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Description of document: National Highway Traffic Safety Administration (NHTSA) periodic reports provided by WESTAT in contract DTNH22-11-D-00237: Examine the Effects of Inhaled Cannabis on Driving Performance, 2011-2014

Request date: 24-December-2014

Released date: 25-March-2015

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Source of document: Freedom of Information Act Request  
NHTSA  
Executive Secretariat  
1200 New Jersey Avenue, SE  
West Building, 41-304  
Washington, D.C. 20590  
Fax: (202) 493-2929  
[Online FOIA request Email form](#)

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U.S. Department  
of Transportation

**National Highway  
Traffic Safety  
Administration**

1200 New Jersey Avenue, SE  
Washington, DC 20590

**ELECTRONIC MAIL**

March 25, 2015

Re: Freedom of Information Act (FOIA) Request #ES14-005862

This responds to your December 24, 2014 FOIA request seeking a copy of each interim or periodic report provided by WESTAT in contract DTNH22-11-D-00237 regarding the effect of inhaled cannabis on driving performance.

Enclosed is information responsive to your request.

Pursuant to the provisions of 49 CFR Part 7, there is no charge for this request.

I am the person responsible for this decision. If you wish to appeal this decision, you may do so by writing to the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE, West Building, W41-227, Washington, DC 20590, pursuant to 49 CFR § 7.32(d). An appeal must be submitted within 45 from the date of this determination. It should contain any information and argument upon which you rely. The decision of the Chief Counsel will be administratively final.

Very Truly Yours,

A handwritten signature in black ink, appearing to read "Andrew J. DiMarsico".

Andrew J. DiMarsico  
Senior Attorney

Enclosure



# NHTSA/NIDA Monthly Report

SEPTEMBER 2011

<b>PROJECT INFORMATION</b>	<p>Contract Number: DTNH22-11-D-00237/004</p> <p>Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance</p> <p>Period Covered: September 16, 2011 – September 30, 2011</p> <p>COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a></p> <p>PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a></p> <p>Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a></p> <p>PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a></p>
<b>SUMMARY</b>	<p>Provided information to Westat to support contract award from NHTSA to Westat. Continued on-going discussions with NIDA on protocol development. We anticipate a subcontract award from Westat to UI in late October or early November. Until then, no charges will appear on these statements.</p>
<b>TASK C.5.1</b>	<p><u>ACCOMPLISHMENTS</u>: Westat and UI participated on a call with NHTSA/NIDA on Sept. 7<sup>th</sup> to discuss issues related to cost negotiation. Westat efforts for this task were related to setting up the study accounts and materials after contract award.</p> <p><u>NEXT MONTH</u>: Develop format for monthly report and start the process of delivering monthly progress reports.</p>
<b>TASK C.5.2</b>	<p><u>ACCOMPLISHMENTS</u>: Discussed potential dates for briefing in October.</p> <p><u>NEXT MONTH</u>: Prepare for and participate in project kick-off briefing.</p>
<b>TASK C.5.3</b>	<p><u>ACCOMPLISHMENTS</u>: Started the process of planning project tasks and how they will be conducted.</p> <p><u>NEXT MONTH</u>:</p>
<b>TASK C.5.4</b>	<p>This task has yet to begin.</p>
<b>TASK C.5.5</b>	<p><u>ACCOMPLISHMENTS</u>: Held discussions with NIDA staff on the study protocol. This included a teleconference on Sept 6<sup>th</sup>. Continued discussions with UI CRU to keep them apprised of protocol details and confirm costs related to patient overnight stays. Continued discussions with UI risk management and IRB related to potential risks and participant safety.</p> <p><u>NEXT MONTH</u>: Continue discussions with NIDA staff on study protocol details.</p>
<b>TASK C.5.6</b>	<p>This task has yet to begin.</p>

<b>TASK C.5.7</b>	This task has yet to begin.
<b>TASK C.5.8</b>	This task has yet to begin.
<b>TASK C.5.9</b>	This task has yet to begin.
<b>TASK C.5.10</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	None.

UI Project Expenditures*				
Categories	Total Amount Originally Budgeted	September Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$0	\$0	0%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$0	0%
Sub-total	\$272,889	\$0	\$0	0%
Facilities & Administration	\$139,173	\$0	\$0	0%
Simulator Charges	\$92,466	\$0	\$0	0%
Total	\$504,528	\$0	\$0	0%

\*Does not include Westat costs/overhead.



Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

OCTOBER 2011

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	October 1, 2011 – October 31, 2011
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

SUMMARY	Continued communication with Westat to support negotiation of budget and scope. Made progress on Tasks 5.1, 5.2 5.3, and 5.5.
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TASK C.5.1	<u>ACCOMPLISHMENTS:</u> Delivered the September monthly progress report on Oct. 28 <sup>th</sup> . E-mails and phones call were exchanged between NHTSA, UI, and Westat on the content of monthly progress reports.
	<u>NEXT MONTH:</u> Continue to revise the monthly progress report to match NHTSA expectations and deliver the ensuing reports on time by the 15 <sup>th</sup> of each month.

TASK C.5.2	<u>ACCOMPLISHMENTS:</u> The kick-off briefing was held on Oct. 25 <sup>th</sup> . Tim Brown attended the briefing in person with no travel costs to this project since he was already in D.C. for another project's kick-off briefing. The teleconference included other team members from UI, Westat, and NIDA (as well as NHTSA). Westat efforts for this task were related to preparing for and participating in the kick-off briefing. Furthermore, Westat worked with UI in establishing communication and reporting procedures.
	<u>NEXT MONTH:</u> This task is complete. We don't anticipate any more work related to this task.

TASK C.5.3	<u>ACCOMPLISHMENTS:</u> Continued process of planning project tasks and how they will be conducted.
	<u>NEXT MONTH:</u> Deliver work plan.

TASK C.5.4	This task has yet to begin.
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TASK C.5.5	<u>ACCOMPLISHMENTS:</u> Held discussions with NIDA staff on the study protocol. Sent revised versions of the protocol to NIDA on Oct 3 <sup>rd</sup> and Oct 20 <sup>th</sup> . Received an updated protocol on Oct. 25 <sup>th</sup> and the kick-off briefing with NHTSA/NIDA included discussion about open issues related to the protocol. A list of 20 issues was generated and the remainder of the month included work to address these items. We received another revision to the protocol from NIDA on Oct 30 <sup>th</sup> .
	<u>NEXT MONTH:</u> Finalize protocol and start IRB application.

TASK C.5.6	This task has yet to begin.
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<b>TASK C.5.7</b>	This task has yet to begin.
<b>TASK C.5.8</b>	This task has yet to begin.
<b>TASK C.5.9</b>	This task has yet to begin.
<b>TASK C.5.10</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	None.

Project Expenditures				
Categories	Total Amount Originally Budgeted	October Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$2,448	\$2,448	1%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$0	0%
Sub-total	\$272,889	\$2,448	\$2,448	1%
Facilities & Administration	\$139,173	\$1,248	\$1,248	1%
Simulator Charges	\$92,466	\$0	\$0	0%
<b>Total</b>	<b>\$504,528</b>	<b>\$3,696</b>	<b>\$3,696</b>	<b>1%</b>

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

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# NHTSA/NIDA Monthly Report

NOVEMBER 2011

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	November 1, 2011 – November 30, 2011
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

SUMMARY	Made progress on Tasks 5.1, 5.3, and 5.5.
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TASK C.5.1	<u>ACCOMPLISHMENTS:</u> Delivered the October monthly progress report on Nov. 15 <sup>th</sup> .
	<u>NEXT MONTH:</u> Prepare November monthly report.

TASK C.5.2	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

TASK C.5.3	<u>ACCOMPLISHMENTS:</u> Continued process of planning project tasks and how they will be conducted. Delivered work plan as part of the protocol on Nov. 9 <sup>th</sup> .
	<u>NEXT MONTH:</u> We don't anticipate more work on this task since it is nearly complete.

TASK C.5.4	<u>ACCOMPLISHMENTS:</u> This task has yet to begin.
	<u>NEXT MONTH:</u> Commence development of simulation plan sensitive to the effects of cannabis.

TASK C.5.5	<u>ACCOMPLISHMENTS:</u> Received an updated version of the protocol from NIDA on Nov. 3 <sup>rd</sup> . Addressed issues related to the protocol and held a teleconference with NIDA on Nov. 8 <sup>th</sup> . Received another updated version of the protocol on Nov. 9 <sup>th</sup> from NIDA. The protocol was nearing completion by the end of the month.
	Started work on the IRB application. Sent various surveys for NIDA review on Nov. 8 <sup>th</sup> . Sent a template for the informed consent on Nov. 17 <sup>th</sup> . The IRB application was nearing completion by the end of the month.
	<u>NEXT MONTH:</u> Finalize protocol and finalize IRB application.

TASK C.5.6	This task has yet to begin.
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<b>TASK C.5.7</b>	This task has yet to begin.
<b>TASK C.5.8</b>	This task has yet to begin.
<b>TASK C.5.9</b>	This task has yet to begin.
<b>TASK C.5.10</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	None.

Project Expenditures				
Categories	Total Amount Originally Budgeted	November Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$1,339	\$3,787	2%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$0	0%
Sub-total	\$272,889	\$1,339	\$3,787	1%
Facilities & Administration	\$139,173	\$683	\$1,931	1%
Simulator Charges	\$92,466	\$0	\$0	0%
Total	\$504,528	\$2,022	\$5,718	1%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	
		IND/IDE Approval Date		
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

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# NHTSA/NIDA Monthly Report

## DECEMBER 2011

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	December 1, 2011 – December 31, 2011
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

SUMMARY	Made progress on Tasks 5.1, 5.4, and 5.5.
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TASK C.5.1	<u>ACCOMPLISHMENTS:</u> Delivered the November monthly progress report on Dec. 15 <sup>th</sup> .
	<u>NEXT MONTH:</u> Prepare December monthly report.

TASK C.5.2	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

TASK C.5.3	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

TASK C.5.4	<u>ACCOMPLISHMENTS:</u> Held a teleconference on Dec. 16 <sup>th</sup> with NHTSA and NIDA to discuss the start of this task and solicit ideas from everyone. Shared a video of the pre-existing scenario drive from alcohol on Dec. 16 <sup>th</sup> .
	<u>NEXT MONTH:</u> Prepare the scenario specification plan.

TASK C.5.5	<u>ACCOMPLISHMENTS:</u> Sent a draft of the informed consent and altered video release to NHTSA on Dec. 2 <sup>nd</sup> . Completed the IRB application on Dec. 5 <sup>th</sup> . During the teleconference with NHTSA and NIDA on Dec. 16 <sup>th</sup> , it was decided that the IRB would be submitted despite the completion of NHTSA's review of the informed consent and video release. IRB was submitted on Dec. 19 <sup>th</sup> .
	<u>NEXT MONTH:</u> Monitor queries from IRB and answer questions. Anticipating IRB approval sometime in mid/late January.

TASK C.5.6	This task has yet to begin.
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<b>TASK C.5.7</b>	This task has yet to begin.
<b>TASK C.5.8</b>	This task has yet to begin.
<b>TASK C.5.9</b>	This task has yet to begin.
<b>TASK C.5.10</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	None.

Project Expenditures				
Categories	Total Amount Originally Budgeted	December Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$4,863	\$7,311	4%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$0	0%
Sub-total	\$272,889	\$4,863	\$7,311	3%
Facilities & Administration	\$139,173	\$2,480	\$3,728	3%
Simulator Charges	\$92,466	\$0	\$0	0%
Total	\$504,528	\$7,343	\$11,039	2%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date		
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

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# NHTSA/NIDA Monthly Report

## JANUARY 2012

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	January 1, 2012 – January 31, 2012
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.1, 5.4, and 5.5.	
TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS:</u> Delivered the December monthly progress report on Jan. 17 <sup>th</sup> .	
	<u>NEXT MONTH:</u> Prepare January monthly report.	
TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS:</u> Started work on the scenario specification plan.	
	<u>NEXT MONTH:</u> Share first draft of scenario specification plan.	
TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS:</u> Communicated with IRB staff through the staff review process. Investigated issues surrounding storage of cannabis at our facility: locking fridge, door alarm and security system. Communicated with CRU regarding the study include food requirements for patients. Answered NIDA's questions on the IND/IDE applications. Received informed consent and video release from NHTSA after their review had been completed on January 18 <sup>th</sup> .	
	<u>NEXT MONTH:</u> Monitor queries from IRB and answer questions. Anticipating IRB approval sometime in mid/late February.	
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	This task has yet to begin.	

<b>TASK C.5.7: DATA COLLECTION</b>	This task has yet to begin.
<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	IRB approval is taking longer than anticipated. The IRB staff review was delayed due to hold-ups at the University's Pharmaceuticals and Therapeutics committee review. We are anticipating having IRB scheduled for full board review in February.

