

Supporting Statement B for

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

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Revised

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LIST OF ATTACHMENTS:

- Attachment 1: Phone Screening (MSD_PhoneScreening)
- Attachment 2: Driving Survey (MSD_DrivingSurvey)
- Attachment 3: Sleep and Food Intake (MSD_SFI)
- Attachment 4: Stanford Sleepiness Scale (MSD_SSS)
- Attachment 5: Wellness Survey (MSD_Wellness)
- Attachment 6: Simulator Realism (MSD_Realism)
- Attachment 7 : Electronic Version of Driving Survey
(MSD_Driving_Electronic)
- Attachment 8: Electronic Version of Realism Survey
(MSD_Realism_Electronic)
- Attachment 9: Electronic Version of Wellness Survey
(MSD_Wellness_Electronic)

B.1 Respondent Universe and Sampling Methods

Respondents are individuals in Eastern Iowa willing to drive to the University of Iowa Research Park to participate in a study. Using the most recent census data for Iowa, it is estimated that approximately 186,000 individuals of driving age live in the area of recruitment. NADS currently has a database of approximately 7000 individuals who have already expressed interest in participating.

Individuals who have previously expressed an interest in participating will be contacted by phone. Individuals who meet the general inclusion criteria will be randomly selected from the NADS database. If insufficient interest exists the initial group contacted to meet the enrollment targets, , advertisements will be posted to increase the pool of potential subjects in the NADS recruitment database.

B.2 Procedures for the Collection of Information

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This is not a periodic study.

Individuals who have previously expressed an interest in participating will be contacted by phone. The study and its requirements will be explained to them. If interested, the phone screening will be administered to determine eligibility in the study. No responses from this will be recorded other than eligibility status.

Consistent with Section D of the OMB's memorandum entitled "*Facilitating Scientific Research by Streamlining the Paperwork Reduction Act Process*," available at <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11->

[07.pdf](#), NIH has submitted their IRB existing protocols documentation in lieu of parts of the supporting statement. The protocols can be found in the Supplemental Documents section this ICR documentation.

During their study visit, after having provided informed consent, questionnaires will also be used to capture data via the pencil/paper method or electronic survey software:

- Realism Survey - driver perception of the realism of the simulation
- Wellness Survey - how the participant is feeling after completing the drive
- NADS Driving Survey - general demographic information
- Sleep and Intake Questionnaire – self-report sleep, food, alcohol, and caffeine intake
- Stanford Sleepiness Scale – how sleepy a participant is feeling at a given time

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Participation in the survey is voluntary; however, response rate will be maximized by contacting and enrolling only individuals who have previously expressed interest through our participant database or in response to advertisements. The number of participants identified for enrollment is estimated to be 100 (See Supporting Statements A).

B.4 Test of Procedures or Methods to be Undertaken

These instruments have been used extensively in prior studies (see referenced studies in the reports provided below), and have been refined for ease of completion and question comprehension. Some recent reports that document their use are provided below.

1. Brown, T., Lee, J., Schwarz, C, Fiorentino, D., & McDonald, A. (Under Review). *Advanced Countermeasures for Multiple Impairments: Final Report*. Washington, DC: National Highway Traffic Safety Administration.
2. Berka, C., Johnson, R., Raphael, G. & Brown, T. (2012). *Quantification of Behavioral & Physiological Effects on Drugs Using a Mobile Scalable Device*. Carlsbad, CA: Advanced Brain Monitoring.
3. Lee, J., Fiorentino, D., Reyes, M., Brown, T., Ahmad, O., Fell, J., et al. (2010). *Assessing the Feasibility of Vehicle-Based Sensors to Detect Alcohol Impairment* (No. DOT HS 811 358). Washington, DC: National Highway Traffic Safety Administration.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

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