IMPORTANT NOTE:

If you accidentally select the wrong IRB type or "Protocol Process Type" while your Initial Review (IR) application is in draft form (unsubmitted), you may change your selections. Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions regarding your selections *prior* to submitting your Initial Review application.

If your **submitted IR application has been returned to you for requested revisions or additional information,** to streamline the review process **do not make changes** to your selections here **unless instructed to do so by the ORI/IRB.**

Changes to this section cannot be made after initial approval has been issued (the option is not available for MR or CR).

For guidance, see:

- Which IRB should review my research?
- Which Protocol Process Type?
- "Getting Started"

Which IRB

- (•) Medical ( ) NonMedical

Protocol Process Type

- ( ) Exemption
- (•) Expedited (Must be risk level 1)
- ( ) Full

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

A. Research activities that (1) present no more than *minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i)*

Check the appropriate categories that apply to your research project:

☑ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

A. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements.
NOTE: Select Category 1 for compassionate use medical device applications or individual patient expanded access investigational drug applications for which FDA has waived the requirement for full review.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☐ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5) Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research. (Note: Some research in this category may qualify for Exempt review. This listing refers only to research that is not exempt.)
(Note: If submission includes materials previously collected for either non-research or research purposes in a protocol for which IRB approval expired, you may check Category 5. However, a separate category must also be selected for prospective collection of data/specimens obtained solely for research purposes)

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

CONTINUATION REVIEW/FINAL REVIEW

0 unresolved comment(s)

In accordance with federal regulations and/or local policies, the IRB conducts periodic review of all currently approved projects. If you need your IRB approval to continue and you do not complete and submit the required materials in a timely manner, IRB approval will expire at the end of your current approval period.

If you have any questions, please contact the Office of Research Integrity at 859-257-9428 or email IRBsubmission@uky.edu.

To initiate your continuation review (CR)/annual administrative review (AAR), or properly close your study, complete this section and update/correct all other sections of your IRB application as applicable.
*****IMPORTANT*** Before leaving this page to update other sections of your application, be sure to SAVE this section first.**

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1. Status of the Research

Check the statement(s) that best describe(s) the current status of your research:

- ☐ No subjects have enrolled to date.
- ☐ Recruitment and/or enrollment of new subjects or review of records/specimens continue.
- ☐ Study is closed to enrollment, but subjects still receive research-related interventions (e.g., treatment, blood draws).
- ☐ Study enrollment is permanently closed; subjects have completed all research-related interventions; and the study remains active only for long-term follow-up of subjects (see Tool Tip above for info on long-term follow-up of subjects).*
- ☑ Research has progressed to the point that it involves 1) Data analysis, including analysis of identifiable private information or identifiable biospecimens; and/or 2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.*
- ☐ The remaining research activities are limited only to data analysis. There is access to records or specimens either directly or through codes or links to the data.*
- ☐ The remaining research activities are limited only to data analysis. There is no subject/record/specimen identifying codes or links to the data; the researcher or research team cannot readily ascertain the subject's identity.*
- ☐ All study activities are complete. IRB approval can be inactivated.

*Possibility that review will move from Full to Expedited.

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2. If subjects have been enrolled within the last year, and the IRB approved a consent/assent form for your study:

Please attach a complete, signed copy for the last two subjects enrolled with **each** consent/assent form/HIPAA form since the last annual review.
(Example: If 3 different approved consent forms were used since the last annual review, please provide the two most recent signed copies of each version for a total of six.)

Attachments

Attach Type	File Name
Entire Signed Consent Form	Consent 1.2025.pdf
Entire Signed Consent Form	Consent 1.2025 2.pdf

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3. Informed Consent

If the study is **open to subject enrollment, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF (without the IRB Approval stamp) of the currently approved consent/assent document(s), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **open to subject enrollment and the IRB has waived the requirement to document informed consent, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF of the currently approved document used for the informed consent process (e.g., cover letter, phone script), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **closed to subject enrollment, please go to the Informed Consent section of the E-IRB Application and remove Informed Consent Documents designated to get an IRB approval stamp to avoid having them appear valid for enrollment.**

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4. Unanticipated Problems Involving Risk to Subjects or Others/Adverse Events Summary & Assessment

Did any **problems/adverse events** occur during the last 12 months?

○ Yes ◉ No

In the space below, provide a written summary of both unanticipated problems* and available information regarding adverse events since the last review (e.g., initial review or annual/continuing review). The amount of detail provided in such a summary will vary depending on the type of research being conducted; in many cases, such a summary could be a brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and investigator's brochure (if applicable). **The summary must include the PI's assessment whether the problems/adverse events warrant changes to the protocol, consent process, or risk/benefit ratio.**

Note: It is the IRB's expectation that all unanticipated problems involving risk to subjects or others or related deaths requiring prompt reporting are submitted in the appropriate time frame (See Policy [PDF]). Your response to this Annual/Continuing Review is considered assurance that all prompt reportable problems/adverse events have been submitted for IRB review.

*For multisite studies, the written summary should describe external events determined to be unanticipated problems involving risk to subjects or others.

PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Impaired Risk Awareness during Intoxication in DUI Offenders

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

Impaired Risk Awareness

Anticipated Ending Date of Research Project: 11/30/2026

Maximum number of human subjects (or records/specimens to be reviewed) 120

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? ○ Yes ◉ No

Are you requesting that the UK IRB serve as the lead IRB for a multi-site study, **OR** that the UK IRB defer review to another IRB? [Click here for "IRB Reliance" help]
○ Yes ◉ No
If "Yes," before completing your IRB application, fill out the Reliance Request Form and submit it to irbreliance@uky.edu.

PI CONTACT INFORMATION

0 unresolved comment(s)

Principal Investigator (PI) role for E-IRB access
The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be listed as PI here.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.
To change the PI contact information on an application in Researcher edit status:

- click "Change Principal Investigator";
- search for the PI's name using the search feature;
- click "Select" by the name of the Principal Investigator, then "Save Contact Information".

  You will automatically be added as study personnel with editing permissions to continue editing the application.

Change Principal Investigator:

First Name:	Mark	Room# & Bldg:	220B KASTLE HALL
Last Name:	Fillmore	Speed Sort#:	405060044
Middle Name			
Department:	Psychology - 8E120	Dept Code:	8E120
PI's Employee/Student ID#:	00007568	Rank:	Professor
PI's Telephone #:	8592574728	Degree:	Ph.D.
PI's e-mail address:	Fillmore@uky.edu	PI's FAX Number:	8593231979
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	8/31/2023
		RCR Trained:	Yes

Do you, the PI/researcher, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- (●) (Risk Level 1) Not greater than minimal risk
- ( ) (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ( ) (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ( ) (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

*****For Expedited and Exempt Applications, the research activities must be Risk Level 1 (no more than minimal risk to human subjects).*****

Refer to UK's guidance document on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 21 to 45

Study Population:

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider this FDA Guidance on Enrollment of Participants from Underrepresented Populations in Clinical Studies

A total of 60 DUI offenders and 60 non-offender controls (N=120) will be recruited over the course of the grant. Anticipated enrollment will begin 12/30/2021 and continue until 11/30/2026. Subjects will be 80 male and 40 female adult drivers between 21-45 years old. Drivers in this age range are over-represented in traffic-related injury and have the highest prevalence of DUI. The male to female ratio of DUI offenders is approximately 4:1. Although sex differences are not predicted, in an effort to test for potential sex differences, we plan to over-sample female offenders so that women represent at least one-third of the sample. The control group will have the same sex composition to maintain uniformity across groups and groups will be matched on age. All subjects must hold a valid driver's license for at least 5 years and drive on a regular (i.e., weekly) basis. Volunteers provide a comprehensive medical and psychiatric history, including drug use disorders (SCID, DSM-5). Results are reviewed by the study physician. Exclusion criteria include a history of physical or psychiatric disease, pregnancy, breastfeeding, medications, DSM-5 criteria for AUD or other substance abuse disorder (other than nicotine or caffeine use), and other medical conditions that would warrant exclusion from the study. Recent drinking history will be assessed by the Timeline Follow-Back (TLFB). Based on our preliminary data, we do not expect group differences in drinking habits. However, we are prepared to match control subjects to DUI subjects to ensure group similarity. Potential controls will be enrolled with the restriction that each volunteer must match an enrolled DUI subject in terms of average monthly alcohol consumption, as measured by the TLFB. These drinking habit measures will be transformed to z-scores based on our norm-referenced sample of 1500 subjects' drinking habits. Drinking habits less than 0.2 standard deviations apart will be considered matched. This procedure has been used by our group and is effective in matching drinking habits across groups.
All subjects complete a driving history and experience form. The form gathers a comprehensive driving history, including license revocations, traffic violations, and DUI offenses. Participants also complete a standard neuropsychological battery consisting of the Sternberg Short-Term Memory Test, the Digit-Symbol Substitution Test, and the Kaufman Brief Intelligence Test (K-BIT). Eligible volunteers must have IQ greater than 80. Self-reported impulsivity will be assessed using the UPPS-P Impulsivity Scale.

