponsors: NH Portsmouth; GOG

Human

Subjects: 0 patients - special class of patients is females

Purpose: To treat an abnormal growth of the placental tissue which had originated from the uterus using two a drug regimens in chemotherapy. Prior to treatment, the patients will receive a chest x-ray

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

**Study # NHPTS-83: GOG 77. A Randomized Study of Carboplatia
(GDBCA-MSK 241240) versus CHIP...**

Location: NH Portsmouth

Date: 07/84-10/87

Primary

Researchers: H. Wolcott

Sponsors: NH Portsmouth; GOG

Human

Subjects: 0 patients; special class of patients is females

Purpose:

Category:

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-84: GOG 89. A Randomized Comparison of Intravenous Cyclophosphamide. Dororubicin

Location: NH Portsmouth

Date: 06/87-10/87

Primary

Researchers: M. R. Dudzinski

Sponsors: NH Portsmouth; GOG

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine if intraperitoneal-treatment into the abdomen or intravenous-treatment into the vein is the most effective way of administering the chemotherapy drugs with fewest complications. No mention of radiation therapy in this study.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-85: High Resolution CT in the Evaluation of Hemoptysis

Location: NH Portsmouth

Date: 10/91-Present

Primary

Researchers: K. O'Neil

Sponsors: NH Portsmouth

Human

Subjects: 3 patients - special class of patients is adults

Purpose: To determine whether using a high resolution CT scan is better than bronchoscopy in evaluating the source of bleeding in patients with hemoptysis. The two will be compared side by side.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-86: GOG 92. Treatment of Selected Patients with Stage IB...

Location: NH Portsmouth

Date: 12/87-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG

Human

Subjects: 1 patient - special class of patients is females

Purpose: To determine the value of adjunctive pelvic radiation in the treatment of stage 1B carcinoma of the cervix. To determine the morbidity of adjunctive pelvic radiation following radical hysterectomy. Pretreatment includes chest x-ray and CT scan with contrast. Patients receiving whole pelvic irradiation will receive therapy within a range spreading from 46 Gy in 23 fractions of 2 Gy daily to 50.40 Gy in 28 fractions of 1.8 Gy daily.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-87: GOG 109. A Randomized Comparison of 5FU Infusion and Bolus Cisplatin...

Location: NH Portsmouth

Date: 07/93-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG

Human

Subjects: 0 patients - special class of patients is females

Purpose: To determine whether a combination of 5-FU infusion and Bolus Cisplatin used as an adjunct to radiation therapy would help improve the survival rate and decrease extra pelvic failure compared to radiation therapy alone in patients with positive pelvic lymph nodes and or carcinoma of the cervix. Radiation therapy must be started with six weeks after surgery. Patients will receive 5,100 cGy delivered homogeneously to the pelvis in 30 fractions of 170 cGy daily. Patients will be given daily treatments of 5 fractions per week. The radiation source employed was an z-ray beam with a photon energy of 4 MeVs or more. All the patients that were involved in this study will be followed until their death.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

UNABLE TO LOCATE REPORT

Study # NHPTS-88: **GOG 117. Adjuvant Ifosfamide (NSC *109724) and Mesna...**

Location: NH Portsmouth

Date: 07/93-Present

Primary

Researchers: S. Remmenga

Sponsors: NH Portsmouth; GOG

Human

Subjects: 0 patients - special class of patients is females

Purpose:

Category:

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-89: Thyroid Dysfunction Following Therapy for the Head and Neck

Location: NH Portsmouth

Date: 07/88-Present

**Primary
Researchers:** P. Gomez

Sponsors: NH Portsmouth

**Human
Subjects:** 100 patients - special class of patients is adults

Purpose:

Category:

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-90: The Effect of the Addition of Electrical Stimulation...

Location: NH Portsmouth

Date: 05/90-2/92

Primary

Researchers: G. Amuadson

Sponsors: NH Portsmouth

Human

Subjects: 7 patients - special class of patients is adults

Purpose: To examine lumbar fusion rates in patients treated not only by standard debridement by also with addition of electrical stimulation. There is no mention of radiation exposure in this study, so one can assume that it was incidental to x-ray examination of the spinal column and or other long bones.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-91: Supine Cephalometrics in Obstructive Sleep Apnea

Location: NH Portsmouth

Date: 05/90-11/91

Primary

Researchers: S. Freeman

Sponsors: NH Portsmouth

Human

Subjects: 0 patients - special class of patients is adults

Purpose: To develop a simple evaluation of snoring and obstructive sleep apnea, (OSA). The surgical treatment that was used widely up to this point was the surgical removal of the tonsils and a portion of the soft palate and uvula. In this procedure the patient would have his neck x-rayed while he is awake and once again while he is asleep in order to determine the exact surgical location

Category: Other

Records: NH Portsmouth

Classification: Unclassified

Study # NHPTS-92: Effect of Race in Responsiveness to Atrial Natriuretic Peptide...

Location: NH Portsmouth

Date: 09/90-06/93

Primary

Researchers: P. Chidester

Sponsors: NH Portsmouth

Human

Subjects: 28 patients - special class of patients is males

Purpose: To assess potential differences in renal responsiveness to infused atrial natriuretic peptide, the natriuretic portion of the endogenous atrial molecule. In short this was a test to examine the effect of race, blood pressure and sodium intake on hypertension. The renal plasma flow was assessed via the subcutaneous injection of I-125 (15 microcurie) and I-131 (15 microcurie) and then was assessed in the urine and blood samples would be taken.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

**Study # NHPTS-93: ECOG *2580. Phase II Master Protocol for the
Evaluation of New Agents in...**

Location: NH Portsmouth

Date: 08/81-05/83

Primary

Researchers: C. Caldwell

Sponsors: NH Portsmouth

Human

Subjects: 0 patients - special class of patients is adults

Purpose: The purpose of this study was to test the effectiveness of Corticosteroids in treating tumors. To test the effectiveness of the drug on tumor reduction x-rays were taken.

Category: Other

Records: NH Portsmouth

Classification: Unclassified

#

Study # -NHGL-01: "Correlation of Exercise Tolerance Testing and Coronary Angiography."

Location: Unknown

Date: 1982

Primary

Researchers: unknown

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: *unknown*

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-02: "Diagnostic Accuracy of Fiber Optic Duodenoscopy in Upper Gastrointestinal."

Location: unknown

Date: unknown

Primary

Researchers: unknown

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: *Unclassified*

#

Study # NHGL-03: "Bedside Study of CVP and Wedge Pressure in Acute Myocardial Infarction."

Location: unknown

Date: unknown

Primary

Researchers: unknown

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

Study # NHGL-04: "Evaluation of Time-Saving Potential of Persistence Scope."

Location: unknown

Date: unknown

Primary

Researchers: unknown

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records:

Classification: Unclassified

Study # NHGL-05: "To Evaluate Percutaneous Cervical Cordotomy in the Management of Pain."

Location: unknown

Date: unknown

Primary

Researchers: unknown

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-06: "A Study of the Oral Cavity During
Hyperalimentation."**

Location: unknown

Date: unknown

Primary

Researchers: unknown

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-07: "Evaluation of the Oral Surgery Patient for I.V. Sedation."

Location: unknown

Date: unknown

**Primary
Researchers:** unknown

Sponsors: unknown

**Human
Subjects:** unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-08: "Evaluation of Oral Surgery Implants."

Location: unknown

Date: unknown

Primary

Researchers: unknown

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

Study #-NHGL-09:

"VA Cooperative Bowel Prep Study."

Location: unknown

Date: unknown

Primary

Researchers: unknown

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-10: "Evaluation of Long-Term Maintenance Therapy for Patients in Complete Remission From Metastatic Breast Carcinoma."

