



**Human Subjects Office/
Institutional Review Board (IRB)**

105 Hardin Library for the Health Sciences
600 Newton Road
Iowa City, Iowa 52242-1098
319-335-6564 Fax 319-335-7310
irb@uiowa.edu
<http://research.uiowa.edu/hso>

IRB ID #: 201309859

To: Timothy Brown

From: IRB-01 DHHS Registration # IRB00000099,
Univ of Iowa, DHHS Federalwide Assurance # FWA00003007

Re: Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device: Study 3

Protocol Number:

Protocol Version:

Protocol Date:

Amendment Number/Date(s):

Approval Date: 12/17/13

**Next IRB Approval
Due Before:** 10/24/14

Type of Application:

- New Project
 Continuing Review
 Modification

Type of Application Review:

- Full Board:
Meeting Date: 10/24/13
 Expedited
 Exempt

Approved for Populations:

- Children
 Prisoners
 Pregnant Women, Fetuses, Neonates

Source of Support: US Department of Health & Human Services, National Institutes of Health

Investigational New Drug/Biologic Name: Cannabis
Investigational New Drug/Biologic Number: 115085
Name of Sponsor who holds IND: Gary Gaffney

Investigational Device Name:
Investigational Device Number:
Sponsor who holds IDE:

This approval has been electronically signed by IRB Chair:
J. Andrew Bertolatus, BA, MD
12/17/13 1131

NOTICE REGARDING CERTIFICATE OF CONFIDENTIALITY

Since you have not yet obtained a Certificate of Confidentiality from the Department of Health and Human Services, the attached Informed Consent Document has been watermarked "Not for use with subjects – For submission to agency issuing Certificate of Confidentiality." No subjects may be enrolled in this study until you receive and submit the Certificate of Confidentiality to the IRB. You should include the watermarked Consent Document when sending your request for a Certificate. When you receive the Certificate, send a copy of the Certificate to the HSO for placement in the IRB study file. At that time, the HSO will remove the watermark from the Informed Consent Document and return to you a non-watermarked, stamped Informed Consent Document for use in enrolling subjects.

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Agency Notification: If this is a New Project or Continuing Review application and the project is funded by an external government or non-profit agency, the original HHS 310 form, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," has been forwarded to the UI Division of Sponsored Programs, 100 Gilmore Hall, for appropriate action. You will receive a signed copy from Sponsored Programs.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are attached. Please make copies from the attached "masters" for subjects to sign when agreeing to participate. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.) If hospital/clinic patients are being enrolled, a copy of the IRB approved Record of Consent form should be placed in the subject's electronic medical record.

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. Your project "expires" at 12:01 AM on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project on or before that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however the HSO will send a reminder notice approximately 60 and 30 days prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any serious and/or unexpected adverse experience, as defined in the UI Investigator's Guide, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained for a period of three (3) years following the close of the research project. For research that

involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application.

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the "Investigator's Guide to Human Subjects Research." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling 335-6564.