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Kentucky State Census, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:				
Asian:	1			
Black/African American:	3	1		
Latinx:	3			
Native Hawaiian/Pacific Islander:				
White:	45	46		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:	8	4		
Unknown or Not Reported:	1			

If unknown, please explain why:

1 race not reported

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☑ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☐ Patients
- ☐ Appalachian Population

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see also the E-IRB Research Description section on this same topic]
- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For creating your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a “Reliance Consent Form” so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a read-only PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

- [x] Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- [ ] Assent Form
- [ ] Cover Letter (for survey/questionnaire research)
- [ ] Phone Script
- [ ] Informed Consent/HIPAA Combined Form
- [ ] Debriefing and/or Permission to Use Data Form
- [ ] Reliance Consent Form
- [ ] Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- [ ] Stamped Consent Doc(s) Not Needed

Attachments

Informed Consent Process:

Using active voice, in the text box below, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)

- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Will electronic consent form/process be utilized on-site or remotely for this study?

○ Yes ◉ No

If yes, in addition to addressing the above bullet points, describe the e-consent method and platform, including any hyperlinks, videos, or enhancements used to convey information, if applicable. Attach a representation of the e-consent with signature fields. For guidance, see the ORI E-Consent web page.

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.
- *Research Repositories*
  If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template.

Upon arriving at the lab, all participants' proof of age will be checked and each will be asked to sign an informed consent form describing the nature of the experiment and outlining all of the conditions for participation. Consent will be obtained by the Principal Investigator. The consent form provides the potential volunteer with information about the study (e.g., who is conducting it, contact information for the investigators and medical staff, how it is funded, where it will take place, the purpose of the study), what will be required of the volunteer (e.g., time commitment, alcohol consumption, dietary and drug and alcohol use restrictions prior and following sessions), the risks to the volunteer (e.g., side effects), the rights of the volunteer (e.g., confidentiality, voluntary participation), and the benefits of participating (e.g., monetary compensation, scientific knowledge). The informed consent form will be explained thoroughly and signed on-site. Each volunteer will receive a copy of their informed consent document. The PI will review all screening materials and sign off on consent forms. After consent is obtained, participants will provide a breath sample to verify a zero BAC, and urine sample to test for pregnancy or other drug use. Anyone disqualified for a positive test result, or declining to continue at any time after appearing at the research site will received prorated payment for sessions completed and dismissed. Transportation will be provided within Fayette county.
Our previous research in this area finds that participants are quite comfortable with the testing protocol and the reporting of information. Any complaints from the participants regarding the administration of this protocol will be responded to immediately. The PI will be informed of these issues, which will also be documented.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting a waiver of the requirement for the informed consent process.

☐ I am requesting an alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

*If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the **Cover Letter Template** as a guide. There is an English and a Spanish version.*

Option 1

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

Option 2

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

Option 3

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Home page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Griffith	Annie	Project Assistance/Support	SP	Y	N		P	Y	07/02/2024	Y	N	10/01/2021	N	Y
Hays	Lon	Medical Supervisor	SP	Y	N	M.D.	P	Y	11/08/2023	Y	N	06/17/2020	N	Y
Heymsfeld	Sarah	Project Assistance/Support	SP	Y	N		P	Y	07/10/2022	Y	N	08/10/2022	N	Y
Padgett	Kelsey	Study Coordinator	DP	Y	Y	MA	P	Y	04/06/2023	Y	N	04/05/2023	N	Y
Tomaszewski	Grace	Project Assistance/Support	SP	N	N		P	Y	10/08/2023	Y	N	12/05/2022	N	Y
Allen	Holley	Project Assistance/Support	SP	Y	N	M.A.		N	06/15/2020		Y	05/12/2025	N	N
Brown	Jaime	Study Coordinator	DP	Y	Y	B.A.	P	Y	11/09/2023	Y	Y	04/11/2025	N	Y
Burand	Calisse	Project Assistance/Support	SP	Y	N		P	Y	09/03/2023		Y	06/07/2022	N	N
D'Agostino	Alexandra	Project Assistance/Support	SP	Y	N	M.A.		N	07/08/2020		Y	04/11/2025	N	N
Gurney	Elise	Study Coordinator	DP	Y	N	BA		Y	03/30/2023		Y	04/11/2025	N	N
Reeder	Kimberly	Project Assistance/Support	SP	N	N		P				Y	12/17/2022	N	Y
Smith	Cynthia	Project Assistance/Support	SP	N	N		P	Y	08/11/2022		Y	12/05/2022	N	Y
Weafer	Jessica	Project Assistance/Support	SP	Y	N	Ph.D.		N	06/04/2021		Y	06/15/2024	N	N

RESEARCH DESCRIPTION

0 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

Pro Tips:

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section or under the Additional Information section to include supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

Alcohol-related traffic fatality and injury continue to be a major public health problem in the United States. NHTSA reported that in 2018, over 250,000 traffic injuries were alcohol-related, and alcohol was a factor in one-third of all traffic fatalities. Interventions to reduce recidivism in DUI offenders involve motivational interviewing and education with emphasis on increasing the offender's perceptions of the risks associated with alcohol use (i.e., risk awareness). Such prevention efforts have had only modest success. Despite considerable economic resources dedicated to these efforts, DUI remains one of the most frequently repeated offenses, with over one-third of offenders being charged with a second DUI offense within five years. The limited efficacy of existing programs has prompted research to focus on the characteristics of individuals who have been arrested for DUI in efforts to improve prevention and treatment programs. DUI offenders report traits of impulsivity, a characteristic that can heighten sensitivity to the impairing effects of alcohol. Recent laboratory studies conducted by the PI support this working hypothesis. Our research found that, compared with non-offenders, DUI offenders displayed greater impulsivity in response to alcohol coupled with reduced perception of intoxication. The research suggests that the offender's risk awareness is diminished, particularly in the intoxicated state, when critical decisions are made about whether or not to drive. The evidence is an important breakthrough that identifies a promising new treatment approach to reinforce risk awareness during intoxication and reduce recidivism of DUI. This proposal builds on this evidence by testing the efficacy of experiential-based training to increase DUI offenders' perceptions of risk associated with alcohol use.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

The proposal addresses the following Specific Aims:
Aim 1. Test the degree to which acute alcohol administration reduces specific indications of the offender's risk awareness and determine their role in decisions to drive. Our laboratory studies have shown that, in the sober state, impulse control and risk-taking behavior of DUI offenders appear similar to non-offenders, but during alcohol intoxication offenders displayed more impulsivity in response to the drug. The evidence suggests that, when sober, DUI offenders can exert behavioral self-control and recognize risks associated with alcohol. However, once intoxicated, they fail to adequately perceive risk and therefore display increased tendency for risky decisions, such as driving. The proposed research builds on that evidence by comparing DUI offenders and non-offenders in tests of the acute effects of alcohol on multiple key indicators associated with reduced risk awareness: elevated disinhibition/risk-taking and reduced interoceptive awareness of intoxication. Dose-response determinations and time-course analyses will test for prolonged reductions of risk awareness under alcohol in DUI offenders and examine the degree to which individual indicators of risk awareness predict the offender's decisions to drive after drinking.
Aim 2. Test the efficacy of experiential-based training to increase risk awareness during intoxication. Treatment programs to prevent DUI recidivism are based on a general "risk-awareness" approach that instructs offenders about the general risks associated with alcohol intoxication (e.g., the impairing effects at various blood alcohol concentrations). However, our findings suggest that offender's risk awareness might be especially compromised in the intoxicated state. The evidence points to the potential utility of experiential feedback to enhance self-appraisal of one's level of intoxication while drinking. The proposed research will test the efficacy of an innovative experiential-based training approach to improve DUI offenders' ability to appraise their level of intoxication and enhance their risk awareness. DUI offenders will undergo experiential-based training in which they are administered a controlled dose of alcohol and receive structured feedback and mindfulness-based training to accurately appraise the impairing effects of alcohol and estimate their breath alcohol concentration. The research tests the hypothesis that the experiential training will increase DUI offenders' risk awareness in the intoxicated state as evident by reduced disinhibition and risk-taking behavior in response to alcohol.
Exploratory Aim. Test the efficacy of experiential-based training to reduce risky alcohol use. It is well recognized that negative alcohol outcome expectancies can reduce alcohol use. Accordingly increased risk awareness also should be indicated by a reduction in hazardous drinking, especially episodes of binge drinking that pose particular risk for DUI. Offenders' alcohol consumption patterns will be assessed before and after experiential training to test its efficacy to reduce hazardous alcohol consumption (e.g., binge drinking episodes).
Significance of Aims. Little is known about how DUI offenders actually respond to alcohol once drinking has begun. Yet, it is during the intoxicated state that the decision to drive or not to drive is made. To our knowledge, our recent laboratory investigations provide the only published studies that examine the acute reactions to alcohol in DUI offenders. Our evidence for the atypical reactions to alcohol among DUI offenders truly breaks new ground and identifies promising mechanisms for behavioral change to reduce recidivism.