Location: Naval Hospital Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To define the activity of new agents in the treatment of advanced head and neck cancer in patients. Patients with squamous cancer of the head and neck were assigned at random to be treated with one of two agents.

Category: Therapeutic research involving radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-11: "Adjuvant Therapy With Tamoxifen Vs. Placebo in Older Post Menopausal Patients With Stage II Breast Cancer."

Location:

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To assess the effectiveness of adjuvant hormonal therapy with Tamoxifen in patients age >65 with Stage II breast cancer.

Category: Treatment use of radiation.

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-12: "Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Assess the impact of short term intensive chemotherapy with Prednisone to prevent disease recurrence and prolong survival in breast cancer patients.

Category: Treatment use of radiation.

Records: Great Lakes

Classification: Unclassified

#

Study # -NHGL-13: "Phase II Master Protocol for the Evaluation of New Treatment in Patients With Advanced Soft Tissue Sarcomas, Bone Sarcomas and Mesothelioma."

Location: Lemuel Shattuck Hospital

Date: 1982

Primary

Researchers: Dr. Ezdinli, Dr. Rosenbaum

Sponsors: ECOG

Human

Subjects: 33

Purpose: To assess the effects of Bruceantin in treating advanced soft tissue sarcomas, bone sarcomas and mesothelioma.

Category: Treatment use of radiation.

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-14: "Radiotherapy With and Without Chemo-Therapy for Malignant Pleural Mesothelioma Localized to One Hemithoraxan Intergroup Study."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To evaluate the efficacy of Adriamycin in improving the disease progression-free interval in patients who have received hemithoracic radiotherapy for Stage I pleural mesothelioma.

Category: Treatment use of radiation.

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-15: "Phase III Treatment of Advanced Malignant Mesothelioma: A Comparison of CIA Vs. CA Intergroup II."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To combine Cyclophosphamide and Adriamycin and compare it to Cyclophosphamide, Dacarbazine and Adriamycin in a prospective fashion in order to assess the contribution, if any to Dacarbazine in patients with mesothelioma.

Category: Treatment use of radiation.

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-16: "Chemotherapy of Adrenal Cortical Carcinoma."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To measure response rates to "moderate dose" Mitotane in patients with well differentiated and/or functioning adrenal cortical carcinomas.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-17: "Combination Chemotherapy or Chemo-Hormonotherapy of Recurrent or Metastatic Breast Cancer in Premenopausal Women."

Location: Great Lakes

Date: 1982

**Primary
Researchers:** Dr. Ezdinli

Sponsors: ECOG

**Human
Subjects:** Unknown

Purpose: Women with metastatic breast cancer who have had no prior chemotherapy for their metastatic disease are to be treated with DAVTH. After six months of treatment, the therapy will be randomized to one of two treatments or observation only.

Category: Treatment use of radiation.

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-18: "Phase III Combination Chemotherapy of Metastatic Breast Cancer Followed by Maintenance or No Maintenance Therapy and Evaluation of DAVTH as Induction Regimen."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To evaluate various combination therapy in the treatment of metastatic breast cancer.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-19: "Phase II-III Evaluation of Combination of Methyl CCNU, Mitomycin-C, Adriamycin and 5-Fluorouracil in Advanced Measurable Gastric Cancer."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To evaluate various combinations of drugs in the treatment of advanced measurable gastric cancer, and determine if any of those combinations are more effective and less toxic than the standard, 5-FU + MeCCNU seven week regimen used previously.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-20: "Phase II Master Protocol for the Evaluation of New Agents in Patients With Esophageal Carcinoma."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To screen new agents or drug combinations for activity in patients with inoperable advanced measurable esophageal squamous cell carcinoma.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-21: "Phase III Comparative of Soft Tissue Sarcomas."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluation of various treatments for soft tissue sarcomas in patients at high risk of recurrence.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-22: "Adjuvant Chemotherapy of Soft Tissue Sarcomas."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluation of adjuvant chemotherapy following primary therapy of soft tissue sarcomas in patients at high risk of recurrence, with survival as the ultimate parameter of success.

Category: Treatment use of radiation.

Records: Great Lakes

Classification: Unclassified

#

Study # -NHGL-23: "Phase II Study of New Agents in Treatment of Advanced Cancer of the Head and Neck."

Location: Great Lakes

Date: 1982

**Primary
Researchers:** Dr. Ezdinli

Sponsors: ECOG

**Human
Subjects:** Unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

Study # -NHGL-24: "Phase III Multiple Myeloma: Evaluation of Combination Chemotherapy in Previously Untreated Patients."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate two regimens, compare the results in terms of response rates, duration of response, toxicity and survival rates in previously untreated patients.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-25: "Protocol for the Treatment of Lympho-Blastic Lymphoma in Adults."

Location: *Great Lakes*

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate the effectiveness of an aggressive multi drug regimen with CNS prophylaxis in the treatment of lymphoblastic lymphoma with respect to objective response rate, duration of response, toxicity, and survival.

Category: Treatment use of radiation

Records: *Great Lakes*

Classification: Unclassified

#

Study # NHGL-26: "Patients With Advanced Hodgkin's Disease Who Have Relapsed."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate Bleo-CCVPP as induction treatment for Hodgkin's Disease relapsing after prior radiation therapy with respect to: complete response rate, duration of complete response, survival, and toxicity.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-27: "Phase II Master Protocol for the Evaluation of New Treatment in Patients With Malignant Melanoma."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To screen new chemotherapeutic agents for activity in patients with metastatic malignant melanoma.

Category: Treatment use of Radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-28: "Phase II Study of Chemotherapy of Advanced Ovarian Cancer Using Low of High Dose Cisdiamminedi-Chlorplantinum."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To determine whether doubling the dose of cis-Diamminedichloroplatinum in the combination chemotherapy of advanced ovarian cancer resistant to alkylating agent treatment leads to an increased response rate, more complete remissions, longer responses, and improved survival.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-29: "Phase II Master Protocol for the Evaluation of New Treatment in Patients With Endometrial Cancer."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Identify new agents with cytotoxic activity in advanced endometrial cancer for use later in Phase III trials.

Category: Treatment use of radiation.

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-30: "A Phase II Study of Disseminated Transitional Cell Carcinoma of the Urinary Tract."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: To determine the activity of new drugs in advanced transitional cell cancer of the urinary tract, and to determine duration of response and survival in patients given these new drugs.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-31: "The Management of Resectable Locally Advanced Primary Breast Cancer."

Location: Great Lakes

Date: 1982

**Primary
Researchers:** Dr. Ezdinli

Sponsors: ECOG

**Human
Subjects:** Unknown

Purpose: To evaluate several therapies to induce longer lasting remissions for patients with resectable locally advanced primary breast cancer.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-32: "Studies in Chemotherapy of Islet Cell Carcinoma."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate different drug therapies in the treatment of metastatic islet cell carcinoma.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-33: "Phase II and III Chemotherapy of Advanced Soft Tissue Sarcomas, Bone Sarcomas and Mesothelioma."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Compare the effectiveness of various induction regimens for soft tissue sarcomas, bony sarcomas and mesotheliomas.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-34: "The Treatment of Acute Non-Lymphocytic Leukemia in the Elderly Full Dose Versus Attenuated Dose."

