Supporting Statement A for

Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device - NIDA

August 29, 2013

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A.1 Circumstances Making the Collection of Information Necessary

This request is for OMB approval of surveys related to multipart trial examining the effectiveness of a mobile scalable device to detect the impairing effects of different drugs. Three drugs are planned to be used in this project across three sub-studies with different subjects for each sub-study: Adderall, Xanax, Cannabis. (Details of use and administration of each of these drugs in the study are provided in the attached Consent forms, in the section that describes Study visits 2 and 3.) Given the increased use of drugs while driving, it is essential to have tools that can accurately detect their presence. This SBIR grant is designed to accomplish that critical aim. This work is authorized in the National Institutes on Drug Abuse under §§ 285o–285o4

The survey data collected as part of this research will be used to help explain the engineering data of driver performance and lab data from biological samples of drug levels. We will be collecting basic demographic information, general health and sleeping/waking habit information, food and beverage consumption, driver perception of the realness our the driving simulator, and how subjects feel after driving. We also ask for information regarding how sleepy a person feels before and after a drive in our simulator. General screening and health questions are asked to screen out individuals to whom harm could occur from taking the study drugs or while operating the simulator, and to identify those that do not meet the inclusion criteria for the study.

A.2 Purpose and Use of the Information Collection

The information collected under this clearance is to be used by staff at the University of Iowa's National Advanced Driving Simulator (NADS) and researchers at Advanced

Brain Monitoring. This information will support the development and refinement of the mobile scalable device for detection of impairing drugs. The overall study is designed to characterize the effects of common recreationally used prescription drugs as well as Cannabis with well known stimulant and sedating effects (Xanax and Adderall) and their relationship to results from the Mobile Alertness Memory Profiler (M-AMP) which includes a set of vigilance and memory tasks. This study will involve a drug dosing intervention, a placebo dosing intervention, monitoring of participants' health condition to participate in each step of the study interventions, and health and wellness condition for discharge after participation in each intervention. All steps of the interventions will be conducted at the National Advanced Driving Simulator at the University of Iowa's Research Park, and participants will be under the medical care of a physician during the intervention. (Complete details of the intervention process are provided in the Informed Consent forms.) Additionally, the information to be collected will assure us that our experimental manipulation for the simulator data collection was effective and thus the engineering and lab data collected can be used intended. Demographic information will allow us to compare the demographics of our sample to the larger driving population. Screening and health questions allow us to insure that the sample meets the inclusion and exclusion criteria for the study. Based on the engineering research studies of the past 10 years at the University of Iowa, 100 subjects will be screened for the study, 72 of these are expected will meet inclusion criteria and consent to participate in the study, and with expected attrition in the course of the study 60 complete data sets will be obtained, for an 83% response rate.

A.3 Use of Information Technology and Burden Reduction

Some data for the study will be collected electronically via Qualtrics survey software. Exceptions to electronic collection include the screening questions over the phone which are not recorded beyond determination of eligibility, and the Stanford Sleepiness Scale which will be collected with pen and paper consistent with its original implementation. A Privacy Impact Assessment, as specified by the NIH Privacy Act Office, has been conducted and is under review by the NIH Privacy Act Office.

A.4 Efforts to Identify Duplication and Use of Similar Information

The data collected is specific to the simulator data set and includes data such as current drowsiness level of individual subject at specific times. Because this data needs to be linked to simulator data, it is not available elsewhere.

A.5 Impact on Small Businesses or Other Small Entities

This Study is funded by an SBIR contract. The respondents will be from the general public in Eastern Iowa, the tool can be used nationally. The study will have a positive impact for the general public. No small businesses will be affected.

A.6 Consequences of Collecting the Information Less Frequently

This information will be collected twice: once with placebo and once while dosed. If these data are not collected, it will not be possible to determine the utility of the system, , --to verify experimental manipulations and protocol compliance, to assess the well-being of subjects.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This proposed project fully complies with all guidelines of 5 FCR 1320.5.

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A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60-day Federal Register Notice of the proposed research was published on March 29, 2013, Volume 78, No. 61, pages 19273–19274. No public comments were received. Consultation for these instruments and methods included:

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Office of Vehicle Safety Research, National Highway Traffic Safety Administration, Department of Transportation

A.9 Explanation of Any Payment of Gift to Respondents

Those eligible to participate based on the phone screening will be enrolled in this study and will complete multiple visits where collection of survey data is only a small portion of their total participation. The respondents will be individuals who have given consent to participate in this larger research study where the primary data of interest is driver performance data collected from driving a simulated car, EEG data and biological data. They are being compensated monetarily for their time and effort to complete their participation in the larger study. Typical subject compensation for basic driving studies

at the National Advanced Driving Simulator is typically $20-25 per hour. Despite the fact that this study includes not only typical driving simulation study activities such as surveys and driving the simulator but also dosing the subjects with active drugs and collection of blood samples, the hourly rate of compensation is only approximately $27 per hour when considering the dosing visits. This does not account for time travelling to and from our facility. This research includes additional risks above and beyond our typical studies including risks associated with the drugs and blood draws. Our Institutional Review Board has approved the compensation plan and had no concerns that the amount was coercive. Total compensation of $250 for completing all study procedures including surveys, dosing, blood draws, simulated driving, and the wait times necessary due to dosing, will be paid.