Testing the efficacy of an experiential-based approach represents a logical next step in identifying targets and impediments to interventions by building on the basic science to date.

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *Community-Based Participatory Research*: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

Subjects attend a familiarization session and are exposed to all performance-based tasks and assessments. Offenders and controls will undergo a pre-training assessment of their responses to alcohol versus placebo on the two key indicators of risk awareness: disinhibition/risk-taking and perceived intoxication. Subjects attend two dose-administration sessions: 0.0 g/kg (placebo – “baseline”) and 0.65 g/kg alcohol to yield a peak BAC of 85 mg/dl (0.085%). Doses are administered on separate days, double-blind in a counterbalanced order. Women tend to achieve higher BACs from a given dose than do men. Reducing the dose to 87% of that given to men adjusts for this difference so that women achieve the same BAC as men. This dose adjustment is used throughout the study. Under each dose, subjects will complete an assessment battery that measures their disinhibition/risk-taking, perceived intoxication, and level of self-efficacy to drive while intoxicated. The entire assessment battery is brief (30 minutes) to accommodate repeated testing and prevent fatigue. Its brevity also minimizes change in BAC during testing. Subjects will complete the battery 6 times following dose administration: 30, 70, 180, 240, 300, and 360 minutes (6 hrs).

The training session occurs within one week after completing the pre-training assessment of intoxicated risk awareness. Subjects will attend a training session in which they are administered a controlled dose of alcohol and receive structured training to accurately estimate their breath alcohol concentration (BAC) and accurately appraise the behavioral impairing effects of alcohol. Half of the DUI offenders (20 men and 10 women) will be randomly assigned to the training condition and the other half assigned to an alcohol-exposure-only “control” condition. Non-offender, control subjects will undergo the same group assignment procedure. At the beginning of the training session, subjects will receive 0.65 g/kg alcohol to yield a peak BAC of 85 mg/dl (0.085%). This peak BAC was chosen for training because it poses risk for DUI and can be produced by as few as 3-6 drinks, an amount typically consumed per occasion in this population. Training is comprised of two elements: BAC Discrimination and Performance Feedback.

After completing the training session, all subjects will be re-tested on the two indicators of risk awareness in response to 0.65 g/kg alcohol and placebo: disinhibition/risk-taking and perceived intoxication, and on driver self-efficacy. The post-training assessment of alcohol responses is identical to the pre-training assessment. Post-training assessment will be conducted at 1-month post-training to evaluate retention effects.

Alcohol consumption also will be assessed at monthly intervals over a 2-month follow-up to evaluate the training efficacy to reduce high-risk patterns of consumption (e.g., binge episodes). Subjects will complete monthly timeline follow back (TLFB) assessments of their alcohol use online. Tonic alcohol craving is also assessed using the Penn Alcohol Craving Scale (PACS) which is a five-item self-report with strong psychometrics that measures the frequency, intensity, and duration of thoughts about drinking over the past week. At the end of each month, subjects will receive a secure email with a custom link and instructions to complete TLFB and PACS assessments of their drinking and craving for the past month. Key measures of drinking habits will be total drinks over the past month, drinking frequency, and frequency of binge drinking (> 5/4 drinks per occasion for men/women).

Attachments

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

The study will recruit subjects through flyers, brochures, posters, Research Spotlights, ads placed on campus and in the surrounding community and region (Study Team will place/remove ads), including but not limited to the UK Medical Center, UK Clinics, Good Samaritan Hospital, Student Center, UHS, Turfland Clinic, Shriners, University Health Services, the 5 UK Center for Clinical and Translational Research wall mounts, Cardinal Hill, digital monitor screens (that can be used as a poster, postcard, or Featured Research Study on ukclinicalresearch.com), and area facilities and businesses. Subjects may be recruited through paid print and digital advertisements, including brochures, magazines, newspaper (e.g., Herald Leader, Bluegrass Area, Courier Journal, Cincinnati Enquirer, Health & Wellness, Chevy Chaser, Hamburg Journal, Business Lexington, or other publications in the surrounding region e.g., Bluegrass Regional print & digital ads, may include Appalachian counties), Radio (e.g., Sirius, Clear Channel, Cumulus, LM Communications, Public Radio, Pandora, etc.), Television spots, scrolling information on community stations, and theater screens. Recruitment ads may also appear on billboards, Lextran buses, taxicabs, other transportation methods, and Craig'sList. The study will employ a pre-screening eligibility survey to determine if a volunteer meets basic inclusion/exclusion criteria. The study team will build and disseminate the eligibility survey on UK's REDCap which provides HIPAA compliant storage on UK servers and encrypted transmission of survey responses. The portable devices do not download the data, it is directly stored into the secure web-based connection (https) behind the firewall. All files are password protected once entered into the system. All project data is stored and hosted locally. If the study team provides a link to the eligibility
survey, PRS will fold that link into recruitment materials. The link will be included in study information sent to ResearchMatch participants who have indicated interest in the study. Before redirecting the volunteer outside of ResearchMatch and to the REDCap survey, the volunteer is once again asked to confirm their interest in completing the pre-screening survey. All advertisements will be approved by the UK Institutional Review Board (IRB) and the UK Office of Public Relations. Interested individuals will contact the experimenter by email. The intake screens out individuals who: 1) have a medical condition contraindicating alcohol use; 2) have a substance abuse history (with the exception of nicotine); 3) are pregnant; 4) are alcohol abstainers; 5) are minors (under 21); 6) present to any session with a non-zero blood alcohol level prior to study; 7) present to any session urine-positive for benzodiazepines, barbiturates, tetrahydrocannabinol, cocaine, methylphenidate, amphetamine, and opiates; 8) present to any session with impaired field sobriety test performance; 9) have a body mass index of 30 or above. A general description of the study and the criteria for participation will be explained. The general requirements of the tasks will be described. It also will be explained that a participant must fast for 4 hours prior to test sessions. This study will be advertised on recruitment internet webpages in digital or video form (e.g., UKclinicalresearch.com, ResearchMatch.org, CenterWatch.com, CISCRP, UK, Wellnesshealthandyou.org, UK HealthCare monitor screens and UKclinicalresearch YouTube, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK_CCTS Instagram, UK and UKHC social media, and departmental/lab pages. If advertised on UKClinicalresearch.com, the online study flyer will include an option for interested individuals to enter and submit their contact information, they will be asked whether study team can contact them (Yes or No) via study-related text messages, and CCTS will also ask, 'How did you learn about the study? Internet and social media recruitment will follow the terms of use for each site utilized. The study will also be promoted through UK HC monitor screens. Potential participants may be identified from registry databases, including but not limited to ResearchMatch.org, Wellness Health and You, Sanders Brown Center on Aging, Infectious Disease, Dentistry, and the Markey Cancer Center. ResearchMatch.org/uky will be utilized as a recruitment tool for this protocol. ResearchMatch.org/uky is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (Vanderbilt University IRB #090207)." Once UK IRB approval is obtained the researcher or proxy will upload a flyer with no contact information via ResearchMatch email to selected de-identified participants in the ResearchMatch registry. If the de-identified participant selects "Yes, I'm interested!" the researcher or proxy will receive information about participant and they may contact them with more information about their research study. If the participant selects "No, thanks", researcher or proxy will not receive any information from de-identified participant. The CCTS attends outreach activities to promote research participation in general (e.g., Roots & Heritage Festival, Latino Festival, Eastern Kentucky University, Transylvania Health fairs, etc.) and will bring all relevant study flyers that are enrolling participants and using PRS services. This study may also go out on email distribution, listservs, or e- newsletters, e.g., the CCTS list serv, Markey Cancer Affiliates list servs, ResearchMatch.org, Wednesday's Word, Kentucky Office of Rural Health (KORH), Appalachian Translational Research Network (ATRN), etc. We may utilize physician referral letters to community physicians for patient recruitment. Articles and interviews about the researchers and research study may be promoted via UKNow, Kentucky living, and other media outlets. Research and study-related articles published on UKNow may contain standard language directing interested individuals on where to read more about research and current studies. UKPR, UK HealthCare marketing or the CCTS PRS may create videos to promote research, researchers and their studies to local, regional and national media venues and on internal hospital monitors. UK HealthCare may place study recruitment flyers on their internal and external racks (e.g., UK pharmacies, clinics, UK Libraries and Lexington Libraries) or on digital monitors. Participants may be recruited using newsletters, such as In the Loop, Health Matters, Making a difference, and external news letters. The study may also be advertised through UKPR and UKHC outreach activities. UKHC and CCTS have booths at many events, and researchers and coordinators are invited to attend any events that pertain to their study populations. Researchers may participate in radio or TV interviews. General information about their research may be presented with a phone number or website url for more study specify
information. Consenting members of the research team and/or consenting participants may be interviewed about the study for print, radio, or video which may be distributed via the aforementioned activities. All of these sources will be used to recruit participants from the Lexington area and surrounding counties. Interested individuals will contact the project coordinator by email to complete screening. All advertisements will be approved by the UK Institutional Review Board (IRB) and the UK Office of Public Relations. The investigators have extensive experience using this recruitment procedure in communities for alcohol and other drug studies and have recruited over 5000 participants using this method in the past 25 years.