Location: *Great Lakes*

Date: 1982

**Primary
Researchers:** Dr. Ezdinli

Sponsors: ECOG

**Human
Subjects:** Unknown

Purpose: Evaluate full dose versus attenuated dose chemotherapy to achieve marrow aplasia or minimize morbidity.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # -NHGL-35: "Localized Radiotherapy Vs. Localized Radiotherapy and Chemotherapy Vs. Localized Radiotherapy and Half-Body Thorax."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-36: "Phase II Master Protocol for the Evaluation of New Agents in the Treatment of Non Small Bronchogenic Carcinoma."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate new chemotherapeutic agents for activity in patients having advanced non-small cell bronchogenic carcinoma

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-37: "Testicular Cancer Intergroup Study."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate the treatment of surgery alone versus surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular carcinoma.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-38: "Surgical Adjuvant Protocol for Resectable Rectal Carcinoma Modified Duke's B, C1, and CS."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate effects of different therapies in the treatment of resectable rectal carcinoma.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-39: "Phase III Protocol for the Treatment of Favorable Non-Hodgkin's Lymphomas."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Compare various therapies in the treatment of non-Hodgkin's lymphomas and to determine whether there are overall differences in overall survival and remission duration.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-40: "Multiple Myeloma: Timed Sequential High Dose Cyclophosphamide and Vincristine in the Treatment of Multiple Myeloma."

Location: Great Lakes

Date: 1982

**Primary
Researchers:** Dr. Ezdinli

Sponsors: ECOG

**Human
Subjects:** Unknown

Purpose: Evaluate various aspects of treatment including objective and subjective response rates, duration of remission, and survival rates.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-41: "Phase II Master Protocol for the Evaluation of New Agents on Patients With Small Cell Bronchogenic Carcinoma."

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Screen for activity of new agents in patients having advanced small cell bronchogenic carcinoma resistant to treatment with standard agents.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-42: "Phase III Adjuvant Clinical Trial to Compare CMFPT to Alternating CMF(P)TH and TSAVBTH and Short-Versus Long Term Tamoxifen in Premenopausal Patients With Operable N+ Breast Cancer."

Location: Great Lakes

Date: 1982

**Primary
Researchers:** Dr. Ezdinli

Sponsors: ECOG

**Human
Subjects:** 23

Purpose: Evaluate introduction of a non-cross resistant Adriamycin containing regimen in an alternating sequence with CMF(P)TH versus CMFPT alone. Additionally, to evaluate the effects of providing exposure to an antiestrogen for prolonged periods versus discontinuation of its use at the termination of chemotherapy.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-43: "Phase III Comparative Evaluation of Three Intensive Induction Chemotherapy Regimens and Controlled Evaluation of Adjuvant Radiotherapy Consolidation for Unfavorable (Diffuse) Histologic Subtypes of Non-Hodgkin's Lymphoma"

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate three therapies (a four drug regimen, a five drug regimen, and a six drug regimen) in the treatment of unfavorable malignant lymphomas.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study #NHGL- 44: "Phase III Chemohormonal Therapy of Previously Treated Metastatic Breast Cancer in Patients with No Prior Exposure to Adriamycin or Tamoxifen"

Location: Great Lakes

Date: 1982

**Primary
Researchers:** Dr. Ezdinli

Sponsors: ECOG

**Human
Subjects:** Unknown

Purpose: Evaluate the rates and durations of responses to DAVCH and TSAVBH in previously treated women with recurrent, residual or metastatic carcinoma of the breast.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study #NHGL -45: "Phase III Combination Chemotherapy of Advanced Breast Cancer for Women Who Have Received Prior Tamoxifen, but No Prior Adriamycin"

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Evaluate combination therapy in women with carcinoma of the breast.

Category: Treatment use of radiation

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-46: "Phase III Comparison of Cyclophosphamide, Adriamycin, Vincristine, to an Alternating Sequence of CAV and Intensive Hexamethylmelamine, Etoposide (VP-16), Methotrexate Following by a Comparison of Maintenance Vs. No-Maintenance"

Location: Great Lakes

Date: 1982

Primary

Researchers: Dr. Ezdinli

Sponsors: ECOG

Human

Subjects: Unknown

Purpose: Unknown (no abstract available)

Category: Unknown

Records: Great Lakes

Classification: Unclassified

#

Study # -NHGL-47: "Phase II Master Protocol for the Evaluation of New Agents in the Treatment of Breast Cancer"

Location: unknown

Date: unknown

Primary

Researchers: *unknown*

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: unknown

Classification: Unclassified

#

Study # NHGL-48: "ECOG 7181. Phase III Chemohormonal Therapy of Previously Treated Metastatic Breast Cancer in Patients with No Prior Exposure to Adriany or Tanoxifen: A Comparative Evaluation of DATB vs D(DATH) TH."

Location: Great Lakes

Date: 1984

Primary

Researchers: W. S. Suseno

Sponsors: ECOG

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # -NHGL-49: EST 1177. Evaluation of Long-Term Maintenance
Therapy for Patients in Complete Remission Iron Metastatic Breast
Carcinoma**

Location: Great Lakes

Date: 1977-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

Study # -NHGL-50: EST 1878. A Comparative Phase III Trial of cis-Diaminedichloroplatinum vs Adriamycin. Cyclophosphamide.. and cis-Diaminedichloroplatinum and A Phase II Study of TM-26 in Disseminated Transition Cell Carcinoma of the Urinary Tract

Location: Great Lakes

Date: 1978-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: unknown

Classification: Unclassified

#

Study # -NHGL-51: EST 1291. Phase II-III Studies of Adriamycin and 5FU vs. Streptozotocin + 5FU in the Treatment of Carcinoid Tumor

Location: Great Lakes

Date: 1981-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-52: EST 1390. Radiotherapy With and Without
Chemotherapy for Malignant Pleural Mesothelioma Localized to one
Hemithorax - An Intergroup Study**

Location: Great Lakes

Date: 1981-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-53: EST 1480. Phase II Master Protocol for the Evaluation
of New Agents and Combinations in Patients with Lymphoma**

Location: Great Lakes

Date: 1980-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # -NHGL-54: EST 1481. Combination Chemotherapy and Radiotherapy
for Advanced Hodgkin's Disease**

Location: Great Lakes

Date: 1981-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-55: EST 1580. Phase III Combination Chemotherapy With of
Without Consolidation Radiation Therapy for Localized Small Cell
Carcinoma of the Lung**

Location: Great Lakes

Date: 1977-1984

**Primary
Researchers:** Suseno

Sponsors: ECOG, NCI

**Human
Subjects:** Unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # -NHGL-56: EST 2177. Combination Chemotherapy or
Chemohormonotherapy of Recurrent of Metastatic Breast Cancer in Pre-
menopausal Women: Oophorectomy Plus CAF vs CAF Without
Oophorectomy**

Location: Great Lakes

Date: 1977-1983

Primary

Researchers: Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # -NHGL-57: EST 2278. Phase II Master Protocol for the Evaluation of
New Agents in Patients with Esophageal Carcinoma**

Location: Great Lakes

Date: 1977-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-58: EST 2279. Phase II-III Master Protocol for Treatment of
Advanced Pancreatic Adenocarcinoma PALA vs Streptozotocin + ADE
ADR + MeCCMD (SAM)**

Location: Great Lakes

Date: 1977-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-59: EST 2377. Adjuvant Chemotherapy of Soft Tissue
Sarcomas**

Location: Great Lakes

Date: 1978-1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study# NHGL-60: EST 2481. A Protocol for the Treatment of Lymphoblastic
Lymphoma in Adults**

Location: Great Lakes

Date: 1982

Primary

Researchers: Ezdinli, Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-61: ECOG 4176. Surgical Adjuvant Protocol for Resectable
Rectal Carcinoma**

Location: Great Lakes

Date: 1982

Primary

Researchers: Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-62: ECOG EST 4477. Phase III Combined Modality
Treatment Protocol for Stages III and IV Favorable (Modular) Histologic
Subtypes of Non-Hodgkin's Lymphoma**