Project Expenditures				
Categories	Total Amount Originally Budgeted	January Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$6,878	\$14,019	8%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$480	\$480	29%
Sub-total	\$272,889	\$7,358	\$14,499	5%
Facilities & Administration	\$139,173	\$3,753	\$7,394	5%
Simulator Charges	\$92,466	\$0	\$0	0%
Total	\$504,528	\$11,111	\$21,893	4%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date		
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

FEBRUARY 2012

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	February 1, 2012 – February 29, 2012
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.4 and 5.5.	
TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS:</u> Delivered the January monthly progress report on Feb. 15 <sup>th</sup> .	
	<u>NEXT MONTH:</u> Prepare March monthly report.	
TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS:</u> Sent a draft scenario plan to NIDA/NHTSA on Feb. 7 <sup>th</sup> . Held a phone discussion with NIDA/NHTSA to discuss the draft scenario plan on Feb 8 <sup>th</sup> .	
	<u>NEXT MONTH:</u> Develop an internal implementation plan and start drafting changes to scenarios.	
TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS:</u> Communicated with the University's IRB and risk management staff through the IRB approval process. Addressed concerns from risk management and learned that this study's IRB application is finally set for board review on Mar. 5 <sup>th</sup> .	
	<u>NEXT MONTH:</u> Monitor IRB review results and address comments. Submit IND/IED application once we receive materials from NIDA.	
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	This task has yet to begin.	

<b>TASK C.5.7: DATA COLLECTION</b>	This task has yet to begin.
<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	

Project Expenditures				
Categories	Total Amount Originally Budgeted	February Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$2,813	\$17,063	10%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$219	\$699	42%
Sub-total	\$272,889	\$3,032	\$17,762	7%
Facilities & Administration	\$139,173	\$1,547	\$9,058	7%
Simulator Charges	\$92,466	\$0	\$0	0%
Total	\$504,528	\$4,579	\$26,820	5%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date		
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

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# NHTSA/NIDA Monthly Report

## MARCH 2012

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	March 1, 2012 – March 31, 2012
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.4 and 5.5.	
TASK C.5.1: REPORTING	ACCOMPLISHMENTS: Delivered the February monthly progress report on Mar 19 <sup>th</sup> .	
	NEXT MONTH: Prepare April monthly report.	
TASK C.5.2: INITIAL BRIEFING	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.3: WORK PLAN	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.4: SCENARIOS	ACCOMPLISHMENTS: Identified specific locations on the IMPACT scenarios where additional events for this study will be introduced. Developed an internal implementation plan to start drafting changes to scenarios.	
	NEXT MONTH: Implement changes to scenarios.	
TASK C.5.5: IRB, IND, DEA	ACCOMPLISHMENTS: Received comments from IRB board on the review of our application and forwarded to NIDA on Mar 12 <sup>th</sup> . Started discussions regarding study procedures. Started work on DEA, IND, and IED applications with support from NIDA. Received Informed Consent edits from NHTSA on Mar 22 <sup>nd</sup> . Received conditional approval from University IRB on our study on Mar 26 <sup>th</sup> .	
	NEXT MONTH: Monitor status of applications. Continue to refine and document study procedures..	
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	This task has yet to begin.	

<b>TASK C.5.7: DATA COLLECTION</b>	This task has yet to begin.
<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	

Project Expenditures				
Categories	Total Amount Originally Budgeted	March Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$8,437	\$25,516	15%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$699	42%
Sub-total	\$272,889	\$8,437	\$26,215	10%
Facilities & Administration	\$139,173	\$4,303	\$13,370	10%
Simulator Charges	\$92,466	\$0	\$0	0%
Total	\$504,528	\$12,740	\$39,584	8%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date		
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

APRIL 2012

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	April 1, 2012 – April 30, 2012
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

SUMMARY	Made progress on Tasks 5.4 and 5.5.
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TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS</u> : Delivered the March monthly progress report on April 17 <sup>th</sup> . Held a teleconference with NHTSA/NIDA on the 23 <sup>rd</sup> . Finalized dates for the site visit for May.
	<u>NEXT MONTH</u> : Prepare May monthly report. Host visit from NIDA and NHTSA.

TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.

TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.

TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS</u> : Started implementation of changes to scenario in the hardware and software.
	<u>NEXT MONTH</u> : Finish implementation of changes to scenarios..

TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS</u> : Received comments from case report forms from NIDA on the 1 <sup>st</sup> . Received IND number on the 12 <sup>th</sup> .and sent the IND letter to NHTSA/NIDA on the 16 <sup>th</sup> . Sent revised case reports forms to NIDA on the 19 <sup>th</sup> . Worked with NIDA to answer FDA's questions for the IND and sent them to the FDA by the 24 <sup>th</sup> . Received IND/IDE approval on the 27 <sup>th</sup> .
	<u>NEXT MONTH</u> : Monitor status of DEA application. Organize and hold the site visit at NADS.

TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	This task has yet to begin.
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TASK C.5.7: DATA	This task has yet to begin.
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<b>COLLECTION</b>	
<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	

Project Expenditures				
Categories	Total Amount Originally Budgeted	April Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$7,017	\$32,708	20%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$18	\$717	43%
Sub-total	\$272,889	\$7,035	\$33,425	12%
Facilities & Administration	\$139,173	\$3,579	\$17,047	12%
Simulator Charges	\$92,466	\$0	\$0	0%
Total	\$504,528	\$10,614	\$50,471	10%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

MAY 2012

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	May 1, 2012 – May 31, 2012
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

SUMMARY	Made progress on Tasks 5.4 and 5.5.
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TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS</u> : Delivered the March monthly progress report on May 25 <sup>th</sup> . Hosted a site visit from NHTSA and NIDA on the 22 <sup>nd</sup> and 23 <sup>rd</sup> .
	<u>NEXT MONTH</u> : Prepare June monthly report.

TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.

TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.

TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS</u> : Finished implementation of changes to scenario in preparation for site visit. Visitors from NHTSA and NIDA drove the scenario on NADS-1 and then provided comments. A list of revisions that need to be made to the scenarios was compiled.
	<u>NEXT MONTH</u> : Work on revisions to scenario and then generate 2 versions in preparation for the pilot study.

TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS</u> : Worked on protocol amendment and resubmitted to FDA and IRB. Generated a cover letter and a new 1571 for FDA. Ordered three laptop PCs that will be dedicated to running the various tests (E-Prime, Rogers, BART). These laptops were not budgeted as part of the study and thus are being paid from internal funds. Received comments from case report forms from NIDA on the 1 <sup>st</sup> . Received Certificate of Confidentiality on the 14 <sup>th</sup> . Sent <a href="http://ClinicalTrials.org">ClinicalTrials.org</a> responses for NIDA review on the 25 <sup>th</sup> and received comments on the 29 <sup>th</sup> .
	<u>NEXT MONTH</u> : Monitor status of DEA application. Host site visit from DEA in late June.

TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	This task has yet to begin.
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<b>TASK C.5.7: DATA COLLECTION</b>	This task has yet to begin.
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<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	We are unable to start pilot testing due to delays with receiving the DEA approval. The necessary paperwork has been filed and staff are regularly communicating with DEA officials to move process along.
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<b>Project Expenditures</b>				
<b>Categories</b>	<b>Total Amount Originally Budgeted</b>	<b>May Expenditures</b>	<b>Total Expenditures</b>	<b>Total Percentage Budget Used</b>
Labor	\$165,696	\$13,127	\$45,978	28%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$717	43%
Sub-total	\$272,889	\$13,127	\$46,695	17%
Facilities & Administration	\$139,173	\$6,695	\$23,814	17%
Simulator Charges	\$92,466	\$6,605	\$6,605	7%
Total	\$504,528	\$26,427	\$77,114	15%

\*Does not include Westat costs/overhead.



Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	Within 4 weeks of receipt	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	TBD/Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: TBD/within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	TBD/Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	TBD/Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	TBD/Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	TBD/Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	TBD/Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	TBD/Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

## JUNE 2012

<b>PROJECT INFORMATION</b>	<p>Contract Number: DTNH22-11-D-00237/004</p> <p>Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance</p> <p>Period Covered: June 1, 2012 – June 30, 2012</p> <p>COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a></p> <p>PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a></p> <p>Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a></p> <p>PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a></p>
<b>SUMMARY</b>	<p>Made progress on Tasks 5.4 and 5.5. Cheryl Roe has left NADS and has been replaced by Jennifer Henderson in the role of coordinator for this study. All communications to Cheryl should now be directed to Jennifer at <a href="mailto:Jennifer-henderson@uiowa.edu">Jennifer-henderson@uiowa.edu</a> or 319-335-4775.</p>
<b>TASK C.5.1: REPORTING</b>	<p><u>ACCOMPLISHMENTS:</u> Delivered the April monthly progress report on June 15<sup>th</sup>.</p> <p><u>NEXT MONTH:</u> Prepare July monthly report.</p>
<b>TASK C.5.2: INITIAL BRIEFING</b>	<p><u>ACCOMPLISHMENTS:</u> This task is complete.</p> <p><u>NEXT MONTH:</u> N/A.</p>
<b>TASK C.5.3: WORK PLAN</b>	<p><u>ACCOMPLISHMENTS:</u> This task is complete.</p> <p><u>NEXT MONTH:</u> N/A.</p>
<b>TASK C.5.4: SCENARIOS</b>	<p><u>ACCOMPLISHMENTS:</u> Started work on the revisions to scenario based on comments from site visit in May.</p> <p><u>NEXT MONTH:</u> Complete 2 scenarios in preparation for the pilot study.</p>
<b>TASK C.5.5: IRB, IND, DEA</b>	<p><u>ACCOMPLISHMENTS:</u> Hosted a site visit from the DEA on the 28<sup>th</sup>. The site visit went well and DEA was given all information requested in a timely manner. We anticipate full approval from DEA in July.</p> <p>Received the investigational devices on the 5<sup>th</sup> and began process of familiarization with the use/operation of these devices.</p> <p>Revised the participant visit timeline and sent it for review to NIDA/NHTSA on the 6<sup>th</sup>.</p> <p>Revised the case report forms and sent for review to NIDA/NHTSA on the 7<sup>th</sup>.</p> <p>Ordered an additional freezer, refrigerator and scale to support the requirements of the study.</p> <p><u>NEXT MONTH:</u> Monitor approval notice from DEA.</p>

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	This task has yet to begin; however we are fielding inquiries from ClinicalTrials.gov.
<b>TASK C.5.7: DATA COLLECTION</b>	This task has yet to begin.
<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	<p>We are unable to start pilot testing due to delays with receiving the DEA approval. The DEA visited our facility on June 28<sup>th</sup> and left satisfied that everything met their requirements and expectations. As of the writing of this report, we still have not received official approval. Item #8 (Pilot Study) on the milestone and deliverables list was supposed to be complete 3 months after receiving IRB/IND approval. We are unable to move forward with conducting the pilot study as DEA approval is also required us to receive the Cannabis and use it for the pilot study.</p> <p>We have not been able to begin recruiting and screen individuals as IRB material will not be released until DEA license is in place.</p> <p>Scenarios are not yet complete but are continued to be refined while we await the DEA license.</p>

Project Expenditures				
Categories	Total Amount Originally Budgeted	June Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$14,208	\$60,459	36%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$2,467	\$3,183	192%
Sub-total	\$272,889	\$16,675	\$63,642	23%
Facilities & Administration	\$139,173	\$8,504	\$32,457	23%
Simulator Charges	\$92,466	\$41,830	\$41,830	45%
Total	\$504,528	\$67,009	\$137,929	27%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

JULY 2012

PROJECT INFORMATION	Contract Number: DTNH22-11-D-00237/004
	Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered: July 1, 2012 – July 31, 2012
	COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.4 and 5.5.
TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS</u> : Delivered the June monthly progress report on July 20 <sup>th</sup> .
	<u>NEXT MONTH</u> : Prepare August monthly report.
TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS</u> : Continued refinement on revisions to scenarios.
	<u>NEXT MONTH</u> : Put final touches on 2 scenarios in preparation for the pilot study.
TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS</u> : DEA requested more information about NADS after their visit. This information was sent to them quickly to facilitate a quick turnaround on formally receiving DEA approval documents. We received the registration number electronically on July 30 <sup>th</sup> but won't receive the paper copy for another couple of weeks.
	Worked with NIDA to finalize case report forms, shipping schedule and the process for ordering cannabis.
	<u>NEXT MONTH</u> : Submit DEA form 222. Start ordering Cannabis in preparation for pilot study.
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	This task has yet to begin; however we are fielding inquiries from ClinicalTrials.gov.