Attachments

Attach Type	File Name
Advertising	DUI flyer controls Fillmore IRB 60239_stamped.pdf
Advertising	DUI flyer DUIs Fillmore IRB 60239 (2) stamped new.pdf
Advertising	DUI Fillmore_Video_Stamped for IRB.pdf
Advertising	DUI flyer DUIs Fillmore IRB 60239 for WHY.pdf
Advertising	controls Fillmore_Video_clean for IRB.pdf

Advertising	controls Fillmore_Video_Stamped for IRB.pdf
Advertising	bus ad Proof V2.C-STAMPED.pdf
Advertising	PSYCH-089a_flyer_clean_STAMPED.pdf
Advertising	PSYCH-089a_MON_STAMPED.pdf
Advertising	PSYCH-089a_social media_STAMPED.pdf

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project. List medications that are explicitly forbidden or permitted during study participation.

Subjects attend a familiarization session and are exposed to all performance-based tasks and assessments. At pre-training, subjects' responses to alcohol are tested to assess two key indicators of reduced risk awareness during intoxication: 1) increased disinhibition/risk-taking and 2) reduced perception of intoxication. Subjects then undergo an intoxicated risk awareness training session in which they receive a controlled alcohol dose with structured feedback and training to accurately appraise the impairing effects of alcohol and estimate their BAC. Post-training increase in intoxicated risk awareness will be assessed at a one month follow-up.
Participants will be tested individually. Test sessions will occur on separate days with a minimum of two days between sessions and a maximum inter-session interval of one week. Sessions begin between 10:00 AM and 6:00 PM. Experimenters will be blind with respect to the DUI classification. Participants abstain from alcohol and other drug use for 24 hours prior to sessions. Breath and urine samples are obtained prior to sessions to verify zero BACs, check for recent drug use, and confirm that women are not pregnant. If a subject tests positive for a drug, and it is determined that the drug is not regularly used, the session is rescheduled. If subjects test positive a second time, they are discontinued. Subjects attend two dose-administration sessions: 0.0 g/kg (placebo – "baseline") and 0.65 g/kg alcohol to yield a peak BAC of 85 mg/dl (0.085%). Doses are administered on separate days, double-blind in a counterbalanced order. Subjects will complete the battery 6 times following dose administration: 30, 70, 180, 240, 300, and 360 minutes (6 hrs). We expect that all subjects will reach a 0.02 BAC between 300 and 360 min. An Intoxilyzer SD-5 (CMI Inc.) will analyze breath samples beginning 30 minutes after drinking onset. Testing is identical in the placebo session.
The training session occurs within one week after completing the pre-training assessment of intoxicated risk awareness. Subjects will attend a training session in which they are administered a controlled dose of alcohol and receive structured training to accurately estimate their breath alcohol concentration (BAC) and accurately appraise the behavioral impairing effects of alcohol. Half of the DUI offenders (20 men and 10 women) will be randomly assigned to the training condition and the other half assigned to an alcohol-exposure-only "control" condition. Non-offender, control subjects will undergo the same group assignment procedure. At the beginning of the training session, subjects will receive 0.65 g/kg alcohol to yield a peak BAC of 85 mg/dl (0.085%). This peak BAC was chosen for training because it poses risk for DUI and can be produced by as few as 3-6 drinks, an amount typically consumed per occasion in this population. Training is comprised of two elements: BAC Discrimination and Performance Feedback.
BAC Discrimination Training: Subjects will be trained to accurately estimate their BAC using the Body Scan Exercise with BAC feedback. The aim of the exercise is to increase awareness of the interoceptive cues associated with alcohol intoxication to improve their accuracy of BAC estimation and generalize the training effects outside the laboratory. During the 10 min exercise, subjects are seated comfortably in a quiet room. They listen to an audio recording that instructs them to sequentially focus their attention on individual interoceptive cues of intoxication (e.g., dizziness, sedation, warmth). They are instructed to experience each sensation without distraction from competing thoughts or emotions. Following the body scan, subjects rate the intensity of the interoceptive cues on visual analogue scales that are constantly displayed to subjects providing them with a continuous, real-time visual profile of their current subjective state. Subjects then estimate their current BAC using the BAC estimation scale and receive immediate feedback on the accuracy of their estimation in graphic display that compares their estimated BAC to their actual BAC obtained by the breathalyzer. BAC discrimination training is conducted five times during the session: twice during the ascending limb of the BAC curve, at peak BAC, and twice during the descending limb.
Performance Feedback Training: This training element targets the driver's self-efficacy by increasing their awareness of the behavioral impairing effects of alcohol that are experienced at BACs at and even below the legal limit (50-80 mg/dl). At peak BAC, subjects will perform a visual reaction time (RT) task and grooved pegboard motor coordination task and receive immediate graphic feedback comparing their intoxicated performance to sober levels measured during the familiarization session. The RT task measures RT (msec) to visual stimuli (X, O) and the pegboard task assesses fine motor coordination by the placement of key shaped pegs into key holes, measured by time to complete the entire set. Performance feedback will be displayed to subjects as a bar graph depicting their performance at peak BAC during the session against their sober level performance which is the mean score of the final training block obtained during the familiarization session.
Alcohol consumption also will be assessed at monthly intervals over a 2-month follow-up to evaluate the training efficacy to reduce high-risk patterns of consumption (e.g., binge episodes). Subjects will complete monthly timeline follow back (TLFB) assessments of their alcohol use online. Tonic alcohol craving is also assessed using the Penn Alcohol Craving Scale (PACS) which is a five-item self-report with strong psychometrics that measures the frequency, intensity, and duration of thoughts about drinking over the past week.
We also assess the degree to which subjects perceive improvement in their interoceptive ability as a result of the training. The Multidimensional Assessment of Interoceptive Awareness Ver. 2 (MAIA-2) is a 37-item self-report measure of eight dimensions of self-perceived interoceptive ability. Dimensions especially relevant to the body scan are Noticing (awareness of body sensations), Attention Regulation (ability to sustain attention to body sensations), and Body Listening (active listening to the body for insight). Subjects will complete the MAIA-2 at the outset of the pre-training and the 1-month post-training assessment.
Alcohol Exposure-only Control Condition: These subjects undergo the same dose exposure over the session but receive no body scan training or feedback concerning BAC or performance. In addition to controlling for alcohol exposure during training, this condition also controls for activity and experimenter contact. These subjects perform a standard audio-guided mindfulness exercise that

focuses on breathing and relaxation but with no reference to alcohol, its effects, or cues for intoxication. Subjects also estimate their BAC and perform the RT and pegboard task, but receive no feedback.
Alcohol consumption also will be assessed at monthly intervals over a 2-month follow-up to evaluate the training efficacy to reduce high-risk patterns of consumption (e.g., binge episodes). Subjects will complete monthly timeline follow back (TLFB) assessments of their alcohol use online. Tonic alcohol craving is also assessed using the Penn Alcohol Craving Scale (PACS) which is a five-item self-report with strong psychometrics that measures the frequency, intensity, and duration of thoughts about drinking over the past week. At the end of each month, subjects will receive a secure email with a custom link and instructions to complete TLFB and PACS assessments of their drinking and craving for the past month. Key measures of drinking habits will be total drinks over the past month, drinking frequency, and frequency of binge drinking (> 5/4 drinks per occasion for men/women).