Location: Great Lakes

Date: 1982

**Primary
Researchers:** Suseno

Sponsors: ECOG, NCI

**Human
Subjects:** unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study # NHGL-63: ECOG 4591. Phase II Master Protocol for Evaluation of
New Agents in Patients with Small Cell Bronchogenic Carcinoma**

Location: Great Lakes

Date: 1982-1983

**Primary
Researchers:** *Suseno*

Sponsors: ECOG, NCI

**Human
Subjects:** unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

**Study #NHGL-64: ECOG 5477. Phase III Comparative Evaluation of 3
Intensive Induction Chemotherapy.**

Location: Great Lakes

Date: 1982

Primary

Researchers: Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records: Great Lakes

Classification: Unclassified

#

Study # NHGL-65: ECOG 4181. Phase III Adjuvant Therapy for Post-menopausal Women with Breast Cancer

Location: Great Lakes

Date: 1982-1984

Primary

Researchers: Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records:

Classification: Unclassified

#

Study # ~~NHGL-66~~: Clinical Protocols, Rationales and Procedures for using Two Diagnostic Drugs, HIDA and DMSA

Location: Great Lakes

Date: Unknown

Primary

Researchers: Unknown

Sponsors: Unknown

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records:

Classification: Unclassified

#

Study # ~~NHGL-67~~: Phase III Combination Chemotherapy With or Without Consolidation Radiation Therapy for Loclized Small Cell Carcinoma of the Lung.

Location: Great Lakes

Date: Unknown

**Primary
Researchers:** Unknown

Sponsors: Unknown

**Human
Subjects:** unknown

Purpose: unknown (abstract not available)

Category: unknown

Records:

Classification: Unclassified

#

**Study # NHGL-68: Combination Chemotherapy and Radiotherapy
for Advanced Hodgkin's Disease. Location: Great Lakes**

Date: 1982-1984

Primary

Researchers: Suseno

Sponsors: ECOG, NCI

Human

Subjects: unknown

Purpose: unknown (abstract not available)

Category: unknown

Records:

Classification: Unclassified

#

Study #NHPHIL-01: Evaluation of the Cardiovascular and Anti-Anginal Effect of Mixidine

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: C. J. Pepine

Sponsors: McNeil Labs

Human

Subjects: 0 patients

Purpose: The purpose of this study is to evaluate the cardiovascular effects of Mixidine in patients with angina pectoris before and during controlled atrial tachycardia or exercise. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostics.

Records: Naval Hospital, Philadelphia.

Classification: Unclassified

#

Study #NHPHIL-02: Preventive Control of Hyperlipemia in Naval Personnel

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: C. J. Pepine

Sponsors: ECOG

Human

Subjects: 23 patients

Purpose:

Category:

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-03: Histochemical Determination of Enzymatic Activity in Blood Disorders

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: R. A. Burningham

Sponsors: NH Philadelphia Research Service (Hematology) and ECOG

Human

Subjects: 0 patients

Purpose: To survey the patterns of phosphorylase activity in acute and chronic leukemias, myelofibrosis, polycythemia rubra vera, leukemoid reaction, and preleukemic states such as refractive normoblastic aneuphenias, and thrombocytopenias. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic.

Records: Naval Hospital, Philadelphia.

Classification: Unclassified

#

Study #NHPHIL-04: Chemotherapy of Selected Blood Disease

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: R. A. Burningham

Sponsors: Matthews Research, Inc. Alexandria/ECOG

Human

Subjects: 0 patients

Purpose: Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic.

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-05: A Study of Incidence of Deep Vein Thrombosis in Post OP and Bed Ridden Patients Using Impedence Phlebography Techniques

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: R. S. Golo

Sponsors: NA

Human

Subjects: 27 patients

Purpose: Impedance phlebography was used as a screening technique in the early diagnosis of deep vein thrombosis. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic.

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-06: The Use of Cephalothin Peritoneal Irrigation in Appendicitis

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: R. S. Golo

Sponsors: NA

Human

Subjects: 150 patients

Purpose: Compare treatment of the local peritoneal site following an appendectomy by evaluating the complication rate in irrigation with saline, irrigation with cephalothin and no irrigation. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic.

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-07: Vitamin E Levels in Patients with Cirrhosis

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: R. A. Burningham

Sponsors: NA

Human

Subjects: 25 patients.

Purpose: To examine the incidence of vitamin E deficiency in patients with cirrhosis of diverse etiologies, and correlate levels of vitamin E with the presence or absence of hemolysis and sensitivity of red cells to the peroxide hemolysis test. Exposure to radiation was incidental to being a part of the protocol.

Category: *Other research, diagnostic*

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-08: Evaluation of Small Bowel Microflora in Cancer Patients with and without Therapy and their Possible Role in Systemic Infectious Complications

Location: Naval Hospital, Philadelphia

Date: 1974

Primary

Researchers: R. A. Chappelka, R. A. Burningham, and M. D. Dickman

Sponsors: NA

Human

Subjects: 40 patients

Purpose: To follow the changes in the microflora of the small bowel of cancer patients prior to and during immunosuppressive therapy. To determine the advisability for employing simultaneous antimicrobial therapy and to determine whether those organisms that colonize the small bowel cause systemic infectious complications.

Category: ??

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-09: Treatment and Retention of Naval Personnel Evaluation of False Master's Test

Location: Naval Hospital, Philadelphia

Date: 1973

Primary

Researchers: C. J. Pepine and C. R. Bemiller

Sponsors: NA

Human

Subjects: 0 patients

Purpose: To study clinical, ECG, hemodynamic, and coronary features of patients with 1) angina pectoris; 2) normal coronary anatomy; and 3) positive ECG stress tests. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-10: Inflammatory Dermatophytosis in Military Personnel: The Role of Delayed Hypersensitivity in Prevention of Infection

Location: Naval Hospital, Philadelphia

Date: 1973

Primary

Researchers: W. L. Davis

Sponsors: NA

Human

Subjects: 20 patients

Purpose: To identify the factors involved in hypersensitivity during human dermatophyte infection and in protective immunity to re-infection. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-11: Assessment of Platelet Function in Patients with Coronary Artery Disease

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: J. Lazarchick

Sponsors: NA

Human

Subjects: 15 patients

Purpose: Platelet function in patients with coronary artery disease was studied using carbon-14 serotonic uptake and release. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic tracer study

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-12: Cholinergic Therapy of Reflux Esophagitis in Post-Gastrectomy Patients: A Randomized Double-Blind Crossover Study

Location: Naval Hospital, Philadelphia

Date: 1974

Primary

Researchers: T. J. Humphries, D. O. Castell, and R. H. Higgs

Sponsors: NA

Human

Subjects: 50 patients

Purpose: To determine the effect of regular oral Bethanechol therapy on 1) heartburn symptoms; 2) antacid consumption; and 3) gross and microscopic evidence of esophagitis in patients who have had a vagotomy and antrectomy. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-13: Evaluation of Cardiorespiratory Effects of Perhexiline in Patients with Angina Pectoris

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: C. J. Pepine

Sponsors: W. S. Merrell and Thomas Jefferson Hospital

Human

Subjects: 20 patients

Purpose: To evaluate the long term antianginal effects of Perhexiline maleate in patients with significant coronary artery disease documented with coronary arteriography. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-14: Ileal Reflux After Gastric Alkalinization Coagulation System in Patients with Chronic Hypoxia

Location: Naval Hospital, Philadelphia

Date: 1971-1972

Primary

Researchers: G. M. Jervey

Sponsors: NA

Human

Subjects: 0 patients

Purpose: To evaluate the relationship of stimulation of endogenous gastrin release by gastric alkalinization to the ability to reflux barium into the terminal ileum during barium enema examination. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic tracer study

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-15: Urinary Adicification and Ammonia Levels in Cirrhotic and Normal Subjects

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: F. Garcia

Sponsors: NA

Human

Subjects: 20 patients

Purpose: To determine the effect of oral ingestion of vitamin C (ascorbic acid) on ammonia excretion in the urine and serum ammonia levels. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic tracer study

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-16: The Clinical Effect of Topical 1% 8-Methoxypsoralen Followed by Near Ultraviolet Light on Proven Dermatophytosis

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: H. L. Parlette

Sponsors: NA

Human

Subjects: 24 patients

Purpose: To test the clinical effectiveness of the combination of commercially available 1% 8-methoxypsoralen and blacklight (320-400 nm) irradiation in the eradication of superficial fungal infections of the skin and nails. This study involved non-ionizing radiation.