<b>TASK C.5.7: DATA COLLECTION</b>	This task has yet to begin.
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<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	<p>Given that we still haven't received formal DEA approval, we haven't been able to begin pilot testing as planned. We have made every effort to be responsive to DEA questions and see slow progress towards receiving approval.</p> <p>Item #8 (Pilot Study) on the milestone and deliverables list was supposed to be complete 3 months after receiving IRB/IND approval. We are unable to move forward with conducting the pilot study as DEA approval is also required us to receive the Cannabis and use it for the pilot study.</p> <p>We have not been able to begin recruiting and screen individuals as IRB material will not be released until DEA license is in place.</p>
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<b>Project Expenditures</b>				
<b>Categories</b>	<b>Total Amount Originally Budgeted</b>	<b>July Expenditures</b>	<b>Total Expenditures</b>	<b>Total Percentage Budget Used</b>
Labor	\$165,696	\$8,735	\$69,193	42%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$2,410	\$5,593	338%
Sub-total	\$272,889	\$11,145	\$74,786	27%
Facilities & Administration	\$139,173	\$5,684	\$38,141	27%
Simulator Charges	\$92,466	\$41,830	\$41,830	45%
Total	\$504,528	\$58,659	\$154,757	31%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*





# NHTSA/NIDA Monthly Report

## AUGUST 2012

<b>PROJECT INFORMATION</b>	<p>Contract Number: DTNH22-11-D-00237/004</p> <p>Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance</p> <p>Period Covered: August 1, 2012 – August 31, 2012</p> <p>COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a></p> <p>PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a></p> <p>Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a></p> <p>PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a></p>
<b>SUMMARY</b>	<p>Made progress on Tasks 5.4 and 5.5. Dowlin Johnson, one of our graduate students from Pharmacy, is no longer going to be available to help us with the study. We had brought Dowlin on-board in June with the idea that study was going to enter data collection over the summer. Dowlin is being replaced by Kayla Smith, a undergraduate student who has been working at NADS on various studies for over a year.</p>
<b>TASK C.5.1: REPORTING</b>	<p><u>ACCOMPLISHMENTS:</u> Delivered the July monthly progress report on August 20<sup>th</sup>.</p> <p><u>NEXT MONTH:</u> Prepare September monthly report.</p>
<b>TASK C.5.2: INITIAL BRIEFING</b>	<p><u>ACCOMPLISHMENTS:</u> This task is complete.</p> <p><u>NEXT MONTH:</u> N/A.</p>
<b>TASK C.5.3: WORK PLAN</b>	<p><u>ACCOMPLISHMENTS:</u> This task is complete.</p> <p><u>NEXT MONTH:</u> N/A.</p>
<b>TASK C.5.4: SCENARIOS</b>	<p><u>ACCOMPLISHMENTS:</u> Finished refinement of 2 scenarios for pilot study.</p> <p><u>NEXT MONTH:</u> Test practice drive for screening drives. Perform simulator drives to ensure that we are ready for pilot testing. This is particularly with respect to having to switch the simulator between the NIDA and CWIM (another NHTSA project) on a daily basis as both data collection are anticipated to overlap each each.</p>
<b>TASK C.5.5: IRB, IND, DEA</b>	<p><u>ACCOMPLISHMENTS:</u> The DEA Form 222 was submitted on the 3<sup>rd</sup>.</p> <p><u>NEXT MONTH:</u> Anticipate receiving Cannabis in September.</p>
<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<p>This task is anticipated to start in September.</p>

<b>TASK C.5.7: DATA COLLECTION</b>	This task has yet to begin.
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<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	<p>Given that we still haven't received formal DEA approval, we haven't been able to begin pilot testing as planned. We have made every effort to be responsive to DEA questions and see slow progress towards receiving approval.</p> <p>Item #8 (Pilot Study) on the milestone and deliverables list was supposed to be complete 3 months after receiving IRB/IND approval. We are unable to move forward with conducting the pilot study as DEA approval is also required us to receive the Cannabis and use it for the pilot study.</p> <p>We have not been able to begin recruiting and screen individuals as IRB material will not be released until DEA license is in place.</p>
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Project Expenditures				
Categories	Total Amount Originally Budgeted	August Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$8,721	\$77,901	47%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$1,963	\$5,147	311%
Sub-total	\$272,889	\$10,684	\$83,048	30%
Facilities & Administration	\$139,173	\$5,449	\$42,354	30%
Simulator Charges	\$92,466	\$0	\$41,830	45%
Total	\$504,528	\$16,133	\$167,232	33%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

## SEPTEMBER 2012

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	September 1, 2012 – September 30, 2012
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.4 and 5.5, and 5.6.	
TASK C.5.1: REPORTING	ACCOMPLISHMENTS: Delivered the August monthly progress report on September 18 <sup>th</sup> .	
	NEXT MONTH: Prepare October monthly report.	
TASK C.5.2: INITIAL BRIEFING	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.3: WORK PLAN	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.4: SCENARIOS	ACCOMPLISHMENTS: Prepared to start pilot study.	
	NEXT MONTH: Start the pilot study. Continue development on remaining 4 scenarios in preparation for start of main study in November.	
TASK C.5.5: IRB, IND, DEA	ACCOMPLISHMENTS: The cannabis arrived at our facility in the first half of the month and was secured in the double-locked and alarmed facilities that we built specifically for this study. This was an unplanned expense that was not budgeted for and was funded internally.	
	NEXT MONTH: Any IRB mod required based on the Pilot will be submitted.	

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<b>ACCOMPLISHMENTS:</b> We started recruiting subjects for the study and ran the first day of screening in the NADS-1 on Sept. 17 <sup>th</sup> .
	<b>NEXT MONTH:</b> Continue this process in preparation for start of main study in November.
<b>TASK C.5.7: DATA COLLECTION</b>	This task has yet to begin.
<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	<p>So far, UI has spent 53% of the labor budget (\$88K out of \$165K) (shown in Table 1). If we carry out the project as planned then a budget overrun of approximately \$59K is projected (shown in Table 2). The reasons for budget issues can be attributed to the following:</p> <ol style="list-style-type: none"> <li>1. An extended process of obtaining IRB, IND and DEA approval. This process required more time and effort than initially planned and budgeted.</li> <li>2. Staff changes required resources to train new staff and allow time for familiarization with to study procedures.</li> <li>3. The development effort being greater than anticipated as scenarios updates took longer than anticipated to test and validate.</li> </ol> <p>UI also encountered project-related costs that required improvements to the facility. These costs are shown in Table 3 and were in the amount of \$11,623. These costs were paid by internal accounts.</p> <p>All of the budget numbers presented assume a total budget for this study in the amount of \$504,528. We'd like to note that, so far, UI has received an allocation of \$370,000 (of which ~\$186,000 has been spent). We request that NHTSA provides us with an indication of when the remainder amount of the overall study budget will be allocated.</p> <p>We are proposing scheduling a teleconference to discuss these issues and devise a plan for moving forward.</p>

Table 1: Total Project Expenditures		
Task	Labor Direct Budget	Estimated Labor Direct Expenditures
5.1: Reporting	\$14,909	\$12,000
5.2: Initial Briefing	\$2,460	\$3,000
5.3: Work Plan	\$4,548	\$5,000
5.4: Scenarios and Pilot	\$32,211	\$42,873
5.5: IRB, IND, DEA	\$5,401	\$21,000
5.6: Recruitment, Screening,	\$11,296	\$4,663
5.7: Data Collection	\$61,745	\$0
5.8: Analysis	\$23,250	\$0
5.9: Final Report	\$6,720	\$0
5.10: Assist with Final Briefing	\$3,155	\$0
<b>Total</b>	<b>\$165,696</b>	<b>\$88,536</b>

Table 2	
Forecasted	10/18/2012
Spent through September	\$88,536
Gary Gaffney Uncharged	\$10,096
October '12	\$11,500
November '12	\$8,000
December '12	\$8,000
January '13	\$11,000
February '13	\$8,000
March '13	\$11,000
April '13	\$8,000
May '13	\$11,000
June '13	\$8,000
July '13	\$6,900
August '13	\$6,900
September '13	\$7,500
<b>Direct Sub-Total</b>	<b>\$204,431</b>
<b>Indirect</b>	<b>\$19,755</b>
<b>Total</b>	<b>\$224,186</b>
<b>Overrun</b>	<b>\$58,490</b>

Table 3 - UI Contribution	
Item Description	UI Contribution
Installation of exhausts in participant dosing rooms	\$10,079
Alarmed security system for cannabis storage	\$966
Cabinets and shelves for storage room	\$577
<b>UI Contribution Total</b>	<b>\$11,623</b>

Project Expenditures				
Categories	Total Amount Originally Budgeted	September Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$10,872	\$88,536	53%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$0	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$380	\$4,577	276%
Sub-total	\$272,889	\$11,252	\$93,113	34%
Facilities & Administration	\$139,173	\$5,738	\$47,972	34%
Simulator Charges	\$92,466	\$0	\$41,830	45%
Total	\$504,528	\$16,990	\$182,915	36%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*





# NHTSA/NIDA Monthly Report

OCTOBER 2012

<b>PROJECT INFORMATION</b>	<p>Contract Number: DTNH22-11-D-00237/004</p> <p>Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance</p> <p>Period Covered: October 1, 2012 – October 31, 2012</p> <p>COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a></p> <p>PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a></p> <p>Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a></p> <p>PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a></p>
<b>SUMMARY</b>	Made progress on Tasks 5.4 and 5.5, and 5.6.
<b>TASK C.5.1: REPORTING</b>	<p><b>ACCOMPLISHMENTS:</b> Delivered the September monthly progress report on October 24<sup>th</sup>. This report highlighted budget issues which were discussed in November (covered in next month's report).</p> <p><b>NEXT MONTH:</b> Prepare November monthly report.</p>
<b>TASK C.5.2: INITIAL BRIEFING</b>	<p><b>ACCOMPLISHMENTS:</b> This task is complete.</p> <p><b>NEXT MONTH:</b> N/A.</p>
<b>TASK C.5.3: WORK PLAN</b>	<p><b>ACCOMPLISHMENTS:</b> This task is complete.</p> <p><b>NEXT MONTH:</b> N/A.</p>
<b>TASK C.5.4: SCENARIOS</b>	<p><b>ACCOMPLISHMENTS:</b> Finish final preparations for pilot data collection. Conducted and completed the pilot study. Started reduction of pilot data.</p> <p><b>NEXT MONTH:</b> Finish reduction of pilot data. Conduct analysis and provide recommendations for changes to scenarios. Finish changes to all six scenarios and prepare for start of main data collection.</p>
<b>TASK C.5.5: IRB, IND, DEA</b>	<p><b>ACCOMPLISHMENTS:</b> Held a discussion with NIDA/NHTSA in early October on opening up range for alcohol experience. This was to make it possible to find enough participants that meet the criteria to participate in the study.</p> <p><b>NEXT MONTH:</b> Any IRB mod required based on the Pilot will be submitted.</p>

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<b>ACCOMPLISHMENTS:</b> Started recruitment of subjects for main study.
	<b>NEXT MONTH:</b> Continue recruitment and conduct screenings.
<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> This task has yet to begin.
	<b>NEXT MONTH:</b> Start main data collection.
<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	

Project Expenditures				
Categories	Total Amount Originally Budgeted	October Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$14,398	\$103,221	62%
Subject Payment	\$32,690	\$0	\$0	0%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$125	\$125	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$4,639	280%
Sub-total	\$272,889	\$14,523	\$107,985	40%
Facilities & Administration	\$139,173	\$6,954	\$55,072	40%
Simulator Charges	\$92,466	\$0	\$41,830	45%
Total	\$504,528	\$21,477	\$204,887	41%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

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# NHTSA/NIDA Monthly Report

NOVEMBER 2012

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	November 1, 2012 – November 30, 2012
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Made progress on Tasks 5.4 and 5.5, and 5.6.
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<b>TASK C.5.1: REPORTING</b>	<b>ACCOMPLISHMENTS:</b> Delivered the September monthly progress report on October 24 <sup>th</sup> . This report highlighted budget issues which were discussed in November (covered in next month's report).
	<b>NEXT MONTH:</b> Prepare November monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<b>ACCOMPLISHMENTS:</b> This task is complete.
	<b>NEXT MONTH:</b> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<b>ACCOMPLISHMENTS:</b> This task is complete.
	<b>NEXT MONTH:</b> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<b>ACCOMPLISHMENTS:</b> Finished reduction of raw simulator data from the pilot study. Analyzed the data and provided recommendations to NIDA/NHTSA on changes to scenario on Nov. 16 <sup>th</sup> . Received approval from NIDA on Nov. 20 <sup>th</sup> to make the changes and move ahead. Performed the changes to scenario, training materials and prepared for the start of the main data collection.
	<b>NEXT MONTH:</b> None.