Attachments

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

Volunteers provide a comprehensive medical and psychiatric history, including drug use disorders (SCID, DSM-5). Recent histories of drinking behavior and drug use will be assessed by the Timeline Follow-Back (TLFB). A computerized screening test, the Structured Clinical Interview for DSM 5 (SCID), will be used to assess the presence of drug use disorders. The health screening will include a questionnaire to assess the subject's current state of health as well as any previous medical conditions and/or hospitalizations, this includes questions about allergies to foods and drugs. All subjects complete a driving history and experience form. The form gathers a comprehensive driving history, including license revocations, traffic violations, and DUI offenses. Participants also complete a standard neuropsychological battery consisting of the Sternberg Short-Term Memory Test, the Digit-Symbol Substitution Test, and the Kaufman Brief Intelligence Test (K-BIT). Self-reported impulsivity will be assessed using the UPPS-P Impulsivity Scale.
Disinhibition/Risk-taking will be assessed by three measures: inhibitory control, impulsive decision-making, and driver risk-taking. Inhibitory control is assessed by a cued go/no-go task that requires subjects to respond quickly to go targets and inhibit responses to no-go targets. Impulsive decision-making is assessed by the Two-Choice Impulsivity Paradigm (TCIP). On each trial, two monetary rewards are presented that differ in amount and subjects have the option to choose a smaller reward that is delivered sooner versus the larger reward delivered later. Driver risk-taking is measured by a driving simulation task (STISIM Drive, Systems Technology, Inc.) set on a metropolitan multi-lane street. Drivers earn monetary reinforcements for quickly completing the drive but lose money for crashing. Average speed (mph) and accidents are also recorded. Perceived Intoxication will be assessed by self-report 100 mm visual analogue scales (VAS) that measure subjective level of intoxication, perceived impairment, and driver self-efficacy (i.e., willingness and ability to drive) ranging from "none at all" to "very much". Subjects will also estimate their blood alcohol concentration on a Likert-type rating scale ranging from 0 to 160 mg/dl with a center reference point of 80 mg/dl indicated as the "legal limit".
Subjects will perform a visual reaction time (RT) task and grooved pegboard motor coordination task and receive immediate graphic feedback comparing their intoxicated performance to sober levels measured during the familiarization session. The RT task measures RT (msec) to visual stimuli (X, O) and the pegboard task assesses fine motor coordination by the placement of key shaped pegs into key holes, measured by time to complete the entire set.
Alcohol consumption also will be assessed at monthly intervals over a 2-month follow-up to evaluate the training efficacy to reduce high-risk patterns of consumption (e.g., binge episodes). Subjects will complete monthly timeline follow back (TLFB) assessments of their alcohol use online. Tonic alcohol craving is also assessed using the Penn Alcohol Craving Scale (PACS) which is a five-item self-report with strong psychometrics that measures the frequency, intensity, and duration of thoughts about drinking over the past week. At the end of each month, subjects will receive a secure email with a custom link and instructions to complete TLFB and PACS assessments of their drinking and craving for the past month. Key measures of drinking habits will be total drinks over the past month, drinking frequency, and frequency of binge drinking (> 5/4 drinks per occasion for men/women).

Attachments

Attach Type	File Name
DataCollection	UPPS-P-PaperCopy.doc
DataCollection	1.TLFB_instructions.docx
DataCollection	medical history form.docx
DataCollection	MAIA2 2018.05.27.pdf
DataCollection	Penn_Alcohol_Craving_Scale_171.pdf
DataCollection	driver history.pdf
DataCollection	AUDIT.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;

- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

All of the equipment and space needed to conduct this study is available in Kastle Hall. There is a private room for testing volunteers. All the procedures used in this study have been approved for and employed in previous studies conducted by this research group.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

The potential risks to participants are minimal owing to the safeguards in place. Participants remain in the laboratory area during the experiment. The questionnaires and behavioral tests in the proposed research are of a benign nature. The risks to the study volunteers are those related to the ingestion of alcohol. Common side effects of the proposed doses of alcohol include mild fatigue 3-4 hours after administration. Vomiting is extremely unlikely given the moderate doses administered. The doses to be administered were chosen to minimize, if not eliminate, the chance of adverse effects. For an average weight individual (i.e., 75 kg), the maximum alcohol dose to be administered in the proposed study translates to the alcohol content of 5 standard drinks (e.g., beers). The doses are typically below what many adults in this age range customarily consume (5 or more drinks). PI (Fillmore) has administered doses of this range to over 5000 participants over the past 25 years without incident of serious adverse effects. No accidents or other adverse consequences have ever occurred to participants who have received alcohol in the PI's laboratory. Dr. Lon Hays (M.D.) will provide medical consultation and 24 hour on-call support for all participants

There is also the risk that a volunteer's Protected Health Information (PHI) may be seen by others. PHI is considered individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present, or future physical or mental health conditions of an individual that may be used or disclosed. The following PHI will be collected as part of this project: names (individual, employer, relatives, etc.), address, telephone number, Social Security number, dates (birth, admission, discharge), mental and physical health history, drug use history, results from mental and physical health screening, and data from experimental measures. Private health information collected about subjects will be self-reported. The study does not include access to subjects' electronic or paper medical records, etc. All data will be coded by participant number only and any personal identifiers linking participants to their reports on questionnaires will be detached and destroyed as soon as participation is completed or disqualification occurs. In addition, the PI has a Certificate of Confidentiality under the authority of Section 301(d) of the Public Health Service Act [42 U.S.C. S 241 (d)], in order to protect against involuntary disclosure of the identities of research subjects participating in research.

Psychological discomfort from exposure to a pregnancy test or the upset that might result from an unexpected non-negative outcome represents the last area of possible risk or concern. These tests do, of course, require the participant's consent and cooperation, and all potential female participants are given advance notice of this test during initial phone contact. The PI's standard operating procedures will call for the exclusive use of a trained assistant to give instructions, process the samples, and report the results to participants individually. The assistant will advise participants of the conclusiveness of negative results, and also stress the ambiguity of non-negative outcomes. The assistant will have explained that rather than repeating non-negative tests to try to rule out a possible false-positive, any ambiguous result is grounds for disqualification. The assistant will also immediately offer specific advice about where to get more precise follow-up testing and provide information about how to get counseling if desired.

The benefits of this research are many. The results should provide new information linking cognitive dysfunction to DUI risk. As such, the findings should contribute importantly to the health and safety of drivers and society. Participants in the research derive considerable educational benefit from their participation. Subjects are genuinely interested in studies of alcohol and driving and have many questions about how the drug may affect them. The feedback to participants includes written educational information about the blood alcohol levels and the risks of impairment likely to result from drinking various amounts of alcohol. Participants in our studies often comment that this information is extremely helpful in judging the safety of their drinking practices, and deciding about activities, such as driving after drinking. Given the potential educational benefits that subjects derive from participating in this research, the minimal risk to subjects in this research is reasonable.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

There are no alternative treatments.

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Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.
- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate retention policies and will adhere to applicable facility requirements.

If this study will use de-identified data from another source, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.

If applicable, describe procedures for sharing data/specimens with collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

The research material consists of subjects' questionnaire scores, diagnostic test scores, urine analyses for drug metabolites and urine human chorionic gonadotrophin (pregnancy), and their scores on the cognitive-behavioral tasks and the driving simulator. Drug metabolites tested for include: amphetamine and amphetamine salts (e.g., methylphenidate), barbiturates, benzodiazepines, cocaine, opiates, and tetrahydrocannabinol. In addition, urine samples will be obtained at the initial screening and before the start of each experimental session to screen for drugs of abuse and test for pregnancy in women. (No archival records, specimens, or other data will be used). Authentication of drug and pregnancy assays is assured by purchase only from reputable commercial dealers who must adhere and document specific quality standards. All information will be in the form of numerical data and used for research purposes only. Results will be reported only for groups, and no single individual will be identified. All research materials obtained from participants will be collected directly from them at the time of screening and participation. Personal identifiers, such as names, will be removed from subjects' data records. All data will be stored in coded files and locked in the laboratory area. Urine samples will be collected at screening prior to a subject's participation in the experimental protocol. These urine samples will be tested for the presence of a full range of drugs of abuse. Expired air samples will also be taken at these times to detect the presence of recent alcohol consumption. Other research materials obtained from the volunteers include demographic information, the mental and physical health screening information, experimental data, and non-intrusive staff observations. Experimental data include the behavioral and cognitive task battery and simulated driving measures as well as self-reported responses on questionnaires.
Files will not contain the name of the volunteers. Instead, each volunteer will be assigned a unique identifying number. All written documents will be stored in locked cabinets in the PI's laboratory. All data will be retained for a period of at least six years after the end of the IRB approval period. Key access will be limited to immediate laboratory personnel. Electronic information will reside on a stand-alone, password-protected computer. The PI has obtained a Certificate of Confidentiality under the authority of Section 301 (d) of the Public Health Service Act [42 U.S.C. S 241 (d)], in order to protect against any involuntary disclosure of the identities of research participants participating in research.
Several procedures are taken to ensure the safety and comfort of all participants in this research.
i) Subject Screening. The intake screens out individuals who: 1) have a medical condition contraindicating alcohol use; 2) have a substance abuse history (with the exception of nicotine); 3) are pregnant; 4) are alcohol abstainers; 5) are minors (under 21); 6) present to any session with a non-zero blood alcohol level prior to study; 7) present to any session urine-positive for benzodiazepines, barbiturates, tetrahydrocannabinol, cocaine, methylphenidate, amphetamine, and opiates; 8) present to any session with impaired field sobriety test performance; 9) have a body mass index of 30 or above. Subject screening is also ongoing throughout the study. Prior to each test session, participants are re-screened for recent drug or alcohol use, pregnancy and general health status. Participants also must pass a standard field sobriety test prior to each session and once again prior to release from the session. The field sobriety test consists of the walk and turn, the one-leg balance (timed), the Romberg balance, and the finger-to-nose tasks. Performance on this battery prior to alcohol administration is designed to ensure the absence of any performance impairment prior to the session and to serve as a pre-alcohol baseline from which to compare performance on the same battery at the end of the day during release assessment. If alcohol effects are evident at the end of the experimental session, subjects will remain at the testing facility until these effects dissipate. Previous research indicates that by comparing pre- and post-alcohol performance on the experimental tasks and the field sobriety test, subtle levels of impairment can be detected.
ii) Doses. The doses of alcohol to be administered in the proposed research have been administered safely to human volunteers under controlled-laboratory conditions. Dose levels were selected to balance effects and side effects. We anticipate that careful volunteer selection, dose selection, and volunteer monitoring will greatly reduce, if not eliminate, the occurrence of serious adverse