Category: Other research.

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-17: The Behavior of Gaviscon in Gastric Fundus in Erect and Supine Position

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: T. H. Humphries

Sponsors: Marion Labs

Human

Subjects: 0 patients

Purpose:

- (1) To examine the floating and foaming properties of Gaviscon in erect and supine positions.
- (2) To compare the foregoing actions of Gaviscon with those exhibited under similar conditions by a standard antacid. No known radiation exposure.

Category: Other research

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-18: Study of Gastric Ulcers

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: F. Garcia-Torres

Sponsors: NA

Human

Subjects: 7 patients

Purpose: Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-19: Phase I-II Study Using Adriamycin and Cis-Diamminodichloroplatinumin Advanced Solid Tumors

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: H. J. Long

Sponsors: NA

Human

Subjects: 50 patients

Purpose: To test a chemotherapeutic agent, and radiation exposure was incidental to being a part of the study.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

**Study #NHPHIL-20: Comparison of Four Methods of Bowel Preparation for
Colonoscopy**

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: R. S. Woodward

Sponsors: NA

Human

Subjects: 0 patients

Purpose: TO compare the efficacy, patient acceptance, nursing acceptance, and cost of the standard method of bowel preparation in use at NH Philadelphia with that to three commercial bowel evacuant kits; 1) Evacu-kit; 2) Fleet barium prep kit #1; and 3) Fleet barium prep kit #2. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-21: Efficacy of Sucralfate in the Treatment of Gastric Ulcers

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: T. J. Humphries

Sponsors: Marion Labs

Human

Subjects: 0 patients

Purpose: To evaluate the safety and effectiveness of sucralfate in the treatment of duodenal ulcer when compared to placebo. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic tracer

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-22: Effect of Combination Oral Contraceptives on Nephrogenous Cyclic Adenosine Monophosphate

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: J. G. Bell

Sponsors: NA

Human

Subjects: 20 patients

Purpose: To examine the effect of estrogen (50 micrograms) and progesterone in the form of oral contraceptives on the nephrogenous fraction of urinary CAMP. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-23: Tamoxifen w/wo Sequential Chemotherapy for Recurrent Metastatic Breast Cancer in Patients with Positive Estrogen Receptors

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: D. L. Trump

Sponsors: U of Penn

Human

Subjects: 0 patients

Purpose:

- (1) To determine the tumor response rate of Tamoxifen in patients with metastatic breast cancer in whom estrogen receptors are not available.
- (2) To compare the effect of sequentially adding combination chemotherapy Tamoxifen on tumor size, duration of response, change in performance status and survival. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-24: Monoamine Oxidase: Clinical Use as an Indicator of Incipient Hepatic Fibrosis

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: T. J. Humphries

Sponsors: NA

Human

Subjects: 20 patients

Purpose: To determine the clinical usefulness of the determination of plasma monamine oxidase (MAO) and its isoenzymes in the detection of varying degrees of fibrosis in the human liver. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-25: Study of the Effect of Jogging on Cardiorespiratory Fitness of Alcoholics in the NRMC Alcohol Rehab Unit

Location: Naval Hospital, Philadelphia

Date:

Primary

Researchers: P. L. McKelvy

Sponsors: NA

Human

Subjects: 0 (alcoholics)

Purpose:

- (1) To determine if the patients on the NRMC Philadelphia Alcohol Rehab Unit (ARC) possess the symptoms of deconditioning reported in older alcoholics.
- (2) To determine if jogging 1 kilometer per day for 20 days during hospitalization on the ARC will result in objective improvement of their cardiorespiratory fitness. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

#

Study #NHPHIL-26: A Comparison Study of Ultrasound and Oral Cholecystography in Detecting Gallstones

Location: Naval Hospital, Philadelphia

Date: 1977

Primary

Researchers: C. Duncan

Sponsors: NA

Human

Subjects: 0 patients

Purpose: To evaluate the ability of ultrasound and oral cholecystography in detecting gallstones. To determine if one mode is superior to another or if they are complimentary. Exposure to radiation was incidental to being a part of the protocol.

Category: Other research, diagnostic

Records: Naval Hospital, Philadelphia

Classification: Unclassified

Study #NMRU2-01: Chromium-51 Studies in Wilson's Disease

Location: NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NMRU2-02: Copper Absorption in Wilson's Disease

Location: NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NMRU2-03: Muscle Copper, Zinc and Manganese Levels in Wilson's Disease:
Studies With the Use of Neutron Activation Analysis.**

Location: NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

**Study #NMRU2-04: Abnormalities of the Physiology of Copper in Wilson's Disease:
The Whole-Body Turnover of Copper.**

Location: NMRU2 (Taipei) and Clinical Study Center, San Francisco

Date: 1971

Primary

Researchers: O. Reilly, S., Strickland, G. T., Weber, P.M.3, Beckner, W. M., Shipley L.

Sponsors: NIH Grant NB-07102 and 83

Human

Subjects: 38 Chinese at NMRU2 and 41 at San Francisco General Hospital

Purpose: To study copper physiology in Wilson's disease.

Category: Other

Records: Journal Article

Classification: Unclassified

#

Study #NMRU2-05: Decreased Calcium Absorption (CaAb) on Cholestyramine Therapy

Location: NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NMRU2-06: Hypersplenism in Wilson's disease

Location: NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NMRU2-07: Turnover Studies of Copper and Homozygotes and Heterozygotes for Wilson's Disease and Controls: Isotope Tracer Studies Using Copper-67 and Copper-64

Location: NMRU2 (Taipei)

Date: 1972

Primary

Researchers: Strickland, G. T., Beckner, W. M., Lew, M. L., O'Reilly, S.

Sponsors: Bureau of Medicine and Surgery, U. S. Navy

Human

Subjects: 62 Chinese subjects

Purpose: To examine the genetic features of Wilson's disease.

Category: Other

Records: NMRU-2 and Journal Articles

Classification: Unclassified

#

Study #NMRU2-08: Clinical Studies of Capillariasis Philippinesis

Location: NMRU2 (Taipei)

Date: 1972

Primary

Researchers: Watten, R. H., Beckner, W. M., Cross, J. H., Gunining, J. J., Jarimillo, J.

Sponsors: Bureau of Medicine and Surgery, U. S. Navy

Human

Subjects: Unknown

Purpose: To study plasma protein loss in stool.

Category: Journal Article

Records:

Classification: Unclassified

#

Study #NMRU2-09: Cesium-137 Turnover Rates in Human Subjects of Different Ages

Location: NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NMRU2-10: Body Composition and Starvation

Location: NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NMRU2-11: Isotope Studies in Intestinal Capillariasis

Location: NMRU2 (Taipei)

Date: 1972

Primary

Researchers: R. T.Devine

Sponsors: Naval Medical Research and Development Command

Human

Subjects: Unknown

Purpose: To study plasma volume and protein loss

Category: Other

Records: Journal Article

Classification: Unclassified

#

Study #NMRU2-12: Iodine-131 Studies in Schistosomiasis

Location: NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study# NMRU2-13: Intestinal Capillariasis: A New Disease in Man

Location:NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects**

Purpose:

Category:

Records:

Classification:Unclassified

#

Study# NMRU2-14: Preliminary Observations on a New Disease in Man - Intestinal Capillariasis

Location:NMRU2 (Taipei)

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects**

Purpose:

Category:

Records:

Classification:Unclassified

Study #SMRL-01: Aerotitis Media in Submariners

Location: Submarine Medical Research Laboratory

Date: 1946

Primary

Researchers: H. L. Haines, MD and J. D. Harris, PhD

Sponsors: Sound Laboratory, Medical Research Dept., US Submarine Base.