<b>TASK C.5.5: IRB, IND, DEA</b>	<b>ACCOMPLISHMENTS:</b> Submitted a modification to IRB based on the pilot study.
	<b>NEXT MONTH:</b> None

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS</u> : Started recruitment of subjects for main study.
	<u>NEXT MONTH</u> : Continue recruitment and conduct screenings.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS</u> : This task has yet to begin.
	<u>NEXT MONTH</u> : Start main data collection.

<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	
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Project Expenditures				
Categories	Total Amount Originally Budgeted	November Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$18,632	\$121,999	74%
Subject Payment	\$32,690	\$2,224	\$2,224	7%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$125	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$116	\$4,755	287%
Sub-total	\$272,889	\$20,972	\$129,103	47%
Facilities & Administration	\$139,173	\$10,696	\$65,842	47%
Simulator Charges	\$92,466	\$0	\$41,830	45%
Total	\$504,528	\$31,668	\$236,775	47%

\*Does not include Westat costs/overhead.

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

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# NHTSA/NIDA Monthly Report

## DECEMBER 2012

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	December 1, 2012 – December 31, 2012
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.4 and 5.5, 5.6, and 5.7. Started main data collection.	
TASK C.5.1: REPORTING	ACCOMPLISHMENTS: Delivered the November monthly progress report on December 24 <sup>th</sup> .	
	NEXT MONTH: Prepare January monthly report.	
TASK C.5.2: INITIAL BRIEFING	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.3: WORK PLAN	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.4: SCENARIOS	ACCOMPLISHMENTS: Final adjustments were made to scenario restarts. Adjusted event markers for events to maintain consistency with documentation.	
	NEXT MONTH: None.	
TASK C.5.5: IRB, IND, DEA	ACCOMPLISHMENTS: Received IRB approval for modification submitted in November.	
	NEXT MONTH: None	
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	ACCOMPLISHMENTS: Recruit participants and conduct screenings. .	
	NEXT MONTH: Continue to recruitment and screen participants.	

TASK C.5.7: DATA COLLECTION	<b>ACCOMPLISHMENTS:</b> Started main data collection. Developed a timeline for the staff/student effort required to run the NIDA protocol.		
	<b>Description</b>	<b>As of 12/31/12</b>	<b>As of 1/29/13</b>
	# enrolled (that have signed consent forms and have been screened)	21	21
	# randomized	10	10
	# of people ceased participation	1	2
	# of people being run	6	5
	# of people eligible for randomized that haven't been randomized	4	4
<b>NEXT MONTH:</b> Continue main data collection.			

TASK C.5.8: ANALYSIS	This task has yet to begin.
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TASK C.5.9: REPORT	This task has yet to begin.
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TASK C.5.10: ASSIST WITH FINAL BRIEFING	This task has yet to begin.
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PROBLEMS / DELAYS	NADS is in the process of creating a request for additional funding. The need for more funding was initially called out in the Sept. '12 monthly progress report. A phone call was scheduled between NHTSA, NIDA and NADS on Nov 6, '12 to discuss the need for the request. During the call, NADS presented ideas on how the study scope could be adjusted to manage the budget issues. Scope adjustments were not received as acceptable so the primary outcome of this meeting was for NADS to provide a written justification for the need for additional funding.
	NHTSA (Dereece Smither) checked on the progress of NADS' response on Dec 7, '12. Given that the primary reason for the request for additional funding was because NADS was exercising a research protocol that it hadn't experienced before, we wanted to put it in practice in December to determine the difference between our initial budget estimates and the actual expenditures. Now that December is complete, NADS has documented this difference and is generating a written justification which will be delivered to NHTSA during the week of January 28 <sup>th</sup> .

Project Expenditures				
Categories	Total Amount Originally Budgeted	December Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$14,983	\$137,190	83%
Subject Payment	\$32,690	\$0	\$2,224	7%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$125	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$100	\$4,855	293%
Sub-total	\$272,889	\$15,083	\$144,395	53%



Facilities & Administration	\$139,173	\$7,692	\$73,641	53%
Simulator Charges	\$92,466	\$0	\$41,830	45%
<b>Total</b>	<b>\$504,528</b>	<b>\$22,775</b>	<b>\$259,866</b>	<b>52%</b>

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
<b>Total</b>			<b>146.25</b>	<b>39.00</b>

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

## JANUARY 2013

<b>PROJECT INFORMATION</b>	Contract Number: DTNH22-11-D-00237/004
	Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered: January 1, 2013 – January 31, 2013
	COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
<b>SUMMARY</b>	Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection.
<b>TASK C.5.1: REPORTING</b>	<b>ACCOMPLISHMENTS:</b> Delivered the December monthly progress report on January 30 <sup>th</sup> . Provided a response to NHTSA query about invoices in late January.
	<b>NEXT MONTH:</b> Prepare February monthly report.
<b>TASK C.5.2: INITIAL BRIEFING</b>	<b>ACCOMPLISHMENTS:</b> This task is complete.
	<b>NEXT MONTH:</b> N/A.
<b>TASK C.5.3: WORK PLAN</b>	<b>ACCOMPLISHMENTS:</b> This task is complete.
	<b>NEXT MONTH:</b> N/A.
<b>TASK C.5.4: SCENARIOS</b>	<b>ACCOMPLISHMENTS:</b> This task is complete.
	<b>NEXT MONTH:</b> N/A.
<b>TASK C.5.5: IRB, IND, DEA</b>	<b>ACCOMPLISHMENTS:</b> Developed a updated timeline for how much staff effort is required to support this study. This timeline was used to develop a justification for additional funding.
	<b>NEXT MONTH:</b> None
<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<b>ACCOMPLISHMENTS:</b> Continue recruiting participants and conduct screenings. .
	<b>NEXT MONTH:</b> Continue to recruitment and screen participants.

TASK C.5.7: DATA COLLECTION	<b>ACCOMPLISHMENTS:</b> Started main data collection. Developed a timeline for the staff/student effort required to run the NIDA protocol.		
	<b>Description</b>	<b>As of 01/31/13</b>	<b>As of 02/26/13</b>
	# enrolled (that have signed consent forms and have been screened)	21	29
	# randomized	10	12
	# of people ceased participation	1	2
	# of people being run	6	4
	# of people eligible for randomized that haven't been randomized	4	4
	<b>NEXT MONTH:</b> Continue main data collection.		

TASK C.5.8: ANALYSIS	This task has yet to begin.
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TASK C.5.9: REPORT	This task has yet to begin.
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TASK C.5.10: ASSIST WITH FINAL BRIEFING	This task has yet to begin.
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PROBLEMS / DELAYS	A justification for additional funding was delivered to NHTSA on Feb 6, 2013.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	January Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$11,956	\$148,858	90%
Subject Payment	\$32,690	\$972	\$3,196	10%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$125	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$240	\$5,095	308%
Sub-total	\$272,889	\$13,168	\$157,274	58%
Facilities & Administration	\$139,173	\$1,623	\$80,210	58%
Simulator Charges	\$92,466	\$15,411	\$57,241	62%
Total	\$504,528	\$30,202	\$294,725	58%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Total			162.00	54.75

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

## FEBRUARY 2013

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	February 1, 2013 – February 28, 2013
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection.	
TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS:</u> Delivered the January monthly progress report on February 26 <sup>th</sup> .	
	<u>NEXT MONTH:</u> Prepare March monthly report.	
TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS:</u> None.	
	<u>NEXT MONTH:</u> None	
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	<u>ACCOMPLISHMENTS:</u> Continue recruiting participants and conduct screenings. .	
	<u>NEXT MONTH:</u> Continue to recruitment and screen participants.	

TASK C.5.7: DATA COLLECTION	<b>ACCOMPLISHMENTS:</b> Continued main data collection. Recruitment continues to be an issue.	
	<b>Description</b>	<b>As of 02/26/13</b>
	# enrolled (that have signed consent forms and have been screened)	29
	# randomized	12
	# of people ceased participation	2
	# of people being run	4
	# of people eligible for randomized that haven't been randomized	4
	<b>NEXT MONTH:</b> Continue main data collection.	

TASK C.5.8: ANALYSIS	This task has yet to begin.
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TASK C.5.9: REPORT	This task has yet to begin.
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TASK C.5.10: ASSIST WITH FINAL BRIEFING	This task has yet to begin.
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PROBLEMS / DELAYS	A justification for additional funding was delivered to NHTSA on Feb 6, 2013.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	February Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$12,337	\$160,498	97%
Subject Payment	\$32,690	\$0	\$3,196	10%
Subject Transportation	\$3,646	\$0	\$0	0%
Use of CRU	\$68,850	\$0	\$125	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$98	\$5,194	313%
Sub-total	\$272,889	\$12,435	\$169,013	62%
Facilities & Administration	\$139,173	\$6,342	\$86,197	62%
Simulator Charges	\$92,466	\$0	\$57,241	62%
Total	\$504,528	\$18,777	\$312,450	62%

\*Does not include Westat costs/overhead.



NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Total			199.25	54.75

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

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# NHTSA/NIDA Monthly Report

## MARCH 2013

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	March 1, 2013 – March 31, 2013
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
SUMMARY	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
	Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection.	
TASK C.5.1: REPORTING	ACCOMPLISHMENTS:	Delivered the February monthly progress report on April 5, 2013.
	NEXT MONTH:	Prepare April monthly report.
TASK C.5.2: INITIAL BRIEFING	ACCOMPLISHMENTS:	This task is complete.
	NEXT MONTH:	N/A.
TASK C.5.3: WORK PLAN	ACCOMPLISHMENTS:	This task is complete.
	NEXT MONTH:	N/A.
TASK C.5.4: SCENARIOS	ACCOMPLISHMENTS:	This task is complete.
	NEXT MONTH:	N/A.
TASK C.5.5: IRB, IND, DEA	ACCOMPLISHMENTS:	None.
	NEXT MONTH:	Work on annual regulatory renewals for IND.
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	ACCOMPLISHMENTS:	Continue recruiting participants and conduct screenings.
	NEXT MONTH:	Continue to recruitment and screen participants.

TASK C.5.7: DATA COLLECTION	<b>ACCOMPLISHMENTS:</b> Held a meeting with NIDA regarding quality of data on the 25 <sup>th</sup> . Held meetings with CRU to cover procedures and provide additional training to staff who are involved. Continued main data collection. Recruitment continues to be an issue.	
	<b>Description</b>	<b>As of 03/29/13</b>
	# enrolled (that have signed consent forms and have been screened)	33
	# randomized	15
	# of people ceased participation	2-4
	# of people being run	3
	# of people eligible for randomized that haven't been randomized	4
	<b>NEXT MONTH:</b> Continue main data collection.	

TASK C.5.8: ANALYSIS	This task has yet to begin.
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TASK C.5.9: REPORT	This task has yet to begin.
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TASK C.5.10: ASSIST WITH FINAL BRIEFING	This task has yet to begin.
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PROBLEMS / DELAYS	A justification for additional funding was delivered to NHTSA on Feb 6, 2013.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	March Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$12,660	\$174,227	105%
Subject Payment	\$32,690	\$5,708	\$8,904	27%
Subject Transportation	\$3,646	\$58	\$58	2%
Use of CRU	\$68,850	\$0	\$125	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$5,194	313%
Sub-total	\$272,889	\$18,426	\$188,508	69%
Facilities & Administration	\$139,173	\$9,398	\$96,139	69%
Simulator Charges	\$92,466	\$23,117	\$80,358	87%
Total	\$504,528	\$50,940	\$365,005	72%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.7	Main data collection	18.00	8.25
Total			217.25	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

APRIL 2013

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	April 1, 2013 – April 30, 2013
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection.	
TASK C.5.1: REPORTING	ACCOMPLISHMENTS: Delivered the March monthly progress report on March 15, 2013.	
	NEXT MONTH: Prepare May monthly report.	
TASK C.5.2: INITIAL BRIEFING	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.3: WORK PLAN	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.4: SCENARIOS	ACCOMPLISHMENTS: This task is complete.	
	NEXT MONTH: N/A.	
TASK C.5.5: IRB, IND, DEA	ACCOMPLISHMENTS: Worked on annual regulatory renewals for IND.	
	NEXT MONTH: N/A.	
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	ACCOMPLISHMENTS: Continue recruiting participants and conduct screenings. .	
	NEXT MONTH: Continue to recruitment and screen participants.	

TASK C.5.7: DATA COLLECTION	<u>ACCOMPLISHMENTS</u> : Held meetings with CRU to cover issues related to running 3 participants on one day. We agreed to provide one person from NADS to help out with activities at CRU on those days when we run 3 participants. Continued main data collection. Recruitment continues to be an issue.	
	<b>Description</b>	<b>As of 4/30/2013</b>
	# enrolled (that have signed consent forms and have been screened)	43
	# randomized	21
	# of people ceased participation	3 or 5 – depends on criteria – 3 withdrew after at least one dosing visit, 2 withdrew prior to first dosing visit
	# of people being run	3 continuing from last week, 3 beginning this week (6 total this week)
	# of people eligible for randomized that haven't been randomized	4
	# completed	6
	# phone screened (includes scheduled for screening/training visit, SF)	317
# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	153	
<u>NEXT MONTH</u> : Continue main data collection.		