effects. A longstanding objective of the PI is to employ sensitive behavioral measures that can detect effects of low alcohol doses. For example, the maximum alcohol dose administered is 0.65 g/kg alcohol which, for a person of average weight (80 kg), represents the alcohol content of 5 beers and produces a mean peak BAC of 85 mg/dl (0.085%), which is the legal limit used to prosecute for impaired driving. Moreover, the dose is typical of what many adults customarily consume, and has been administered to volunteers in the PI's laboratory for over two decades without ill effects (e.g., nausea, vomiting). The PI has tested over 5000 participants in alcohol studies and no accidents or other adverse consequences have ever occurred to participants who have received alcohol in his laboratory. All volunteers will be thoroughly informed of the various adverse effects which they might experience and will be appropriately cautioned concerning their activities in the hours after study participation. Since participation is voluntary, volunteers can withdraw at any time if they find the behavioral procedures or alcohol effects undesirable. The research team has extensive experience conducting inpatient and outpatient human behavioral pharmacology studies with healthy volunteers, DUI offenders, those with ADHD, and volunteers with histories of drug abuse, and we have never observed a serious adverse effect.
iii) Behavioral Testing and Laboratory Environment. During the course of participation in the research, a subject could experience dissatisfaction or discomfort with the experimental procedures. Because participation is voluntary, subjects can withdraw at any time if they find the research procedures or alcohol effects undesirable. A research staff member will be immediately available to address these issues and the study subjects have telephone contact information to reach the study investigators and the study physician. In addition, if individuals become overly distressed or distraught, participation in the study will be discontinued immediately and private consultation with an investigator and/or the study physician will be offered immediately. All subjects are invited and encouraged to attend a private debriefing and exit interview with an investigator during which the details of the study are reviewed, and exit interview questions about the subject's experiences in the study are discussed (e.g., usefulness and completeness of the information provided during recruitment and training, comfort and satisfaction with study participation). Treatment referrals may also be offered at this time.

Protocol management forms will include prompts for research staff members to record any protocol anomalies, data collection problems, concerns with study subjects, or any unusual events that could impact the safety of the subjects or the integrity of the protocol. In addition, the study investigators and study physician are available at all times by telephone to respond to any questions or concerns that occur during the study. Furthermore, investigators will meet with the project staff on a daily basis in the laboratory or by telephone contact to review the study activities. Participants remain in the laboratory area during the experiment. Subjects do not engage in strenuous or hazardous activity. The computer tests, driving simulations, and questionnaires are completed while sitting at a desk. The questionnaires and computer tasks are of a benign nature. "Simulator sickness" (i.e., motion sickness) resulting from the simulated driving task is a potential risk, but is very rare. Symptoms are nausea and dizziness. The PI has tested over 1200 participants in driving simulations, with less than 1% reporting mild simulator sickness. In all cases, symptoms subsided within an hour after discontinuing the driving task. In the event that a subject feels nauseated or dizzy from the driving simulator, we will discontinue the subject and let the subject rest in our lounge with soft drinks and a light meal until symptoms subside. The Behavioral Pharmacology Research Laboratory is equipped with first-aid services and is located less than 0.25 miles from the University's Medical Center and Emergency treatment service.
iv) Detoxification/Debriefing. BACs must fall to 0.02% (20 mg/dl) before volunteers can leave the laboratory after a session. This is in accordance with guidelines on alcohol administration in human experimentation as recommended by the National Advisory Council on Alcohol Abuse and Alcoholism (U.S. Department of Health and Human Services). BACs are determined by breathalyzers that are calibrated to a factory standard every month and are serviced and maintained annually by the CMI Breath Analyzer Instruments Inc. Volunteers also must pass a field sobriety test and sign a release form indicating that they have been informed of their BAC and that they agree not to drive. Volunteers receiving alcohol are provided with transportation to and from each session by Uber (within Fayette county only). They are told not to drive or operate heavy machinery until the following morning. During the detoxification period subjects' comfort is a priority. They receive a hot meal and nonalcoholic beverages in a lounge where they can read or watch movies.
v) Qualifications of Research Team. The research team consists of the PI, Mark Fillmore, Ph.D., and Lon Hays, M.D. Dr. Fillmore is an expert on the behavioral effects and pharmacokinetics of alcohol in humans. He has published over 140 research papers on acute effects of alcohol on human subjects. He serves as an expert witness in legal cases involving alcohol intoxication and is a board member of the IRB at the University of Kentucky. Dr. Hays specializes in addiction psychiatry and provides medical consultation for the project and 24 hour on-call support from the Psychiatry Department. All laboratory technicians have completed the training course on Human Subjects Protection and are CPR and first-aid certified annually.

☑ **UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Check this item to confirm that you will retain all IRB-related records for a minimum of 6 years after study closure.**

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review this guidance for more information on payments to subjects, including restrictions and expectations.

Volunteers will be paid $585 for complete data collection which includes $30 for the familiarization session, $75 for each of the 5 laboratory testing sessions, $15 for each of the 2 online surveys, and a $150 completion bonus. The completion bonus is earned if every component of the study is complete (familiarization session, 5 alcohol sessions, and 2 online surveys). Payment will be provided in the form of a reloadable credit card. Participants will receive a card and the first payment of $255 after they complete the familiarization session, both pre-training visits, and the training visit. They will earn another $150 after completing the 2 post-training visits and $15 after each online survey. The completion bonus of $150 will be earned after the 2nd online survey is completed. These payments will be loaded onto the reloadable credit card.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a

subject will not know what is “standard” – and thus not covered by the sponsor/study – unless you tell them.

There are no anticipated costs to subjects.

Data and Safety Monitoring

The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research or NIH-funded/FDA-regulated clinical investigations.

- If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.
- If this is a non-sponsored investigator-initiated protocol considered greater than minimal risk research, and if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