Human

Subjects: 6,149 young healthy male submariners (732 were treated with standard radiation dose)

Purpose: To identify the optimal treatment for middle ear barotrauma (known then as aerotitis media, which is a rupture of the inner-ear due to inability to equalize pressure because of blocked eustachian tube). Five groups were given different types of treatments (which were common practice in the civilian community) as follows: 1) psychological; 2) topical; 3) x-ray; 4) radium; and 5) dental. The types of treatment were based on some rationale designed to assist the men in accommodating pressure changes without developing aerotitis media. Thirty percent of the submarine applicants were failing the pressure test. **Ninety percent of the those that failed the test were able to sustain pressure following treatment with radium without developing aerotitis media.**

Category: Therapeutic research involving radiation.

Records: SMRL

Classification: Unclassified

#

Study #SMRL-02: Radium Therapy in Aerotitis Media

Location: Submarine Medical Research Laboratory

Date: 1946

Primary

Researchers: Page Northington, CAPT, MC, USNR

Sponsors: Navy

Human

Subjects: 60 aviators.

Purpose: Preventive treatment of aerotitis media, the most common physical ailment among aviators.

Category: Therapeutic research involving radiation.

Records: SMRL

Classification: Unclassified

#

Study #SMRL-03: Aseptic Bone Necrosis Among US Navy divers: Survey of 934 Nonrandomly Selected Personnel

Location: Submarine Medical Research Laboratory

Date: March 1978

Primary

Researchers: W. L. Hunter, R. J. Biersner, R. L. Spahr and C. A. Harvey

Sponsors:

Human

Subjects: 934 US Navy divers

Purpose: 934 US Navy divers were selected and surveyed radiographically using standard techniques (x rays) developed for detecting aseptic bone necrosis (ABN)

Category:

Records: SMRL

Classification: Unclassified

#

Study #NMCLANNAP-01: Comparison of Various Means of Evaluation the Severity of Inversion Ankle Sprains

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: H. M. Black

Sponsors: NA

Human

Subjects: 100 midshipmen

Purpose: Compare the operative findings in all ankle sprains requiring surgery with the pre-operative impression based on: (1) the clinical evaluation; (2) radiography; and (3) contrast arthrography.

Category: Other research, diagnostic

Records: Annapolis

Classification: Unclassified

#

Study #NMCLANNAP-02: Radiological Evaluation of Cervical Spine of Collegiate Football Players

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: J. S. Cox

Sponsors: NA

Human

Subjects: 18 Midshipmen

Purpose: To evaluate the role of minor trauma in causing degenerative changes in the cervical spine. Exposure to radiation was incidental to being a part of the study.

Category: Other research, diagnostic

Records: Annapolis

Classification: Unclassified

#

Study #NMCLANNAP-03: Study of 2 Medial Collateral Ligament Sprains of the Knee

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: W. G. Claney

Sponsors: NA

Human

Subjects: 20 patients

Purpose: A retrospective study to determine if an injury to the medial collateral ligament of the knee classified as a second degree or moderate sprain ever tightens from its initial laxity, and to determine an incidence of those eventually coming to surgery on this joint. Radiation exposure was incidental to the study.

Category: Other research, diagnostic.

Records: Annapolis

Classification: Unclassified

#

Study #NMCLANNAP-04: Study to Establish Normal Range of Ankle Mobility (Talar Tilt) During Inversion Stress

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: H. M. Black

Sponsors: NA

Human

Subjects: 50 midshipmen

Purpose: To establish the normal range of ankle mobility during inversion stress and to determine the degree of measured talar tilt and the incidence of serious sprains, present symptoms, and prospectively, the incidence of recurrent sprains. Standard inversion stress radiographs were obtained on a large number of randomly selected normal subjects.

Category: Other research, diagnostic.

Records: Annapolis

Classification: Unclassified

HAA

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: N. Larmoszuk

Sponsors: NA

Human

Subjects: 0 subjects

Purpose: Radiation exposure was incidental to the study.

Category: Other research, diagnostics.

Records: Annapolis

Classification: Unclassified

#

Study #NMCLANNAP-06: The Rate of the Acromioclavicular Joint in Athletic Injuries

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: J. S. Cox

Sponsors: NA

Human

Subjects: 137 midshipmen

Purpose: X-rays of the acromioclavicular joint. Radiation exposure was incidental to the study.

Category: Other research, diagnostic.

Records: Annapolis.

Classification: Unclassified

#

Study #NMCLANNAP-07: Evaluation of the Modified Bristow Procedure in the Treatment of Recurrent Subluxations and Dislocations of the Shoulder

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: J. S. Cox

Sponsors: NA

Human

Subjects: 150 midshipmen

Purpose: To evaluate the effectiveness of the modified Bristow procedure in the procedure in the treatment of recurrent subluxations and dislocations of the shoulder in a large group of young athletes. Radiation exposure was incidental to the study.

Category: Other research, diagnostic

Records: Annapolis.

Classification: Unclassified

#

Study #NMCLANNAP-08: Evaluation of the Brostrom Procedure for Repair of Chronic Ruptures of the Lateral Ligaments of the Ankle

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: H. M. Black

Sponsors: NA

Human

Subjects: 35 midshipmen

Purpose: To evaluate the effectiveness of a new surgical procedure for the repair of chronic ruptures of the lateral ligaments of the ankle. Radiation exposure was incidental to the study.

Category: Other research, diagnostics.

Records: Annapolis

Classification: Unclassified

#

Study #NMCLANNAP-09: Elmslie-Trillat Procedures for the Management of Dislocations and Subluxations of the Patella

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: J. S. Cox

Sponsors: NA

Human

Subjects: 116 midshipmen

Purpose: Radiation exposure was incidental to the study.

Category: Other research, diagnostic.

Records: Annapolis.

Classification: Unclassified

#

Study #NMCLANNAP-10: Functional Instability of the Ankle Joint

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: J. S. Cox

Sponsors: NA

Human

Subjects: 376 subjects

Purpose: Radiation exposure was incidental to the study.

Category: Other research, diagnostic.

Records: Annapolis

Classification: Unclassified

#

Study #NMCLANNAP-11: Clinical Study of Intraocular Lens Implantation After Cataract Extractions Primary or Secondary

Location: Naval Medical Clinic, Annapolis

Date:

Primary

Researchers: J. E. Sutphin

Sponsors: NA

Human

Subjects: 200 subjects

Purpose: To participate in an FDA clinical investigation of the safety and efficacy of intraocular lenses. Radiation exposure was incidental to the study.

Category: Other research, diagnostic.

Records: Annapolis.

Classification: Unclassified

#

Study #NHJAX-01: A Prospective Cooperative Study into the Etiology of Reye's Syndrome, and the Effectiveness of Current Modes of Therapy

Location: Naval Hospital, Jacksonville

Date: 16 August 1971

Primary

Researchers: M. K. Goldschmidt, LCDR, MC, USN

Sponsors: Naval Hospital, Bethesda

Human

Subjects: Yes

Purpose: To study Reyes syndrome in children. X-ray renograms and nuclear medicine scans were used to evaluate the disease.