Project Expenditures				
Categories	Total Amount Originally Budgeted	April Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$11,016	\$183,733	111%
Subject Payment	\$32,690	\$0	\$8,904	27%
Subject Transportation	\$3,646	\$604	\$662	18%
Use of CRU	\$68,850	\$0	\$125	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$121	\$5,315	321%
Sub-total	\$272,889	\$11,741	\$198,739	73%
Facilities & Administration	\$139,173	\$5,988	\$101,357	73%
Simulator Charges	\$92,466	\$0	\$80,358	87%
Total	\$504,528	\$17,729	\$380,453	75%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.7	Main data collection	18.00	8.25
Apr-13	5.7	Main data collection	39.75	0.00
Total			257.00	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

MAY 2013

PROJECT INFORMATION	Contract Number: DTNH22-11-D-00237/004
	Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered: May 1, 2013 – May 31, 2013
	COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection. Received modification to contract on May 8 <sup>th</sup> . Provided information to NIDA for the progress report to ONDCP.
TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS</u> : Delivered the March monthly progress report on April 15, 2013.
	<u>NEXT MONTH</u> : Prepare June monthly report.
TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS</u> : Requested a modification to the protocol to support running of data collection on Saturdays without CRU support in the afternoons.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	<u>ACCOMPLISHMENTS</u> : Continue recruiting participants and conducting screenings. .
	<u>NEXT MONTH</u> : Continue to recruitment and screen participants.

TASK C.5.7: DATA COLLECTION	<u>ACCOMPLISHMENTS</u> : Continued main data collection. Lack of student availability due to University finals slowed down data collection. Recruitment continues to be an issue. We worked on a plan for running data collection on Saturdays that would help facilitate faster completion of this task.	
	<b>Description</b>	<b>As of 4/30/2013</b>
	# enrolled (that have signed consent forms and have been screened)	49
	# randomized	26
	# of people ceased participation	5 or 7 – depends on criteria – 5 withdrew after at least one dosing visit, 2 withdrew prior to first dosing visit
	# of people being run	7 continuing, 1 beginning this week (8 total)
	# of people eligible for randomized that haven't been randomized	4
	# completed	6
	# phone screened (includes scheduled for screening/training visit, SF)	358
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	178
<u>NEXT MONTH</u> : Continue main data collection.		
TASK C.5.8: ANALYSIS	This task has yet to begin.	
TASK C.5.9: REPORT	This task has yet to begin.	
TASK C.5.10: ASSIST WITH FINAL BRIEFING	This task has yet to begin.	
PROBLEMS / DELAYS	According to the SOW, NADS was supposed to complete data collection within 12 months of IND/IDE & IRB approval. Given that these approvals were achieved on 4/27/12, the data collection was to have been completed by 4/27/13. The summary for Task 4.7 describes the current status of the data collection (49 enrolled out of 60, 6 completed out of 20). NADS is asking NHTSA for guidance on how to proceed, but will continue with data collection unless directed otherwise.	

Project Expenditures				
Categories	Total Amount Originally Budgeted	May Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$165,696	\$10,822	\$195,142	118%
Subject Payment	\$32,690	\$0	\$8,904	27%
Subject Transportation	\$3,646	\$204	\$866	24%
Use of CRU	\$68,850	\$0	\$125	0%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$217	\$5,532	334%
Sub-total	\$272,889	\$11,243	\$210,570	77%
Facilities & Administration	\$139,173	\$5,734	\$107,391	77%
Simulator Charges	\$92,466	\$0	\$80,358	87%
Total	\$504,528	\$16,977	\$398,319	79%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.7	Main data collection	18.00	8.25
Apr-13	5.7	Main data collection	39.75	0.00
May-13	5.7	Main data collection	22.50	0.00
Total			279.50	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

JUNE 2013

PROJECT INFORMATION	Contract Number: DTNH22-11-D-00237/004
	Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered: June 1, 2013 – June 30, 2013
	COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection.
TASK C.5.1: REPORTING	ACCOMPLISHMENTS: Delivered the May monthly progress report on June 18, 2013.
	NEXT MONTH: Prepare July monthly report.
TASK C.5.2: INITIAL BRIEFING	ACCOMPLISHMENTS: This task is complete.
	NEXT MONTH: N/A.
TASK C.5.3: WORK PLAN	ACCOMPLISHMENTS: This task is complete.
	NEXT MONTH: N/A.
TASK C.5.4: SCENARIOS	ACCOMPLISHMENTS: This task is complete.
	NEXT MONTH: N/A.
TASK C.5.5: IRB, IND, DEA	ACCOMPLISHMENTS: Completed annual report for IND, and two IRB modifications (one to add research team members, and one to modify the protocol to increase the total N enrolled).
	NEXT MONTH: N/A.
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	ACCOMPLISHMENTS: Continue recruiting participants and conducting screenings. .
	NEXT MONTH: Continue to recruitment and screen participants.

<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> Continued main data collection. Starting this month, we've been running data collection 5 days per week (Tue-Sat). We are currently on pace to have 14 completors by Aug. 12 <sup>th</sup> (best case scenario).	
	<b>Description</b>	<b>As of 6/30/2013</b>
	# enrolled (that have signed consent forms and have been screened)	59
	# randomized	30 (3 people either completed or in progress with more than 1 #, 1 person lost contact with more than 1 # – total of randomized #s used is thus 34)
	# of people ceased participation	16 (includes all withdrawals and lost contacts)
	# of people being run	6
	# of people eligible for randomized that haven't been randomized	1 (lost contact or have randomized all previous)
	# completed	8
	# phone screened (includes scheduled for screening/training visit, SF)	358
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	178
<b>NEXT MONTH:</b> Continue main data collection.		

<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	Given that main data collection is not yet complete, we won't be able to complete the 'Perform & Submit the Analysis of the NADS Data' by July 27, 2013. Best case scenario will yield 14 completors by August 12 <sup>th</sup> .
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Project Expenditures				
Categories	Total Amount Originally Budgeted	June Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$229,839	\$15,181	\$210,669	92%
Subject Payment	\$32,690	\$3,847	\$12,750	39%
Subject Transportation	\$3,646	\$142	\$1,008	28%
Use of CRU	\$68,850	\$21,405	\$21,530	31%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$631	\$6,163	372%
Sub-total	\$337,031	\$41,206	\$252,120	75%
Facilities & Administration	\$171,886	\$21,014	\$128,581	75%
Simulator Charges	\$92,466	\$12,109	\$92,466	100%
Total	\$601,384	\$74,329	\$473,168	79%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.7	Main data collection	18.00	8.25
Apr-13	5.7	Main data collection	39.75	0.00
May-13	5.7	Main data collection	22.50	0.00
Jun-13	5.7	Main data collection	54.50	0.00
Total			334.00	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

JULY 2013

<b>PROJECT INFORMATION</b>	<p>Contract Number: DTNH22-11-D-00237/004</p> <p>Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance</p> <p>Period Covered: July 1, 2013 – July 31, 2013</p> <p>COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a></p> <p>PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a></p> <p>Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a></p> <p>PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a></p>
<b>SUMMARY</b>	<p>Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection. Hired a new staff person (David Kramer) with a CRC designation to serve as an additional research assistant for the study. This person is also being trained to take over the coordinator role as the current coordinator has been interviewing for other positions. NADS has also begun the process of looking for a 2<sup>nd</sup> research assistant to serve as a replacement if needed.</p>
<b>TASK C.5.1: REPORTING</b>	<p><u>ACCOMPLISHMENTS</u>: The monthly report for June was authored but is still going through internal review.</p> <p><u>NEXT MONTH</u>: Prepare August monthly report.</p>
<b>TASK C.5.2: INITIAL BRIEFING</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.3: WORK PLAN</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.4: SCENARIOS</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.5: IRB, IND, DEA</b>	<p><u>ACCOMPLISHMENTS</u>: Completed IRB modification to add research team members.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<p><u>ACCOMPLISHMENTS</u>: Continue recruiting participants and conducting screenings.</p> <p><u>NEXT MONTH</u>: Continue to recruitment and screen participants.</p>

<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> Continued main data collection. Starting in June, we've been running data collection 4 days per week (Tue, Wed, Thurs, Sat). It is anticipated that the data collection will complete in mid to late October.	
	<b>Description</b>	<b>As of 7/31/2013</b>
	# enrolled (that have signed consent forms and have been screened)	76
	# randomized	39 (3 people either completed or in progress with more than 1 #, 1 person lost contact with more than 1 # – total of randomized #s used is thus 43)
	# of people ceased participation	18 (includes all withdrawals, lost contacts, and dropped)
	# of people being run	8 (2 set to begin in August for 10 total)
	# of people eligible for randomized that haven't been randomized	1 (lost contact or have randomized all previous)
	# completed	11
	# phone screened (includes scheduled for screening/training visit, SF)	536
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	79
<b>NEXT MONTH:</b> Continue main data collection.		

<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	Given that main data collection is not yet complete, we have not been able to complete the 'Perform & Submit the Analysis of the NADS Data' by July 27, 2013. Data collection is anticipated to be completed in mid to late October.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	July Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$229,839	\$17,693	\$228,262	99%
Subject Payment	\$32,690	\$0	\$12,750	39%
Subject Transportation	\$3,646	\$0	\$1,008	28%
Use of CRU	\$68,850	\$0	\$21,530	31%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$6,163	372%
Sub-total	\$337,031	\$17,693	\$269,713	80%
Facilities & Administration	\$171,886	\$9,023	\$137,605	80%
Simulator Charges	\$92,466	\$0	\$92,466	100%
Total	\$601,384	\$26,716	\$499,784	83%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Total			387.25	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

## AUGUST 2013

<b>PROJECT INFORMATION</b>	<p>Contract Number: DTNH22-11-D-00237/004</p> <p>Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance</p> <p>Period Covered: August 1, 2013 – August 31, 2013</p> <p>COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a></p> <p>PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a></p> <p>Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a></p> <p>PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a></p>
<b>SUMMARY</b>	<p>Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection. David Kramer is quickly coming up to speed with his knowledge of the study. He's helping run subjects and has also taken over coordination activities when Rose hasn't been around. NADS is continuing the process of looking for a 2<sup>nd</sup> research assistant to serve as a replacement if needed.</p>
<b>TASK C.5.1: REPORTING</b>	<p><u>ACCOMPLISHMENTS</u>: The monthly reports for June and July were delivered on Aug 21<sup>st</sup>.</p> <p><u>NEXT MONTH</u>: Prepare September monthly report.</p>
<b>TASK C.5.2: INITIAL BRIEFING</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.3: WORK PLAN</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.4: SCENARIOS</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.5: IRB, IND, DEA</b>	<p><u>ACCOMPLISHMENTS</u>: N/A.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<p><u>ACCOMPLISHMENTS</u>: Continue recruiting participants and conducting screenings. .</p> <p><u>NEXT MONTH</u>: Continue to recruitment participants. Screenings will only be conducted on an as needed basis.</p>

<b>TASK C.5.7: DATA COLLECTION</b>	<p><b>ACCOMPLISHMENTS:</b> Continued main data collection. Starting in June, we've been running data collection 4 days per week (Tue, Wed, Thurs, Sat). It is now seems likely that the data collection will need to continue beyond October. There are other activities on the calendar that are going to cause conflicts in late October and November which will likely result in having to pause data collection for a few weeks.</p> <table border="1"> <thead> <tr> <th>Description</th><th>As of 8/28/2013</th></tr> </thead> <tbody> <tr> <td># enrolled (that have signed consent forms and have been screened)</td><td>83</td></tr> <tr> <td># randomized</td><td>41 (3 people either completed or in progress with more than 1 #, 1 person lost contact with more than 1 # – total of randomized #s used is thus 45)</td></tr> <tr> <td># of people ceased participation</td><td>21 (includes all withdrawals, lost contacts, and dropped)</td></tr> <tr> <td># of people being run</td><td>8</td></tr> <tr> <td># of people eligible for randomized that haven't been randomized</td><td>2 (one is currently on alternate status)</td></tr> <tr> <td># completed</td><td>13</td></tr> <tr> <td># phone screened (includes scheduled for screening/training visit, SF)</td><td>582</td></tr> <tr> <td># called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)</td><td>60</td></tr> </tbody> </table> <p><b>NEXT MONTH:</b> Continue main data collection.</p>	Description	As of 8/28/2013	# enrolled (that have signed consent forms and have been screened)	83	# randomized	41 (3 people either completed or in progress with more than 1 #, 1 person lost contact with more than 1 # – total of randomized #s used is thus 45)	# of people ceased participation	21 (includes all withdrawals, lost contacts, and dropped)	# of people being run	8	# of people eligible for randomized that haven't been randomized	2 (one is currently on alternate status)	# completed	13	# phone screened (includes scheduled for screening/training visit, SF)	582	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	60
Description	As of 8/28/2013																		
# enrolled (that have signed consent forms and have been screened)	83																		
# randomized	41 (3 people either completed or in progress with more than 1 #, 1 person lost contact with more than 1 # – total of randomized #s used is thus 45)																		
# of people ceased participation	21 (includes all withdrawals, lost contacts, and dropped)																		
# of people being run	8																		
# of people eligible for randomized that haven't been randomized	2 (one is currently on alternate status)																		
# completed	13																		
# phone screened (includes scheduled for screening/training visit, SF)	582																		
# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	60																		