Reporting of adverse events: Consistent with NIAAA requirements, serious adverse events (SAEs) will be reported to the local IRB and the NIAAA project officer within 48 hours of the occurrence. A summary of all adverse events (regardless of severity) will be included in the annual summary/progress report. Subject running for the referenced project has not yet been initiated and thus, the opportunity for adverse events has not yet occurred. Severe adverse events are not anticipated given the screening and selection process. The procedures and alcohol doses are similar to the previously funded project for which no SAE had occurred. Any SAE in the proposed study will be reported to the PI and the Co-I, Dr. Lon Hays or his attending physician. Milder events, such as nausea and headache, will be reviewed in weekly staff meetings which will include all research assistants, the PI and the Co-I (the latter as needed). Written summaries of all adverse events (regardless of severity) will be provided by the PI to Dr. Hays and the medical support staff. If patterns of adverse events are detected, the protocol will be re-evaluated and amended, as appropriate. Data Quality Assurance and Confidentiality: Most data are collected by and stored on computers solely dedicated for this project. This increases the accuracy and completeness of data collection and ensures the validity and integrity of the data. The data are stored in a unique file on the hard-drive of the computers and are printed after all the tasks are completed. In all instances, the data files do not contain the name of the volunteer, but instead, each volunteer is identified by a unique number. A computer file linking the unique number with the volunteer’s name will be kept on a stand-alone, password-protected computer. Data files for experimental tasks and questionnaire measures from each experimental session will be manipulated and combined into a single electronic spreadsheet for each volunteer by the PI. Data for all volunteers will then be combined into a single electronic spreadsheet and separated by experimental measure for statistical analysis using SYSTAT and SPSS. Data will be analyzed by conventional statistical models and methods (i.e., ANOVA and regression). The alpha level will be set at 5%. The quality of manipulated data and data analyses will be monitored by random inspection by the PI and/or Co-Investigators. Interim analysis of the data will be conducted when 50% of the sample is accrued in each study. Medical Support for Acute Administration of Low Doses of Alcohol: As noted above, physician support for the study has been obtained. Lon Hays, M.D. provides medical consultation and on-call support for the conduct of this study. Dr. Hays or one of his on-call physicians will be available 24 hours per day by phone, pager, and/or direct intervention. Drs. Fillmore and Hays have been successfully collaborating in this manner for several years. The PI has been safely conducting acute alcohol administration studies for over a decade and will directly supervise training regarding the administration protocol.
Reporting of Changes or Amendments to the Protocol: Any potential amendment to the experimental protocol will first be submitted to the UK IRB for review. Acceptance of the proposed amendment by the IRB will be required before any change to the experimental protocol is implemented. As the study is being conducted, the principal investigator will also inform NIAAA promptly of any changes in recruitment or in the protocol that are relevant to safety, as well as any actions taken by the IRB as a result of its continuing (annual or more frequent) review of the study. In the event of any major changes in the status of an ongoing protocol, the PI will inform NIAAA’s program officer immediately. Such changes would include: amendments to the protocol, temporary suspension of subject accrual, or of the protocol, any change in informed consent or IRB approval status, termination of subject accrual, or of the protocol.

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Future Use and Sharing of Material (e.g., Data/Specimens/Information)

If the material collected for this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

N/A

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone who is willing to serve as the cultural consultant to the IRB.

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the "Additional Information/Materials" section. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?
○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?
○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?
○ Yes ○ No
If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ○ Yes ◉ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

I have attached a HIPAA Waiver of Authorization. ○ Yes ◉ No

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any

applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer “no” above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor’s authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition [FDA's PDF] of Significant Risk (SR) device?

- Yes. Device(s) being tested in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices being tested in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required Study Device Form, picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

Attachments

RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- [x] UK Classroom(s)/Lab(s)
- [ ] UK Clinics in Lexington
- [ ] UK Clinics outside of Lexington
- [ ] UK Healthcare Good Samaritan Hospital
- [ ] UK Hospital

Schools/Education Institutions

- [ ] Fayette Co. School Systems *
- [ ] Other State/Regional School Systems
- [ ] Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- [ ] Bluegrass Regional Mental Health Retardation Board
- [ ] Cardinal Hill Hospital
- [ ] Eastern State Hospital
- [ ] Norton Healthcare
- [ ] Nursing Homes
- [ ] Shriner's Children's Hospital
- [ ] Veterans Affairs Medical Center
- [ ] Other Hospitals and Med. Centers

- [ ] Correctional Facilities
- [ ] Home Health Agencies
- [ ] International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky (UK) or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below. When attaching reliance documents, please ensure that you select the correct 'Document Type' from the drop-down menu. See below for the "**Document Types**" in bold, followed by examples of reliance documents for each type:
  - **Individual Investigator Agreement (IIA)**
    - A completed Individual Investigator Agreement

- IRB Approval (Non-UK)
- A Letter of Approval from a Non-UK IRB

- IRB Authorization Agreement (IAA)
- A SMART IRB Agreement
- An OHRP Agreement
- A DoD Agreement
- An IREx Reliance Notification
- Any Reliance Agreement

- Letter of Support & Local Context
- A Letter of Support from an organization at which some research activities are occurring
- Communications Plan
- Local Context Form

Please reach out to IRBReliance@uky.edu if you have any questions or concerns.

- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

List all other non-UK owned/operated locations where the research will be conducted:

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

Please describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

Attachments

B) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Instructions: For various reasons, it is necessary to determine whether your research activities meet the definition of clinical research and/or a clinical trial. Your responses to the next series of questions will make that determination. For more details on the definitions, go to ORI's clinical research vs. clinical trial web page or visit NIH's decision tree for the NIH Clinical Trial definition.

My research activities include one or more of the following:

Patient-oriented research regarding mechanisms of human disease, therapeutic interventions, clinical studies, or development of new technologies
○ Yes ◉ No

Material of human origin (such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects
○ Yes ◉ No

Epidemiologic or Behavioral Studies
○ Yes ◉ No

Outcomes Research or Health Services Research
○ Yes ◉ No

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

☐ Academic Degree/Required Research
☑ Alcohol/Drug/Substance Abuse Research
☐ Biological Specimen Bank Creation (for sharing)
☐ Cancer Research
☐ CCTS-Center for Clinical & Translational Science
☑ Certificate of Confidentiality
☐ Collection of Biological Specimens for banking and use
☐ Community-Based Participatory Research
☐ Deception
☐ Educational/Student Records (e.g., GPA, test scores)
☐ Emergency Use (Single Patient)
☐ Gene Transfer
☐ Genetic Research
☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
☐ Individual Expanded Access or Compassionate Use
☐ International Research
☐ Planned Emergency Research Involving Exception from Informed Consent
☐ Recombinant DNA
☐ Registry or data repository creation

For additional requirements and information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial
- Collection of Biological Specimens for Banking (look up "Banks, Repositories, Registries...")
- Collection of Biological Specimens (look up "Repositories, Registries, Specimen/Tissue Banks...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Banks, Repositories, ...Genetic/Genomic Data Sharing...")
- Gene Transfer

  *For gene transfer research, also go to the E-

- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☐ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee

- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Exception to Informed Consent*

*For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use, storage and disposal of radioactive material and radiation producing devices

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Click applicable listing(s) for additional requirements and information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info-look up "Does the IRB Charge a Fee..."]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Other:

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

NIAAA

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

Attach Type	File Name
GrantContract	Research Strategy DUI IRB MF.docx
GrantContract	2023 Risk grant approval doc.pdf
GrantContract	Fillmore_Mark_3200004473_PADR20 2025.pdf

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP and DoD Summary for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC) - Attach required IBC materials
- Radiation Safety Committee (RSC) - For applicability, see instructions
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Additional Materials:

If you have other materials you would like to include for the IRB's consideration, check all that apply and attach the corresponding documents using the Attachments button below.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Other Documents

Protocol/Other Attachments

NOTE: Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

To view the materials currently attached to your application, click “All Attachments” on the left menu bar.

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

Individuals chosen as signees may remove the application from their Inbox without signing the Assurance Statement by clicking "Return to PI" with a comment about why it is being returned (e.g., specific edits are deemed necessary).

The PI, and personnel chosen as a contact, will receive an email notification that edits are needed, and can find the draft application in both the "Draft" folder and the "Signatures Status" folder located in the menu in the left margin of the default Inbox page. The researcher does not have a 'reply' option to the signee's comments and must make the requested edits directly in the application, or communicate outside the E-IRB system as to why not. Once the response is finalized, the researcher must re-visit the "Assurances Required" section to click the "Return to Signee" button for their re-consideration; the signee will receive an email notification at that time.

Hover your mouse cursor here for additional instructions.

First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Mark	Fillmore	Principal Investigator	Psychology		10/27/2021 02:21 PM	View/Sign
Michelle	Martel	Department Authorization	Psychology		04/05/2023 04:28 PM	View/Sign

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the Principal Investigator Reliance Assurance Statement by digitally signing this application.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Once all Assurance Statement signatures have been acquired, return to this section to submit your application to ORI.

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

SUBMISSION INFORMATION

0 unresolved comment(s)

***** If this Continuation Review entails a change in the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed. Otherwise your submission for IRB review and approval cannot be sent to the Office of Research Integrity/IRB.

If applicable, remember to update the Approval Letter Details text box under the Additional Information section

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and you will receive a message to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects, and I attest to:

1. Having reviewed all the investigational data from this study, including a compilation of all internal and external unanticipated problems.
2. Having reviewed, if applicable, information from the sponsor including updated investigator brochures and data and safety monitoring board reports.

I also attest that I have reviewed pertinent materials concerning the research and concluded either:

A. The human subject risk/benefit relationship is NOT altered, and that it is not necessary to modify the protocol or the informed consent process,
OR,
B. The human subject risk/benefit relationship has been altered, and have previously submitted or am including with this continuation review submission, a modification of the research protocol and informed consent process.

☑ By checking this box, I am providing assurances for the applicable items listed above.