Category: Other research, diagnostic study.

Records: Naval Hospital, Bethesda

Classification: Unclassified

Study # GUAM-01: Radionuclide Biliary Imaging Utilizing 99MTC EHIDA

Location: NH Guam

Date:

Primary

Researchers: T. K. Burkhard, LCDR, MC

Sponsors: N/A

Human

Subjects: Unknown

Purpose:

Category:

Records: Guam

Classification: Unclassified

Study # NHPEN-01: Alterations in Renal Clearance of Digoxin as Modified by Volume Loading, Alkalinization and Diuritics and Measured by Radio-Immunoassay Technique

Location: NH Pensacola

Date: Unknown

Primary

Researchers: D. D. Brown, LCDR, MC

Sponsors: N/A

Human

Subjects: 7 patients - special class of subjects is N/A

Purpose: The general objective of the investigation is to better define the renal handling of the extremely important and widely used cardiac drug, digoxin

Category: Other

Records: NH Pensacola

Classification: Unclassified

Study # NHPEN-02: Clinical Study of Intraocular Lenses

Location: NH Pensacola

Date: Unknown

Primary

Researchers: E. A. Novak

Sponsors: N/A

Human

Subjects: 0 patients - special class of patients is N/A

Purpose: To assess the risk of using intraocular lens to replace the crystalline lens following cataract surgery, by maintaining preoperative, operative and postoperative records to allow evaluation of adverse effects

Category: Other

Records: NH Pensacola

Classification: Unclassified

Study # NHORL-01: Acute Respiratory Disease in Recruits at the Naval Training Center, Orlando Florida

Location: NH Orlando

Date: 11/76-09/81

Primary

Researchers: B. M. Greene, LCDR, MC

Sponsors: N/A

Human

Subjects: 100 patients - special class of patients is recruits that have been admitted with Acute Respiratory Disease

Purpose: To determine whether the virus adenovirus, which is well known cause of acute respiratory disease, is endemic in the recruit population; and whether adenovirus of a vaccine strain, or of a non-vaccine strain is associated with acute respiratory disease

Category:

Records: NH Orlando

Classification: Unclassified

Study # NHORL-02: Smoking and Lung Cancer

Location: NH Orlando

Date: Unknown

Primary

Researchers: J. D. Coteligam , LCDR

Sponsors: VA; University of S. Florida

Human

Subjects: 44 patients - no special class of patients

Purpose: A feasibility study based on other observations to develop a diagnostic procedure to identify individuals that are at a relatively high risk for developing lung cancer prior to detection of frank or metastatic growth. One of the studies done for people predisposed of cancer due to genetic conditions was the sensitivity of cells to x-ray

Category:

Records: NH Orlando

Classification: Unclassified

**Study # NHMEP-01: Clinical Study of Intraocular Lenses Implantation
After Cataract Extraction Precision-Cosmet**

Location: NH Memphis

Date: Unknown

Primary

Researchers: J. Troupe, LCDR, MC

Sponsors: N/A

Human

Subjects: 0 patients - special class of subjects is N/A

Purpose: To assess the risk of using intraocular lens to replace the crystalline lens following cataract surgery, by maintaining preoperative, operative and postoperative records to allow evaluation of adverse effects

Category: Other

Records: NH Memphis

Classification: Unclassified

Study # NHCHA-01: Inderal Treatment of Menopausal Vasomotor Symptoms

Location: NH Charleston

Date: Unknown

Primary

Researchers: J. M. Alcock, LT, MC

Sponsors: N/A

Human

Subjects: 100 patients - special class of subjects is females with severe vasomotor symptoms

Purpose: To study the effects of a drug called Propranolol on menopausal vasomotor instability. CxRay if not done within the last two years will be performed on all patients entering the study.

Records: NH Charleston

Classification: Unclassified

Study # NHCHA-02: Double Blind Prospective Study of Aerosolized Steroids in Group

Location: NH Charleston

Date: Unknown

Primary

Researchers: B. G. Edwards

Sponsors: FDA

Human

Subjects: 50,000 patients - special class of patients is premenopausal women with inoperable breast cancer.

Purpose: To compare the value of 2 drug treatment regimens as primary induction treatment for metastatic or inoperable breast cancer in premenopausal women.

Category: Other

Records: NH Charleston

Classification: Unclassified

Study # NHNAP-01: Full Thickness Skin Cultures in Betadine Scrubbed and Betadine Sprayed Surgical Patients

Location: NH Naples

Date: 11/80-11/81

Primary

Researchers: M. J. Saldena, CDR, MC

Sponsors: N/A

Human

Subjects: 200 patients - special class of patients is adults

Purpose: To observe if there is any difference in wound infection rate between fully scrubbed betadine patients and sprayed betadine patients undergoing clean lower abdominal surgery over a period of 8 months. A 2mm full thickness skin will be taken from each patients to be studied.

Category: Other

Records: NH Naples

Classification: Unclassified

Study # NRDC-01: Investigation of Hemotologic and Pathologic Response to Decompression

Location:

Date:

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose:

Category:

Records:

Classification: Unclassified

#

Study #NRL-01: Freeze-Dried Human Red Blood Cells

Location: Cryopharm Corporation, Pasadena, CA. (1991)

Date: 1991

Primary Researchers: Pending determination.

Sponsors: Navy Medical Research and Development Center (NMR&D)

Human Subjects: Four volunteers. Informed consent determination pending.

Purpose: To evaluate the safety and circulation time of freeze dried red blood cells.

Category: The blood cells were labeled with trace amounts of radioactivity in order to make direct measurements.

Records: The original contract is at the Office of Naval Research. Any other records on the Study can be found at NMR&D. POC is CDR Peter Kent, MC, USN (301) 295-0880.

Classification: None

#

Study #NRL-02: Circulating Red Cell Volume and Body Hematocrit in Normal Pregnancy and the Puerperium by Direct Measurement, Using Radioactive Red Cells

Location: Harvard Medical School The Boston Lying-in Hospital Massachusetts Institute of Technology

Date: 1951

Primary Researchers: William L. Caton, Charles C. Roby, Duncan E. Reid, Randolph Caswell, C.J. Maletskos, Rex G. Fluharty and John G. Gibson

Sponsors: Charles H. Hood Foundation, Office of Naval Research, Atomic Energy Commission and National Institute of Health

Human

Subjects: Twelve pregnant women, patients of the Boston Lying-in Hospital, cooperated in the study. No other information is available regarding these women. Informed consent determination pending.

Purpose: To determine, by direct measurement, the volume of the circulating red cell mass during normal pregnancy and the period during and just after childbirth

Category: Radioactive iron was used to "tag" red cells, enabling the researchers to make direct measurements.

Records: The only known record of this Study was found in the open scientific literature:

"Circulating Red Cell Volume and Body Hematocrit in Normal Pregnancy and the Puerperium by Direct Measurement, Using Radiactive Red Cells, "American Journal of Obstetrics and Gynecology, Volume 61, No 6, pages 1207-1217, June 1951.

Classification: None

#

Study #NRL-03: Persistence and Utilization of Maternal Iron for Blood Formation During Infancy

Location: Harvard Medical School, The Radioactivity Center, The Boston Lying-in Hospital, Massachusetts Institute of Technology, Children's Hospital and Peter Bent Brigham Hospital

Date: 1955

Primary Researchers: Clement A. Smith, Ruth B. Cherry, John G. Gibson, Charles C. Roby, C.J. Maletskos, William L. Caton and Duncan Reid

Sponsors: Committee on Growth, Office of Naval Research, Atomic Energy Commission. American Cancer Society, Harvard Medical School, National Institute of Health and Massachusetts Institute of Technology

Human Subjects: Eleven pregnant women and sixteen infants from the Boston Lying-in Hospital. No other information is available regarding these women. Informed consent determination pending.