A.10 Assurance of Confidentiality Provided to Respondents

The proposed study has been submitted and is subject to approval by 'the University of Iowa' IRB. The University of Iowa IRB has reviewed the proposed new work in conjunction with the continuing review of the Phase 1 study, and has asked for separate submissions for each of the sub-studies for Phase2 be submitted. IRB approval letters for the first two sub-studies are attached. The application for the cannabis sub-study is in process, and the IRB approval letter will be submitted when it becomes available. A Certificate of Confidentiality is in progress for the sub-studies investigating Xanax and Adderall, and a separate Certificate of Confidentiality is in progress for the sub-study investigating cannabis. These will be submitted when they become available. The personal information collected will be kept private under the Privacy Act, and to the

extent permitted by law. Every effort will be made to protect participants' privacy. No personal identities will be used in the study, and each subject will be assigned a unique identification number and information collected will be identified by these ID numbers rather than names. The online data will be maintained on a secure server during the duration of the research. Data linking subject ID with identifiers and all printed records will be kept in a locked cabinet accessible only to the PI and those closely involved in the research. All study participants will complete informed consent document that outline the confidentiality procedures. In analysis, data will be aggregated so that no personally identifiable information (PII) can be obtained from all data reports and published material. All electronic and paper data pertaining to identifiable data on subjects will be securely stored for three years, in keeping with NIH requirements, and then destroyed unless otherwise directed by NIDA. Standard human subjects guidelines will be followed. The proposed project will fully comply with the Federal Registry Notice. Personal identifiable information is being collected and the Privacy Act will apply. A Privacy Impact Assessment has been done and is in review by the NIH Privacy Act Office.

A.11 Justification for Sensitive Questions

General health history questions are asked as a safety precaution to insure that individuals who participate do not have a condition that would prove to be danger to the staff or the individual. Subjects are told that they will need to answer several health-related questions before they can be scheduled for a study session because some pre-existing health conditions result in subjects not being eligible for participation. The responses to these questions are not recorded; they are administered over the phone as a pre-screening measure for the study.

Questions about cannabis use are asked to insure that the subjects to be enrolled in this portion of the study are actually cannabis users. This is required because the subject population to be tested is cannabis users. This requirement is a safety precaution to insure that the subjects are familiar with this controlled substance and are not likely to have adverse events in response to its use and to comply with institutional requirements at the University of Iowa.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Number of Respondents:

Sixty completed data sets are required for this study (twenty in each of the drug comparison groups). Based on ten years of prior simulator research studies conducted at the University of Iowa's National Advanced Driving Simulator over the past decade, it is estimated that 100 individuals will need to be phone screened and 72 individuals will need to be enrolled to obtain the 60 completed data sets. Subject attrition once enrolled can result from individual experiencing simulator disorientation, adverse responses to the drugs used or the blood draws, or schedule conflicts. Based on prior experience, the requested sample of 100 individuals for screening should be sufficient to obtain the final sample size.

Estimated Burden on Respondents:

Table A.12-1 (below) shows the estimated burden of hours requested for this project, based on prior experience with the instruments in previous studies. There are no instruments per se for the blood draw, dosing, and the wait times necessary due to dosing. (Details for these are provided in the Consent Forms, and these forms are included as substitutes for instruments.)

A.12 - 1 ESTIMATES OF HOUR BURDEN				
Type of Respondent	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden per Response (in hours)**	**Annual Hour Burden**
Adults – Phone Screening	100	1	10/60	17
Adults – Consent Process, In-Person Screening Adderall	100	1	45/60	75
Adults – Consent Process, In-Person Screening Xanax		1	45/60	75
Adults – Consent Process, In-Person Screening Cannabis		1	45/60	75
Adults – Driving Survey	72	1	15/60	18
Adults – Realism Survey		1	3/60	4
Adults - Sleep and Intake Questionnaire		2	3/60	7
Adults - Stanford Sleepiness Scale		6	1/60	7
Adults – Dosing/Driving/Waiting		2	4	576
Adults – Wellness Survey		2	2/60	5
Totals	100			859

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondents	Hourly Wage Rate	Respondent Cost
Individuals who only complete the phone screening	28	1	10	$23	$ 107
Subjects who complete all procedures	72	1	284	$23	$7838
Totals	100				$7945

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start-up, operational, or maintenance costs to the respondents in providing the information required by this research.

A.14 Annualized Cost to the Federal Government

The 1-year total project costs are estimated to be $235,000. Total costs associated with the project are estimated to be approximately $400,000 over a 2-year contract performance period. Of this, it is estimated that 2 full-time-equivalent staff members will spend 144 hours of their time to manage and administer this portion of the project. Assuming an annual fully loaded salary of $69,800, personnel costs will be $4832 over a 1-year period. In addition, it is estimated that one full-time-equivalent NIDA staff member will spend 5 percent of his or her time (104 hours) to manage and administer the project. Assuming an annual salary of $100,000, government personnel

costs will be $5,000 over a 1-year period. The 1-year total project costs are $235,000 ($230,000 plus $5,000).

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16 Plans for Tabulation and Publication and Project Time Schedule

General demographic data will be tabulated with simple means and standard deviations to describe the sample. There are no plans for any "complex analytical techniques" to be used with this data as it will be used to help qualify the simulator data. It is estimated that this data will be collected during Quarter 3 of Fiscal Year 2013 through Quarter 4 of Fiscal Year 2014. Publication will occur the first two quarters of Fiscal Year 2015.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed on each instrument form.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in OMB Form 83-1, item 19, "Certification for Paperwork Reduction Act Submissions."