Attachment 16

Certificate of Confidentiality

July 19,2013

Dr. Nadine Rogers
Scientific Review Officer
NJDA
Office of Extramural Affairs

Dr. Rogers:

We are requesting a Certificate of Confidentiality for the project titled Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device. If anything further is needed, please contact Timothy Brown at 319-335-4785 or timothy-l-brown@uiowa.edu.

1. Name and address of applicant research institution:
National Advanced Driving Simulator, University of Iowa
2401 Oakdale Blvd
Iowa City, TA 52242

2. Sites where the research will be conducted and a brief description of the facilities available for the conduct of the research:
National Advanced Driving Simulator, University of Iowa
2401 Oakdale Blvd
Iowa City, lA 52242

The National Advanced Driving Simulator is a research facility with secure building access. There are three fully enclosed prep rooms separated from administrative offices in which participant briefing and debriefing occurs. Another room holds the simulator used for the study and is adjacent to the hallway in which the prep rooms are located.

3. Title of the research project: Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device

4. Source and number of the supporting grant: NIDA N44DA-12-1206

5. IRB Approval: See Attached Approval and Assurance

6. Name and address of applicant and key personnel.

Timothy L. Brown, Ph.D.
National Advanced Driving Simulator, University oflowa
2401 Oakdale Blvd.
Iowa City, lA 52242
timothy-l-brown@uiowa.edu
phone:319-335-4785
fax:319-335-4658

Dr. Brown received his Doctorate of Philosophy from the University oflowa in 2000 in the area ofHuman Factors Engineering. He has worked at the Iowa Driving Simulator, Cognitive Systems Laboratory and National Advanced Driving Simulator studying multiple facets of driving, including impairment. He has prior experience studying the impacts of alcohol and drugs on driving.

Gary R. Gaffney M.D.
National Advanced Driving Simulator, University oflowa Hospital and Clinics, University oflowa
240 I Oakdale Blvd.
Iowa City, lA

Dr. Gaffney received his Doctorate of Medicine from the University of Iowa in I981. Dr. Gaffney has 23 years in the practice of child and adolescent psychiatry and is currently the Director of the Autism Clinic at the University oflowa Hospitals and Clinics, Iowa City, Iowa. Dr. Gaffney has numerous publications in Autism, Tourette's Syndrome, Psychopharmacology, Genetics, and Brain Imaging. He has prior experience studying the impacts of alcohol and drugs on driving.

Gary Milavetz, Pharm.D.
National Advanced Driving Simulator, College of Pharmacy, University oflowa
2401 Oakdale Blvd.
Iowa City, lA

Dr. Milavetz received his Doctorate of Pharmacy from the University of Minnesota in 1980. He has worked with the National Advanced Driving Simulator on prior studies investigating alcohol and drugs on driving. His research interests include the pharmacotherapeutics of respiratory medications. He has numerous original research publications on the pharmacokinetics, pharmacodynamics and clinical efficacy of medications used to treat respiratory disease.

7. Beginning date and expected end date of the project: August 15, 2013 – 30 September 2014

8. Concise description of the study aims and research methodology; include number, source and description of the human subjects.

The overall study is designed to characterize the effects of common recreationally used prescription drugs (Xanax and Adderall) with well-known stimulant and sedating effects, as well as cannabis, and their relationship to results from the Mobile Alertness Memory Profiler (M-AMP) which includes a set of vigilance and memory tasks..

The aim of this research is to assess drug effects on driving and to explore the utility of the Mobile Alertness Memory Profiler (M-AMP) assessment in detecting drug effects that effect driving.

Subjects will be 18-40 years of age. A total of twenty subjects are needed to complete the study. It is anticipated that up to twenty-six will need to be enrolled to reach this target. Although an equal sample of males and female subject are desired for completing this study, some imbalance will be allowed.

The studies involve three visits – a screening visit and two dosing visits. The dosing visits include a clean (placebo) visit and a drugged visit. Participants will be enrolled into one of three studies (Xanax, Adderall, or Cannabis) depending upon the timing of recruitment. The screening visit will last about 45 minutes and will include drug and pregnancy testing as well as screening for physical/psychological health. A simulator drive is also done. Each of the dosing visits will last approximately five to six hours and will involve baseline M-AMP assessment, a baseline drive, M-AMP assessment after dosing, a dosed drive, and dosed M-AMP assessment. There will also be blood sampling before dosing, before driving, and after driving. Multiple questionnaires are administered at each dosing visit, including demographic, wellness, sleepiness, realism, and a sleep and food intake.

9. Means used to protect subjects' identities (e.g., coded by number, kept in locked files).
All study documents with the exception of the Consent Documents will be identified only by an assigned subject number. The master list linking the subject to their assigned number will be kept by the research coordinator in a password protected file on a secure network. During data collection and analysis, paper/hard documents will be kept in a locked cabinet within a secure building that can only be entered by personnel with a marlock key. After completion of analysis, all hard copies except the Informed Consent Documents will be scanned, placed on a CD and placed into the NADS archival room that has limited access by designated archival personnel. The original Informed Consent Documents will be stored in the NADS archival room that has limited access by designated archival personnel. The Consent Documents and other study documents identified by subject number are stored separately.

Electronic study documents, identified only by subject 10 number, will be coded by research staff onto a computer. Electronic study data is collected and recorded onto data storage media and will be password protected and can only be accessed by investigator, study personnel, or system administrator. All videotapes and questionnaires will be locked in filing cabinets during the data analysis phase and will only be accessible by study personnel. Data will be transferred to a permanent data storage area at the end of the project where it will only be available to the funding agency, principal investigator, or research team members. Simulator data is captured and initially stored on a mirrored RAID system located within a limited access area of the NADS facility. This data is behind a hardline firewall. Access to study data is controlled through validated user login, authentication protocols and access permissions established on a per-study basis. Data backups are maintained as dual copies on physical hard drive devices. One drive is stored within a secured location on-site, and the other is stored off-site under the auspices of The University of Iowa Information Technology Services. All backup drives are inventoried and access to study data requires a request for access and authorization from a designated authority.

10. Reasons for requiring confidentiality.
A certificate is being requested because we will be administering prescription drugs to subjects enrolled in this study, and will be collecting data on what drugs are in their system while enrolled in the study.

11. Drug Enforcement Administration Certificate of Registration: See Attached

12. Assurances of the following: See Attached

Assurances

This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.

The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.

All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Tim Brown

Signature of Principal Investigator

Signature of Institutional Official

JAMES C. WALKER

Name and Title of Institutional Official

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REGISTRATION NU\'IBER 4100964
DRUG SCHEDULES REGISTERED 122N33N45

REGISTRATION ISSUED 02/03/2012
REGISTRATION EXPIRES 09/30/2013

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Researcher

RESPONSffiLE INDIVIDUAL. . Gary R Gaffney, Medical Doctor

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