Purpose: To measure the persistence and utilization of transplacental iron during infancy.

Category: Radioactive iron was used to "tag" red cells, enabling the researchers to make direct measurements.

Records: The only known record of this Study was found in the open scientific literature:

"Persistence and Utilization of Maternal Iron for Blood Formation During Infancy," Journal of Clinical Investigation, Volume 34, No 9, pages 1391-1402, September 1955.

Classification: None

#

Study #NRL-04: Effect of Total Thyroidectomy on Function of Metastatic Thyroid Cancer

Location: Thyroid Clinic of Massachusetts Hospital, Memorial Hospital, Sloan-Kettering Institute, and Massachusetts Institute of Technology

Date: 1948

Primary

Researchers: Rulon W. Rawson, L.D. Marinelli, Bengt N. Skanse, Jack Trunnell and Rex G. Fluharty

Sponsors: American Cancer Society and Office of Naval Research

Human

Subjects: 21 patients received the treatment outlined in this Study. Patient's initials were listed, as well as an identification number. Informed consent determination pending.

Purpose: To determine the effect of total thyroidectomy on the function of metastatic thyroid cancer.

Category: Trace amounts of radioactive iodine were used to diagnose thyroid cancer.

Records: The only known record of this Study was found in the open scientific literature:

"Effect of Total Thyroidectomy on Function of Metastatic Thyroid Cancer," Journal of Clinical Endocrinology, Volume 8, No. 10, pages 826-841, October 1948.

Classification: None

#

Study #NRL-05: Principals in the Use of Artificial Radioactive Cobalt for Treatment of Cancer.

Location: Ohio state University Research Foundation

Date: 1948-1949

Primary

Researchers: Pending determination.

Sponsors: Office of Naval Research

Human Subjects: Pending determination.

Purpose: Pending determination.

Category: Pending determination.

Records: Pending determination.

Classification: Pending determination. None Presumed.

#

Study #NRL-06: Research on a New Method for Radiation Detection.

Location: Massachusetts Institute of Technology

Date: 1951-1955

Primary Researchers: Pending determination.

Sponsors: Office of Naval Research

Human Subjects: Pending determination.

Purpose: Pending determination.

Category: Pending determination.

Records: Pending determination.

Classification: Pending determination. None presumed.

#

Study #NRL-07: Research on the Effects of Ultrahigh Electromagnetic Radiation (High Power Radiation) on Biological Material and the Possible Health Of --

Location: University of Pennsylvania

Date: 1955-1957

Primary Researchers: Pending determination.

Sponsors: Office of Naval Research

Human Subjects: Pending determination.

Purpose: Pending determination.

Category: Pending determination.

Records: Pending determination

Classification: Pending determination. None presumed.

#

Study #NRL-08: Effects of Radiation Associated With Growth.

Location: Tufts College Medical School

Date: 1948-1950

Primary Researchers: Pending determination.

Sponsors: Office of Naval Research

Human Subjects: Pending determination.

Purpose: Pending determination.

Category: Pending determination

Records: Pending determination.

Classification: Pending determination. None presumed.

#

Study #NRL-09: Skin Changes Produced by Low Voltage Roentgen Ray Irradiation.

Location: New York Post Graduate School and Hospital

Date: 1949

Primary Researchers: Pending determination.

Sponsors: Office of Naval Research

Human Subjects: Pending determination

Purpose: Pending determination.

Category: Pending determination.

Records: Pending determination.

Classification: Pending determination. None presumed.

#

Study #NRI-10: Studies of Distribution of Isotopes in Therapy With Particular Reference to Radioiodine

Location: Memorial Hospital for the Treatment of Cancer and Allied Diseases

Date: 1948

Primary Researchers: Pending determination.

Sponsors: Office of Naval Research

Human Subjects: Pending determination.

Purpose: Pending determination.

Category: Pending determination.

Records:

Classification: Pending determination. None presumed.

#

Study #NRI-11: RDX Toxicity

Location: University of Maryland

Date: 1974-1975

Primary Researchers: Pending determination.

Sponsors: Office of Naval Research

Human Subjects: Pending determination.

Purpose: Pending determination.

Category: Pending determination.

Records: Pending determination.

Classification: Pending determination. None presumed.

#

**Study #NRL-12: INTELCON RAD TECH, INTELCON Industries, Inc. Gulf
Energy and Environmental Systems**

Location: University of Maryland

Date: 1973-1975

Primary Researchers: Pending determination.

Sponsors: Office of Naval Research

Human Subjects: Pending determination.

Purpose: Pending determination.

Category: Pending determination

Records: Pending determination.

Classification: Pending determination. None presumed.

#

Study #NRDL -01: Decontamination of Synthetic Radioactive Fallout From Intact Human Skin

Location: Naval Radiological Defense Laboratory

Date: 1951

Primary

Researchers: A. L. Baietti

Sponsors:

Human

Subjects: 45 volunteers

Purpose: Abstract not available at this time.

Category: Research

Records: The National Archives, San Bruno, CA

Classification: Unclassified

#

Study #NRDL -02: Protecting and Cleaning Hands Contaminated By Synthetic Fallout Under Field Conditions

Location: Naval Radiological Defense Laboratory

Date: 1959

**Primary
Researchers:**

Sponsors:

**Human
Subjects:**

Purpose: Abstract not available at this time.

Category:

Records: The National Archives, San Bruno, CA

Classification: Unclassified

#

Study #NRDL -03: Some Aspects of Recent Findings Pertaining to the Body Composition of Athletes, Obese Individuals and Patients

Location: Naval Radiological Defense Laboratory

Date: 1959

Primary

Researchers: A. R. Behnke and W. L. Taylor

Sponsors: BUMED

Human

Subjects: 32

Purpose: To analyze the gross composition of the human body . Procedures included determinations of whole-body density and the use of dilution techniques involving the use of radionuclides.

Category: Research, diagnostic tracer study.

Records: The National Archives, San Bruno, CA

Classification: Unclassified

#

Study #NRDL -04: Total Exchangeable Potassium and Chloride and Total Body Water in Health Men of Varying Water and Fat Content

Location: Naval Radiological Defense Laboratory

Date: 1959

Primary

Researchers: E. A. Boling, W. L. Taylor, C. Entenman, and A. R. Behnke

Sponsors: BUMED

Human

Subjects: 36 healthy men

Purpose: To measure the exchangeable potassium, exchangeable chloride, and total body water in a group of 36 healthy men of varying water and fat content using potassium-42, bromine-82 and tritiated water as tracers. The total radiation received per individual was less than 0.2 rad.

Category: Research, diagnostic tracer study.

Records: The National Archives, San Bruno, CA

Classification: Unclassified

#

Study #NRDL -05: Rapid Assay Procedures for Tritium Labeled Water in Body Fluids

Location: Naval Radiological Defense Laboratory

Date: 1959

Primary

Researchers: B. A. Vaughn and E. A. Boling

Sponsors: BUMED

Human

Subjects: 12 active healthy men.

Purpose: To test two new methods (rapid vacuum sublimation and simplified internal standardization) for tritiated water radioassay with an application to body water determination in active and healthy humans.

Category: Research, diagnostic tracer study.

Records: The National Archives, San Bruno, CA

Classification: Unclassified

#

Study #NRDL -06: Some Factors Influencing the B-dosage of Troops

Location: Naval Radiological Defense Laboratory

Date: Unknown

Primary

Researchers: Unknown

Sponsors: Unknown

Human

Subjects: Unknown

Purpose: Unknown (abstract not available)

Category: Unknown

Records: The National Archives, San Bruno, CA

Classification: Unclassified

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