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.090	klars2	5/27/2025 3:20:16 PM
	GrantContract	Fillmore_Mark_3200004473_PADR20 2025.pdf	2025 Grant Contract	0.620	ktpa223	5/12/2025 10:42:41 AM
	CR_EntireConsent	Consent 1.2025 2.pdf	Signed Consent form	0.243	ktpa223	5/12/2025 10:00:43 AM
	CR_EntireConsent	Consent 1.2025.pdf	Signed Consent form	0.240	ktpa223	5/12/2025 10:00:29 AM
	GrantContract	2023 Risk grant approval doc.pdf	Grant approval	0.480	ktpa223	7/20/2023 10:44:17 AM
	Advertising	PSYCH-089a_social media_STAMPED.pdf	social media ad	1.028	jblac2	12/17/2022 2:06:54 PM
	Advertising	PSYCH-089a_MON_STAMPED.pdf	new ad	0.097	jblac2	12/17/2022 2:06:36 PM
	Advertising	PSYCH-089a_flyer_clean_STAMPED.pdf	new flyer	1.017	jblac2	12/17/2022 2:06:20 PM
	Advertising	bus ad Proof V2.C-STAMPED.pdf	bus ad for DUI Study	0.394	jblac2	11/17/2022 10:20:10 AM
	Advertising	controls Fillmore_Video_Stamped for IRB.pdf	video advertisement stamped	12.306	jblac2	6/7/2022 12:36:30 PM
	Advertising	controls Fillmore_Video_clean for IRB.pdf	video advertisement stamped	12.256	jblac2	6/7/2022 12:36:05 PM
	Advertising	DUI flyer DUIs Fillmore IRB 60239 for WHY.pdf	WHY stamped flyer	0.160	jblac2	5/10/2022 7:21:31 PM
	Advertising	DUI Fillmore_Video_Stamped for IRB.pdf	video advertisement	0.906	jblac2	5/5/2022 12:06:10 PM
	Advertising	DUI flyer DUIs Fillmore IRB 60239 (2) stamped new.pdf	stamped flyer	0.257	jblac2	1/10/2022 10:09:53 AM
	Advertising	DUI flyer controls Fillmore IRB 60239_stamped.pdf	control flyer	0.189	jblac2	11/16/2021 2:42:05 PM
	GrantContract	Research Strategy DUI IRB MF.docx	grant	0.563	jblac2	10/27/2021 1:02:12 PM
	DataCollection	AUDIT.pdf	AUDIT	0.006	jblac2	10/19/2021 3:02:02 PM
	DataCollection	driver history.pdf	driver history	0.043	jblac2	10/19/2021 3:01:20 PM
	DataCollection	Penn_Alcohol_Craving_Scale_171.pdf	PAC scale	0.032	jblac2	10/19/2021 1:50:29 PM
	DataCollection	MAIA2 2018.05.27.pdf	MAIA2	0.106	jblac2	10/19/2021 1:50:13 PM
	DataCollection	medical history form.docx	medical history	0.013	jblac2	10/19/2021 1:49:53 PM
	DataCollection	1.TLFB_instructions.docx	TLFB	0.018	jblac2	10/7/2021 7:03:57 PM
	DataCollection	UPPS-P-PaperCopy.doc	UPPS	0.037	jblac2	10/7/2021 7:03:24 PM

Protocol Changes

Click link to sort Changed Date
Expedited Categories XPCategory0 changed by ktpa223 on 5/14/2025 10:46:00 AM
~~Y~~
Expedited Categories XPCategory1 changed by ktpa223 on 5/14/2025 10:46:00 AM
~~N~~
Expedited Categories XPCategory2 changed by ktpa223 on 5/14/2025 10:46:00 AM
~~N~~
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~~N~~
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~~N~~
Expedited Categories XPCategory7 changed by ktpa223 on 5/14/2025 10:46:00 AM
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HIPAA HIPAADeIdentificationCertForm changed by ktpa223 on 4/11/2025 5:33:28 PM
~~N~~
Informed Consent ElectronicConsent changed by ktpa223 on 4/11/2025 5:32:41 PM
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Project Information IsSubEnrollDataSpecimen changed by ktpa223 on 5/14/2025 11:02:08 AM
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Research Attributes EpidemiologicBehavioralStudies changed by ktpa223 on 4/11/2025 5:34:14 PM
~~N~~
Research Attributes MaterialOfHumanOrigin changed by ktpa223 on 4/11/2025 5:34:14 PM
~~N~~
Research Attributes OutcomesHealthServicesResearch changed by ktpa223 on 4/11/2025 5:34:14 PM
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Research Attributes PatientOrientedResearch changed by ktpa223 on 4/11/2025 5:34:14 PM
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Research Sites MultisiteLeadInvestigator changed by ktpa223 on 4/11/2025 5:33:48 PM
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Risk Level RiskCategory changed by ktpa223 on 5/14/2025 9:09:29 AM
~~3~~1
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~~2~~
Subject Demographics AsianMale changed by ktpa223 on 5/12/2025 10:10:27 AM
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Subject Demographics BlackAfricanAmericanFemale changed by ktpa223 on 5/12/2025 10:10:27 AM
~~4~~1
Subject Demographics BlackAfricanAmericanMale changed by ktpa223 on 5/12/2025 10:10:27 AM
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Subject Demographics HispanicLatinoFemale changed by ktpa223 on 5/12/2025 10:10:27 AM
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Subject Demographics IfUnknownExplain changed by ktpa223 on 5/12/2025 10:10:27 AM
1 race not reported
Subject Demographics MoreThanOneRaceFemale changed by ktpa223 on 5/12/2025 10:10:27 AM
~~4~~
Subject Demographics MoreThanOneRaceMale changed by ktpa223 on 5/12/2025 10:10:27 AM
~~8~~
Subject Demographics OtherUnknownMale changed by ktpa223 on 5/12/2025 10:10:27 AM
~~1~~
Subject Demographics WhiteCaucasianFemale changed by ktpa223 on 5/12/2025 10:10:27 AM
~~30~~16
Subject Demographics WhiteCaucasianMale changed by ktpa223 on 5/12/2025 10:10:27 AM
~~45~~6

Study Personnel Changes:

Status	PPIdentity	ProtocolID	PersonID	RoleInProtocol	IsContact	LastName	FirstName	Email	DeptCode	RoomBuilding	SpeedSort	PhoneNum	DeptDesc	AuthorizedConsent	ResponsibilityInProject	Degree	Rank	StatusFlag	IsRemoved	ModBy	ModDate	SFI	IsPIRN	MiddleName
Deleted	1024790	104252	12214513	SP	N	D'Agostino	Alexandra	dagostino@uky.edu						Y	Project Assistance/Support	M.A.			Y	ktpa223	4/11/2025 5:33:11 PM	N		
Deleted	1024792	104252	12316910	SP	N	Allen	Holley	Holley.Allen@uky.edu						Y	Project Assistance/Support	M.A.			Y	ktpa223	5/12/2025 10:11:09 AM	N		
Deleted	1024795	104252	12698149	DP	N	Gurney	Elise	Elise.Gurney@uky.edu						Y	Study Coordinator	BA			Y	ktpa223	4/11/2025 5:32:51 PM	N		

Project Information Comment by Karen Larson - ORI to PI on 5/14/2025 10:53:32 AM
Please mark "No" to "After approval, will the study be open to enrollment of new subjects or new data/specimen collection?" Scroll down and click SAVE.

Informed Consent Comment by Karen Larson - ORI to PI on 5/14/2025 1:06:48 PM
Still need to do- Go to All Attachments and remove the clean Consent Form uploaded on 11.18.21.

Informed Consent Comment by Karen Larson - ORI to PI on 5/14/2025 10:51:57 AM
Please mark "Stamped Consent Doc(s) Not Needed" Scroll down and click SAVE. Go to All Attachments and remove the clean Consent Form uploaded on 11.18.21.

Continuation/Final Review Comment by Beverly Raisor - ORI to IRB/PI on 5/14/2025 10:44:21 AM
I apologize for the confusion. I should have changed the review type before I returned the submission. I have made this correction and you should be able to select the correct expedited category now. Thanks!

Continuation/Final Review Comment by Kelsey Padgett - PI to PI on 5/14/2025 10:39:28 AM
Risk level was updated. Where are the Expedited categories?
Thanks

Continuation/Final Review Comment by Beverly Raisor - ORI to IRB/PI on 5/13/2025 8:36:37 AM
It appears the study can be reviewed using expedited procedures based on how the CR section has been completed. Please mark the following category in the "Expedited Categories" section: "Study was originally approved by the full IRB at a convened meeting." Please also, update the "Risk Level" section to Risk Level 1 - not greater than minimal risk. Once these changes have been made, please resubmit the study in eIRB.