<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	<p>Given that main data collection is not yet complete, we have not been able to complete the 'Perform &amp; Submit the Analysis of the NADS Data' by July 27, 2013. Data collection is not likely to be completed by late October.</p> <p>We held a teleconference with NHTSA on September 19<sup>th</sup> to provide the following update:</p> <ul style="list-style-type: none"> <li>We have completed 13 participants up to now.</li> <li>There are 7 more participants that were being run. However, 4 participants have ended their participation in the last two weeks; 3 of these have cited multiple re-schedulings due to simulator issues as the reason for ending their participation. The 3 participants that are currently enrolled can be completed by the middle of October (barring any unforeseen delays) for a target completed total of 16.</li> <li>The simulator has been experiencing more problems related to the IG (Image Generation) system being down. The latest problem required 3 person-weeks effort to fix and caused a 2 week delay to the NIDA data collection. We have also now exhausted the last of our spare parts and no more spare parts are available. The system is currently operational but can go down at any moment. When the IG goes down the next time, it will result in the system have reduced capability at best. More likely, the system will go down permanently and will not be able to be resurrected due to a lack of availability of replacement parts.</li> <li>Over the course of the past year, there have been 8 instances of problems related to the IG and 5</li> </ul>
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instances of problems related to the projectors. While we've made every effort to minimize downtime, a number of problems have resulted in delays that kept us from running data collection.

- The IG is the set of 2 dozen computers and graphics cards (the three 8ft. tall cabinets in the image below) that are responsible for generating the graphics for the NADS. There are also a set of 8 projectors in the dome that display the graphics on the dome walls of the NADS. Both the IG and projectors were last replaced/updated on the NADS in about 2005. In addition to the hardware components, the IG and projectors have custom vendor-supplied software that integrates these components with the rest of the simulator, tunes the quality of graphics, warps the graphics to be displayed on the curved walls of the dome, etc.



- Due to the age of these components, their mediocre performance and reliability issues, the IG and projectors need to be replaced on the NADS. This is something that we've been planning for over the course of the last year. Our original plan was to update these components this summer. However, this plan was postponed as NIDA data collection was still not completed and the sponsor wanted us to complete the data collection prior to performing the upgrade.
- During the past year, we have worked on identifying the hardware components that make up the new IG and projector display system. We have also been writing a large portion of the software internally. A lot of the effort is being performed internally as that helps control costs and also gives us greater control over the components (both for usability and upgrades) moving forward.
- There is a high risk that if we do not proceed with the upgrade that we will see more significant and long term lost simulator time and further delays to data collection. Therefore, we are planning to replace the existing the IG and projectors starting in mid-October and going through most of December. This will require pausing data collection activity on the NADS-1. We will start screening participants in December with the goal of enrolling them for starting data collection in January.

Project Expenditures				
Categories	Total Amount Originally Budgeted	August Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$229,839	\$19,642	\$248,432	108%
Subject Payment	\$32,690	\$0	\$12,751	39%
Subject Transportation	\$3,646	\$0	\$1,008	28%
Use of CRU	\$68,850	\$0	\$21,530	31%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$0	\$6,297	380%
Sub-total	\$337,031	\$19,642	\$290,018	86%
Facilities & Administration	\$171,886	\$100,017	\$147,909	86%
Simulator Charges	\$92,466	\$0	\$92,466	100%
Total	\$601,384	\$119,659	\$530,393	88%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Total			436.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

SEPTEMBER 2013

<b>PROJECT INFORMATION</b>	<p>Contract Number: DTNH22-11-D-00237/004</p> <p>Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance</p> <p>Period Covered: September 1, 2013 – September 30, 2013</p> <p>COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a></p> <p>PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a></p> <p>Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a></p> <p>PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a></p>
<b>SUMMARY</b>	<p>Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection. We have a new team member that's helping us out with the study. His name is Andrew Spurgin and he's a graduate student from the UI College of Pharmacy. The College and Dr. Gary Milavetz have graciously made Andrew available to help out with the project at no cost to the project.</p>
<b>TASK C.5.1: REPORTING</b>	<p><u>ACCOMPLISHMENTS</u>: The monthly report for August was delivered on Sept. 23<sup>rd</sup>.</p> <p><u>NEXT MONTH</u>: Prepare October monthly report.</p>
<b>TASK C.5.2: INITIAL BRIEFING</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.3: WORK PLAN</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.4: SCENARIOS</b>	<p><u>ACCOMPLISHMENTS</u>: This task is complete.</p> <p><u>NEXT MONTH</u>: N/A.</p>
<b>TASK C.5.5: IRB, IND, DEA</b>	<p><u>ACCOMPLISHMENTS</u>: A surprise DEA inspection occurred on September 4<sup>th</sup> in relation to this project. The project staff meet with the DEA agents and went over cannabis supplies, cannabis accounting, license status, and security. The inspection was successful with no major issues identified.</p> <p><u>NEXT MONTH</u>: N/A.</p>

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<b>ACCOMPLISHMENTS:</b> Continue recruiting participants and conducting screenings. .
	<b>NEXT MONTH:</b> Continue to recruitment participants. Screenings will only be conducted on an as needed basis.

<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> Continued main data collection. Data collection has been slowing due to participants dropping out, problems with the simulator, staff vacation schedules (approved several months ago) and a lack of availability of the CRU.	
	<b>Description</b>	<b>As of 9/30/2013</b>
	# enrolled (that have signed consent forms and have been screened)	83
	# randomized	41 (2 people completed, 1 person withdrew, 1 person lost contact with more than 1 # – total of randomized #s used is thus 45)
	# of people ceased participation	26 (includes all withdrawals, lost contacts, and dropped)
	# of people being run	2
	# of people eligible for randomized that haven't been randomized	2 (one is currently on alternate status)
	# completed	14
	# phone screened (includes scheduled for screening/training visit, SF)	597
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	62
<b>NEXT MONTH:</b> Continue main data collection.		

<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	Given that main data collection is not yet complete, we have not been able to complete the 'Perform & Submit the Analysis of the NADS Data' by July 27, 2013. Data collection will not be completed by late October.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	September Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$229,839	\$14,238	\$262,605	114%
Subject Payment	\$32,690	\$0	\$12,751	39%
Subject Transportation	\$3,646	\$0	\$1,008	28%
Use of CRU	\$68,850	\$0	\$21,530	31%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$646	\$6,943	419%
Sub-total	\$337,031	\$14,884	\$304,837	90%
Facilities & Administration	\$171,886	\$7,591	\$155,467	90%
Simulator Charges	\$92,466	\$0	\$92,466	100%
Total	\$601,384	\$22,475	\$552,770	92%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Total			445.25	63.00



Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

## OCTOBER 2013

PROJECT INFORMATION	Contract Number: DTNH22-11-D-00237/004
	Project Title: Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered: October 1, 2013 – October 31, 2013
	COTR(TO): Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD: Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI: Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM: Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.5, 5.6, and 5.7. Continued main data collection. We have a new team member that's helping us out with the study. His name is Andrew Spurgin and he's a graduate student from the UI College of Pharmacy. The College and Dr. Gary Milavetz have graciously made Andrew available to help out with the project at no cost to the project.
TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS</u> : The monthly report for August was delivered on Sept. 23 <sup>rd</sup> .
	<u>NEXT MONTH</u> : Prepare October monthly report.
TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS</u> : This task is complete.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS</u> : N/A.
	<u>NEXT MONTH</u> : N/A.
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	<u>ACCOMPLISHMENTS</u> : Continue recruiting participants and conducting screenings. .
	<u>NEXT MONTH</u> : Continue to recruitment participants. Screenings will only be conducted on an as needed basis.

<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> Continued main data collection. We only have one participant enrolled in the study at this time. More screenings will need to be performed in November. This will hopefully help us get to faster resumption of data collection once the NADS upgrade is completed in late December.	
	<b>Description</b>	<b>As of 9/30/2013</b>
	# enrolled (that have signed consent forms and have been screened)	83
	# randomized	41 (2 people completed, 1 person withdrew, 1 person lost contact with more than 1 # – total of randomized #s used is thus 45)
	# of people ceased participation	27 (includes all withdrawals, lost contacts, and dropped)
	# of people being run	1
	# of people eligible for randomized that haven't been randomized	2 (one is currently on alternate status)
	# completed	14
	# phone screened (includes scheduled for screening/training visit, SF)	612
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	66
<b>NEXT MONTH:</b> Continue main data collection.		

<b>TASK C.5.8: ANALYSIS</b>	This task has yet to begin.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	Given that main data collection is not yet complete, we have not been able to complete the 'Perform & Submit the Analysis of the NADS Data' by July 27, 2013.
	Two months ago, we informed NHTSA about the need to take the NADS-1 simulator down for projector and IG upgrades in late October. We are currently a 4 week delay in the procurement of projectors. Therefore, rather than take the simulator down as originally planned, we'd like to take the opportunity to continue the data collection into November and through most of December. This will allow us to conduct a few more days of data collection. This should result in the completion of one more participant. We also plan on conducting more screenings as time allows.
	This study has exhausted nearly all of the funding amount. It is estimated that it will take another \$150K to complete all of the remaining 6 participants (we currently have 14 completed). The estimate is predicated on being able to complete the remaining data collection in 3 months and expediting the analysis, report and briefing tasks. NADS is planning to cover the overrun on this project at our cost.

Project Expenditures				
Categories	Total Amount Originally Budgeted	October Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$229,839	\$12,758	\$277,941	121%
Subject Payment	\$32,690	\$12,737	\$25,488	78%
Subject Transportation	\$3,646	\$264	\$1,272	35%
Use of CRU	\$68,850	\$0	\$21,530	31%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$47	\$6,989	422%
Sub-total	\$337,031	\$25,806	\$333,220	99%
Facilities & Administration	\$171,886	\$13,161	\$169,942	99%
Simulator Charges	\$92,466	\$0	\$92,466	100%
Total	\$601,384	\$38,967	\$595,628	99%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Total			450.25	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

## NOVEMBER 2013

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	November 1, 2013 – November 30, 2013
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.6, 5.7 and 5.8. Resumed main data collection.	
TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS:</u> The monthly report for October was delivered on Dec. 1 <sup>st</sup> .	
	<u>NEXT MONTH:</u> Prepare December monthly report.	
TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS:</u> N/A.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	<u>ACCOMPLISHMENTS:</u> Continue recruiting participants and conducting screenings. Placed a recruitment ad in a local newspaper.	
	<u>NEXT MONTH:</u> Continue to recruit participants. Screenings will only be conducted on an as needed basis.	

<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> Resumed main data collection.	
	<b>Description</b>	<b>As of 11/30/2013</b>
	# enrolled (that have signed consent forms and have been screened)	92
	# randomized	47 (2 people completed, 1 person withdrew, 1 person lost contact with more than 1 # – total of randomized #s used is thus 51)
	# of people ceased participation	29 (includes all withdrawals, lost contacts, and dropped)
	# of people being run	5 will begin first week of December, 1 will wait till slot opens on F/Sat
	# of people eligible for randomized that haven't been randomized	1
	# completed	14
	# phone screened (includes scheduled for screening/training visit, SF)	684
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	51
<b>NEXT MONTH:</b> Continue main data collection.		

<b>TASK C.5.8: ANALYSIS</b>	Started working on scripts to reduce the raw simulator data. Part of this work necessitated revisions to the scenario specification document.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	Given that main data collection is not yet complete, we have not been able to complete the 'Perform & Submit the Analysis of the NADS Data' by July 27, 2013.
	We are planning to continue data collection through December, January and February. We will bring the new IG online sometime in January. This should be seamless and not cause any delays to this data collection. The projector upgrade is now being pushed back to March due to procurement delays and scheduling conflicts with other data collections. This should allow us to get 20 completers before the projector upgrade. The drawback to this approach is that one of the projectors could fail and it would interrupt data collection until the problem was fixed or necessitate a projector upgrade.
	This study has exhausted all of the funding amount. It is estimated that it will take another \$150K to complete all of the remaining 6 participants (we currently have 14 completed). The estimate is predicated on being able to complete the remaining data collection in 3 months and expediting the analysis, report and briefing tasks. NADS is planning to cover the overrun on this project at our cost.



Project Expenditures				
Categories	Total Amount Originally Budgeted	November Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$229,839	\$17,292	\$296,122	129%
Subject Payment	\$32,690	\$0	\$25,488	78%
Subject Transportation	\$3,646	\$0	\$1,272	35%
Use of CRU	\$68,850	\$0	\$21,530	31%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$37	\$7,027	424%
Sub-total	\$337,031	\$17,329	\$351,439	104%
Facilities & Administration	\$171,886	\$8,838	\$179,234	104%
Simulator Charges	\$92,466	\$0	\$92,466	100%
Total	\$601,384	\$26,167	\$623,139	104%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Total			463.50	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



# NHTSA/NIDA Monthly Report

## DECEMBER 2013

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	December 1, 2013 – December 31, 2013
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
<b>SUMMARY</b>	Made progress on Tasks 5.6, 5.7 and 5.8. Resumed main data collection.	
<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u> The monthly report for November was prepared but not delivered.	
	<u>NEXT MONTH:</u> Prepare January monthly report.	
<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> N/A.	
	<u>NEXT MONTH:</u> N/A.	
<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> Continue recruiting participants and conducting screenings.	
	<u>NEXT MONTH:</u> Continue to recruit participants. Screenings will only be conducted on an as needed basis.	

<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> Resumed main data collection.	
	<b>Description</b>	<b>As of 12/31/2013</b>
	# enrolled (that have signed consent forms and have been screened)	93
	# randomized	48 (2 people completed, 1 person withdrew, 1 person lost contact with more than 1 # – total of randomized #s used is thus 52)
	# of people ceased participation	30 (includes all withdrawals, lost contacts, and dropped)
	# of people being run	4 active with 2 starting in January for a total of 6
	# of people eligible for randomized that haven't been randomized	1
	# completed	14
	# phone screened (includes scheduled for screening/training visit, SF)	694
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	44
<b>NEXT MONTH:</b> Continue main data collection.		

<b>TASK C.5.8: ANALYSIS</b>	Continued working on scripts to reduce the raw simulator data.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	Given that main data collection is not yet complete, we have not been able to complete the 'Perform & Submit the Analysis of the NADS Data' by July 27, 2013.
	We are planning to continue data collection through December, January and February. We will bring the new IG online sometime in January. This should be seamless and not cause any delays to this data collection. The projector upgrade is now being pushed back to March due to procurement delays and scheduling conflicts with other data collections. This should allow us to get 20 completers before the projector upgrade. The drawback to this approach is that one of the projectors could fail and it would interrupt data collection until the problem was fixed or necessitate a projector upgrade.
	This study has exhausted all of the funding amount. It is estimated that it will take another \$158K to complete all of the remaining 6 participants (we currently have 14 completed). The estimate is predicated on being able to complete the remaining data collection in 3 months and expediting the analysis, report and briefing tasks. NADS is planning to cover the overrun on this project at our cost.

Project Expenditures				
Categories	Total Amount Originally Budgeted	December Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	\$229,839	\$17,335	\$313,574	136%
Subject Payment	\$32,690	\$0	\$25,488	78%
Subject Transportation	\$3,646	\$0	\$1,272	35%
Use of CRU	\$68,850	\$0	\$21,530	31%
Data Backup Equipment	\$350	\$0	\$0	0%
Other Costs / Misc.	\$1,657	\$368	\$7,395	446%
Sub-total	\$337,031	\$17,703	\$369,259	110%
Facilities & Administration	\$171,886	\$9,028	\$188,322	110%
Simulator Charges	\$92,466	\$0	\$92,466	100%
Total	\$601,384	\$26,731	\$650,047	108%

\*Does not include Westat costs/overhead.

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Total			480.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*





# NHTSA/NIDA Monthly Report

## JANUARY 2014

PROJECT INFORMATION	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	January 1, 2014 – January 31, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>
SUMMARY	Made progress on Tasks 5.6, 5.7 and 5.8. Completed 2 more participants for a total of 16 completers.	
TASK C.5.1: REPORTING	<u>ACCOMPLISHMENTS:</u> The monthly report for December was delivered on February 3 <sup>rd</sup> .	
	<u>NEXT MONTH:</u> Prepare February monthly report.	
TASK C.5.2: INITIAL BRIEFING	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.3: WORK PLAN	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.4: SCENARIOS	<u>ACCOMPLISHMENTS:</u> This task is complete.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.5: IRB, IND, DEA	<u>ACCOMPLISHMENTS:</u> N/A.	
	<u>NEXT MONTH:</u> N/A.	
TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING	<u>ACCOMPLISHMENTS:</u> Continue recruiting participants and conducting screenings.	
	<u>NEXT MONTH:</u> Continue to recruit participants. Screenings will only be conducted on an as needed basis. February will be the last month for screenings.	

<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> Continued main data collection.	
	<b>Description</b>	<b>As of 12/31/2013</b>
	# enrolled (that have signed consent forms and have been screened)	98
	# randomized	52 (2 people completed, 1 person withdrew, 1 person lost contact with more than 1 # – total of randomized #s used is thus 56)
	# of people ceased participation	34 (includes all withdrawals, lost contacts, and dropped)
	# of people being run	4
	# of people eligible for randomized that haven't been randomized	2
	# completed	16
	# phone screened (includes scheduled for screening/training visit, SF)	732
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	38
	<b>NEXT MONTH:</b> Continue main data collection.	

<b>TASK C.5.8: ANALYSIS</b>	Continue reducing the raw simulator data.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	Given that main data collection is not yet complete, we have not been able to complete the 'Perform & Submit the Analysis of the NADS Data' by July 27, 2013.
	Data collection will continue through February. We will bring the new IG online sometime in February to minimize chances of the old IG going down and interrupting data collection. The projector upgrade is scheduled to start in March. Our plan is to end data collection on March 8 <sup>th</sup> . The projector upgrade will begin on March 10 <sup>th</sup> . Delayed projects on the NADS-1, following the hardware upgrade to the projectors, will make continuation of any data collection for this effort following the upgrade difficult to impossible.
	This study has exhausted all funds. So far, NADS has covered a deficit of \$63,986.

Project Expenditures				
Categories	Total Amount Originally Budgeted	January Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	10,029	323,572	141%
Subject Payment	32,690	0	25,488	78%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	150	7,544	455%
Sub-total	337,031	10,179	379,406	113%
Facilities & Administration	171,886	5,191	193,497	113%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$15,371	\$665,370	111%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Total			516.50	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	



# NHTSA/NIDA Monthly Report

## FEBRUARY 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	February 1, 2014 – February 28, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Made progress on Tasks 5.6, 5.7 and 5.8. Completed 1 more participant for a total of 17 completers.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u> The monthly report for January was delivered on February 26 <sup>th</sup> .
	<u>NEXT MONTH:</u> Prepare March monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> Continued recruiting participants and conducting screenings.
	<u>NEXT MONTH:</u> There will be no more recruiting and screening activities pending a teleconference to review the state of the entire study.

<b>TASK C.5.7: DATA COLLECTION</b>	<b>ACCOMPLISHMENTS:</b> Continued main data collection. The new IG was brought on-line on February 22 <sup>nd</sup> to mitigate against failures of the old IG. The new IG was successfully used in data collection without any problems. We will continue to use the new IG for this study through the end of data collection.	
	<b>Description</b>	<b>As of 12/31/2013</b>
	# enrolled (that have signed consent forms and have been screened)	98
	# randomized	53 (2 people completed, 1 person withdrew, 1 person lost contact with more than 1 # – total of randomized #s used is thus 57)
	# of people ceased participation	36 (includes all withdrawals, lost contacts, and dropped)
	# of people being run	2
	# of people eligible for randomized that haven't been randomized	1
	# completed	17
	# phone screened (includes scheduled for screening/training visit, SF)	732
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	38
<b>NEXT MONTH:</b> Continue main data collection.		

<b>TASK C.5.8: ANALYSIS</b>	Continue reducing the raw simulator data.
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<b>TASK C.5.9: REPORT</b>	This task has yet to begin.
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<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	<p>Given that main data collection is not yet complete, we have not been able to complete the 'Perform &amp; Submit the Analysis of the NADS Data' by July 27, 2013.</p> <p>Data collection will continue through the first two weekends of March and will end on March 8<sup>th</sup>. The new IG is functioning well for this study. The projector upgrade is scheduled to start in March. Delayed projects on the NADS-1, following the hardware upgrade to the projectors, will make continuation of any data collection for this effort following the upgrade difficult to impossible.</p> <p>This study has exhausted all funds. So far, NADS has covered a deficit of \$76,458. NADS has also provided 462 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at around \$712,378.</p>
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Project Expenditures				
Categories	Total Amount Originally Budgeted	February Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	7,863	331,435	144%
Subject Payment	32,690	0	25,488	78%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	397	7,941	479%
Sub-total	337,031	8,260	387,666	115%
Facilities & Administration	171,886	4,212	197,710	115%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$12,472	\$677,842	113%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*



NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Total			525.25	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	4/27/13 - Within 12 months of IND/IDE & IRB approval	
14	C.5.8	Perform & Submit the Analysis of the NADS Data	7/27/13 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	10/27/12 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	9/27/13 - Within 17 months of IND/IDE & IRB approval	



# NHTSA/NIDA Monthly Report

## MARCH 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	March 1, 2014 – March 31, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Made progress on Tasks 5.6, 5.7 and 5.8. Completed 2 more participant for a total of 19 completers. A teleconference was held on March 6 <sup>th</sup> between NADS, NHTSA and NIDA to discuss the state of the data collection. NADS followed up with a summary of partial completers via e-mail on March 13 <sup>th</sup> . On March 19 <sup>th</sup> , NHTSA informed us that it is reasonable to formally end data collection. The plan is to use the original statistical analysis plan using 19 participants instead of 20.
	We also received a no-cost time extension to complete the remaining tasks with the final end date being Dec. 15, 2014.

<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare April monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> Continued and finished main data collection! The new IG continued to perform well for this data collection.	
	<b>Description</b>	<b>As of 12/31/2013</b>
	# enrolled (that have signed consent forms and have been screened)	98
	# randomized	53 (2 people completed, 1 person withdrew, 1 person lost contact with more than 1 # – total of randomized #s used is thus 57)
	# of people ceased participation	36 (includes all withdrawals, lost contacts, and dropped)
	# of people being run	0
	# of people eligible for randomized that haven't been randomized	0
	# completed	19
	# phone screened (includes scheduled for screening/training visit, SF)	732
	# called and not yet screened and/or scheduled (includes phone tag, messages, said they would call back)	38
	<u>NEXT MONTH:</u> N/A.	

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued data reduction of simulator data. Started preparation for analysis.
	<u>NEXT MONTH:</u> Finish data reduction of simulator data. Continue data analysis.

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> This task has yet to begin.
	<u>NEXT MONTH:</u> This task has yet to begin.

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$89,554. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	March Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	7,672	340,026	148%
Subject Payment	32,690	0	25,488	78%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	82	8,022	484%
Sub-total	337,031	7,754	396,338	118%
Facilities & Administration	171,886	3,954	202,133	118%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$11,708	\$690,937	115%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	



# NHTSA/NIDA Monthly Report

APRIL 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	April 1, 2014 – April 30, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Made progress on Tasks 5.6, 5.7 and 5.8. Completed 2 more participant for a total of 19 completers. A teleconference was held on March 6 <sup>th</sup> between NADS, NHTSA and NIDA to discuss the state of the data collection. NADS followed up with a summary of partial completers via e-mail on March 13 <sup>th</sup> . On March 19 <sup>th</sup> , NHTSA informed us that it is reasonable to formally end data collection. The plan is to use the original statistical analysis plan using 19 participants instead of 20.
	We also received a no-cost time extension to complete the remaining tasks with the final end date being Dec. 15, 2014.

<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare May monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.



<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.
<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.
<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued data reduction.
	<u>NEXT MONTH:</u> Finish data reduction of simulator data. Begin formal data analysis.
<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> This task has yet to begin.
	<u>NEXT MONTH:</u> This task has yet to begin.
<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$99,681. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.

Project Expenditures				
Categories	Total Amount Originally Budgeted	April Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	4,775	346,690	151%
Subject Payment	32,690	0	25,488	78%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	43	8,065	487%
Sub-total	337,031	4,818	403,045	120%
Facilities & Administration	171,886	2,457	205,553	120%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$7,276	\$701,064	117%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	



# NHTSA/NIDA Monthly Report

MAY 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	May 1, 2014 – May 31, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Work on reduction of simulator data.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare June monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued data reduction and analysis of simulator data. Submitted preliminary speed and lane keeping analyses
	<u>NEXT MONTH:</u> Submit additional analysis of simulator data.

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> This task has yet to begin.
	<u>NEXT MONTH:</u> This task has yet to begin.

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$100,266. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	May Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	387	347,077	151%
Subject Payment	32,690	0	25,488	78%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	0	8,065	487%
Sub-total	337,031	387	403,432	120%
Facilities & Administration	171,886	198	205,750	120%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$585	\$701,649	117%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	





# NHTSA/NIDA Monthly Report

JUNE 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	June 1, 2014 – June 30, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Work on reduction and analysis of simulator data. Archived simulator data onto redundant off-site storage.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare July monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued data reduction and analysis of simulator data and submitted analysis of simulator data.
	<u>NEXT MONTH:</u> Submit additional analysis of simulator data.

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> This task has yet to begin.
	<u>NEXT MONTH:</u> This task has yet to begin.

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$109,552. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	June Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	535	347,612	151%
Subject Payment	32,690	8,478	33,966	104%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	0	8,065	487%
Sub-total	337,031	9,013	412,445	122%
Facilities & Administration	171,886	273	206,023	120%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$9,286	\$710,935	118%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	



# NHTSA/NIDA Monthly Report

JULY 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	July 1, 2014 – July 31, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Finished work on reduction and analysis of simulator data. Starting writing sections of the report.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare August monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued data reduction and analysis of simulator data and submitted analysis of simulator data.
	<u>NEXT MONTH:</u> None.

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> Started work on the report.
	<u>NEXT MONTH:</u> Continue work on report.

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$109,552. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	July Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	0	347,612	151%
Subject Payment	32,690	0	33,966	104%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	0	8,065	487%
Sub-total	337,031	0	412,445	122%
Facilities & Administration	171,886	0	206,023	120%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$0	\$710,935	118%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	





# NHTSA/NIDA Monthly Report

## AUGUST 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	August 1, 2014 – August 31, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smither@dot.gov">Dereece.Smither@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Continued collaborative data analysis with NHTSA and NIDA and continued work on sections of the report.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare September monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued work on analyses.
	<u>NEXT MONTH:</u> Continue work on analyses.

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> Continued work on the report.
	<u>NEXT MONTH:</u> Submit draft report.

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$109,552. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
------------------------------	---

Project Expenditures				
Categories	Total Amount Originally Budgeted	August Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	0	347,612	151%
Subject Payment	32,690	0	33,966	104%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	0	8,065	487%
Sub-total	337,031	0	412,445	122%
Facilities & Administration	171,886	0	206,023	120%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$0	\$710,935	118%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	



# NHTSA/NIDA Monthly Report

SEPTEMBER 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	September 1, 2014 – September 30, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Continued collaborative data analysis with NHTSA and NIDA and continued work on sections of the report.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare October monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued work on analyses.
	<u>NEXT MONTH:</u> Continue work on analyses.

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> Submitted draft methodology report.
	<u>NEXT MONTH:</u> Revised report based on comments received.

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$109,552. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
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Project Expenditures				
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NADS-1 Simulator Usage				
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Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	5/6/2014 to Present
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	?
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	





# NHTSA/NIDA Monthly Report

OCTOBER 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	October 1, 2014 – October 31, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Continued collaborative data analysis with NHTSA and NIDA and continued work on sections of the report.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare November monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued work on analyses.
	<u>NEXT MONTH:</u> Continue work on analyses.

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> Submitted revision to methodology report.
	<u>NEXT MONTH:</u> Revised report based on comments received.

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$109,552. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
------------------------------	---

Project Expenditures				
Categories	Total Amount Originally Budgeted	October Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	0	347,612	151%
Subject Payment	32,690	0	33,966	104%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	0	8,065	487%
Sub-total	337,031	0	412,445	122%
Facilities & Administration	171,886	0	206,023	120%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$0	\$710,935	118%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	5/6/2014 to Present
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	?
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	



# NHTSA/NIDA Monthly Report

## NOVEMBER 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	November 1, 2014 – November 30, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Continued collaborative data analysis with NHTSA and NIDA and continued work on sections of the report.
----------------	---

<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare December monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Continued work on analyses.
	<u>NEXT MONTH:</u> Continue work on analyses.

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> Submitted revision to methodology report.
	<u>NEXT MONTH:</u> Revised report based on comments received.

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	This task has yet to begin.
--	-----------------------------

<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$109,552. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
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Sub-total	337,031	0	412,445	122%
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Sep-12	5.6	Screening	9.00	0.00
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Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
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Dec-13	5.7	Main data collection	16.75	0.00
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Jan-14	5.7	Main data collection	29.00	0.00
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Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
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4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
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10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
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15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	?
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	





# NHTSA/NIDA Monthly Report

## NOVEMBER 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	December 1, 2014 – December 15, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Continued collaborative data analysis with NHTSA and NIDA and continued work on sections of the report.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare December monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Submitted final analyses under the contract.
	<u>NEXT MONTH:</u> .

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> Final Methodological report accepted.
	<u>NEXT MONTH:</u> .

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	Participated in final briefing by phone.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$109,552. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
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Sep-12	5.6	Screening	9.00	0.00
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Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
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2		Submit Invoices (D)(M)	Monthly	
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4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
7		NHTSA(TO) comments on the Simulation Plan	02/07/2012 (Within 4 weeks of receipt)	
8	C.5.4	Completion of Simulation and Pilot test & Report of Results (M)(D)	7/27/12 - Within 3 months of IND/IDE approval	11/16/12
9		NHTSA(TO) comments on the Report Results	TBD/Within 4 weeks of receipt	11/20/12
10	C.5.5	Submit Study Protocol for IRB Review & IND/IDE Application (M)(D)	IRB: 12/9/11; IND/IDE: 1/9/12 - within 1 month of IRB approval	12/5/11; 12/16/11
		IND/IDE Approval Date	04/27/2012	
		Receipt of Cannabis from DEA	09/01/2012	
11	C.5.6	Commence Participant Recruitment, Enrollment Screening, & Training (M)	5/27/2012 - Within 1 month of IND/IDE & IRB approval	09/08/2012
12	C.5.7	Initiate Data Collection According to Study Protocol (M)	5/27/12 - Within 1 month of IND/IDE & IRB approval	12/04/2013
13	C.5.7	Complete Data Collection on the NADS (M)	5/30/2014 - Within 12 months of IND/IDE & IRB approval	3/8/2014
14	C.5.8	Perform & Submit the Analysis of the NADS Data	6/30/2014 - Within 15 months of IND/IDE & IRB approval	12/11/2014
15	C.5.9	Submit Draft of the Methodology Report (M)(D)	9/30/2014 - Within 6 months of IND/IDE & IRB approval	12/15/2014
16	C.5.10	Final Briefing (M)(D)	12/15/2014 - Within 17 months of IND/IDE & IRB approval	12/11/2014



# NHTSA/NIDA Monthly Report

## DECEMBER 2014

<b>PROJECT INFORMATION</b>	Contract Number:	DTNH22-11-D-00237/004
	Project Title:	Examine the Effects of Inhaled Cannabis on Driving Performance
	Period Covered:	December 1, 2014 – December 15, 2014
	COTR(TO):	Dereece Smither, 202.366.9794, <a href="mailto:Dereece.Smith@dot.gov">Dereece.Smith@dot.gov</a>
	PI/MD:	Gary Gaffney, 319.335.4838, <a href="mailto:gary-gaffney@uiowa.edu">gary-gaffney@uiowa.edu</a>
	Co-PI:	Tim Brown, 319.335.4785, <a href="mailto:timothy-l-brown@uiowa.edu">timothy-l-brown@uiowa.edu</a>
	PM:	Omar Ahmad, 319.335.4788, <a href="mailto:omar-ahmad@uiowa.edu">omar-ahmad@uiowa.edu</a>

<b>SUMMARY</b>	Continued collaborative data analysis with NHTSA and NIDA and continued work on sections of the report.
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<b>TASK C.5.1: REPORTING</b>	<u>ACCOMPLISHMENTS:</u>
	<u>NEXT MONTH:</u> Prepare December monthly report.

<b>TASK C.5.2: INITIAL BRIEFING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.3: WORK PLAN</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.4: SCENARIOS</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.5: IRB, IND, DEA</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.6: RECRUITING, ENROLLMENT, SCREENING</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.7: DATA COLLECTION</b>	<u>ACCOMPLISHMENTS:</u> This task is complete.
	<u>NEXT MONTH:</u> N/A.

<b>TASK C.5.8: ANALYSIS</b>	<u>ACCOMPLISHMENTS:</u> Submitted final analyses under the contract.
	<u>NEXT MONTH:</u> .

<b>TASK C.5.9: REPORT</b>	<u>ACCOMPLISHMENTS:</u> Final Methodological report accepted.
	<u>NEXT MONTH:</u> .

<b>TASK C.5.10: ASSIST WITH FINAL BRIEFING</b>	Participated in final briefing by phone.
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<b>PROBLEMS / DELAYS</b>	This study has exhausted all funds. So far, NADS has covered a deficit of \$109,552. NADS has also provided 466 hours of NADS-1 usage at no cost to NHTSA. These hours are valued at \$717,772.
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Project Expenditures				
Categories	Total Amount Originally Budgeted	November Expenditures	Total Expenditures	Total Percentage Budget Used
Labor	229,839	0	347,612	151%
Subject Payment	32,690	0	33,966	104%
Subject Transportation	3,646	0	1,272	35%
Use of CRU	68,850	0	21,530	31%
Data Backup Equipment	350	0	0	0%
Other Costs / Misc.	1,657	0	8,065	487%
Sub-total	337,031	0	412,445	122%
Facilities & Administration	171,886	0	206,023	120%
Simulator Charges	92,466	0	92,466	100%
Total	\$601,384	\$0	\$710,935	118%

\*Does not include Westat costs/overhead.

*Please note that due to University reporting expenditures may be listed one month later than actual expenditure date and are only for charges that have cleared the University system.*

NADS-1 Simulator Usage				
Month	Task	Activity	Hours Logged	Hours Billed
May-12	5.4	Scenario development and testing	4.50	4.50
Jun-12	5.4	Scenario development and testing	24.00	24.00
Jul-12	5.4	Scenario development and testing	6.75	0.00
Aug-12	5.4	Scenario development and testing	4.50	0.00
Sep-12	5.4	Scenario development and testing	4.00	0.00
Sep-12	5.6	Screening	9.00	0.00
Oct-12	5.4	Pilot	32.00	0.00
Nov-12	5.4	Scenario development and testing	11.25	0.00
Nov-12	5.6	Screenings	22.25	0.00
Nov-12	5.7	Main data collection	4.00	0.00
Dec-12	5.7	Main data collection	24.00	10.50
Jan-13	5.7	Main data collection	15.75	15.75
Feb-13	5.7	Main data collection	37.25	0.00
Mar-13	5.6	Screening	5.50	0.00
Mar-13	5.7	Main data collection	13.00	8.25
Apr-13	5.6	Screening	7.00	0.00
Apr-13	5.7	Main data collection	32.75	0.00
May-13	5.6	Screening	7.75	0.00
May-13	5.7	Main data collection	14.75	0.00
Jun-13	5.6	Screening	6.50	0.00
Jun-13	5.7	Main data collection	48.00	0.00
Jul-13	5.6	Screenings	20.00	0.00
Jul-13	5.7	Main data collection	32.75	0.00
Aug-13	5.6	Screenings	10.25	0.00
Aug-13	5.7	Main data collection	39.25	0.00
Sep-13	5.7	Main data collection	8.50	0.00
Oct-13	5.7	Main data collection	5.00	0.00
Nov-13	5.6	Screenings	13.25	0.00
Dec-13	5.6	Screenings	0.50	0.00
Dec-13	5.7	Main data collection	16.75	0.00
Jan-14	5.6	Screenings	6.75	0.00
Jan-14	5.7	Main data collection	29.00	0.00
Feb-14	5.7	Main data collection	8.75	0.00
Mar-14	5.7	Main data collection	3.50	0.00
Total			528.75	63.00

Item #	Task #	Deliverables and/or Milestones	Due Date After Award	Actual Date of Delivery
1	C.5.1	Submit Progress Reports (Monthly/Weekly Progress, Teleconference Calls, Adverse Events) (M)(D)	Due date varies by deliverable (see 5.1 for detail)	
2		Submit Invoices (D)(M)	Monthly	
3	C.5.2	Initial Project Briefing (M)(D)	10/25/11	10/25/11
4	C.5.3	Revise the Work Plan (M)(D)	11/14/11	11/09/11
5		NHTSA(TO) comments on the Revised Work Plan	11/28/11	
6	C.5.4	Commence Development of Simulation Plan Sensitive to the Effects of Cannabis Ingestion (M) (D)	12/9/11	12/12/11
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