

Document Coversheet

Study Title: Culturally AdapTed Harm Reduction Intervention: Community Engaged
InterVention for Black Adults that MisusE Opioids and Stimulants

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	9/16/2025
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IRB Number	96815
Coversheet created:	3/17/2026

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.)

MODIFICATION REQUEST SECTION

0 unresolved
comment(s)

*** If this modification changes the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.***

Select One:

- ☒ This modification does not increase risk to study participants.
☐ This modification may or will increase risk to study participants.

Is this modification request due to an Unanticipated Problem/Adverse Event, or Protocol Violation?

- ☐ Yes ☒ No

In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?

- ☐ Yes ☒ No

If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

For each proposed modification, include a justification.

Example: Jane Doe, MD, is being added as co-investigator because she has expertise with the subjects on this protocol. She has completed human subject protections training, and is authorized to obtain consent.

I am requesting to move my hardcopy study data from the off-campus data collection site (Louisville Central Community Center) to my on-campus office, as data collection has completed. This does not require a consent form change, as we will not be consenting new participants due to data collection completion. I made changes to the protocol to detail the transfer and new storage location for the Louisville-site (this is a multisite study and the Cincinnati location is not transferring data to a new location). Thank you

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



Culturally AdapTed Harm Reduction Intervention:
Community Engaged InterVention for Black Adults that
MisusE Opioids and Stimulants

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.



THRIVE

Anticipated Ending Date of Research Project: 10/31/2025

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

68

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:	<input type="text" value="Brittany"/>	Room# & Bldg:	<input type="text" value="247 Dickey Hall"/>
Last Name:	<input type="text" value="Miller-Roenigk"/>	Speed Sort#:	<input type="text" value="405060017"/>
Middle Name:	<input type="text" value="Deanne"/>		
Department:	<input type="text" value="Educational, School and Cou..."/>	Dept Code:	<input type="text" value="8G030"/>
PI's Employee/Student ID#:	<input type="text" value="10707530"/>	Rank:	<input type="text"/>
PI's Telephone #:	<input type="text" value="5024198615"/>	Degree:	<input type="text" value="PhD"/>
PI's e-mail address:	<input type="text" value="Brittany.Miller-Roenigk@uky.edu"/>	PI's FAX Number:	<input type="text"/>
PI is R.N.	<input checked="" type="radio"/> Yes <input type="radio"/> No	HSP Trained:	<input type="text" value="Yes"/>
		HSP Trained Date:	<input type="text" value="7/5/2024"/>
		RCR Trained:	<input type="text" value="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.) to

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](#)

**Aim 1:**

CAB Participants: Aim 1 will recruit up to n = 8 CAB participants. They will be recruited to have approximately 50% gender and age representation across four cohorts: born 1996-2006; born 1985-1995; born 1974-1984; born 1960-1973, with one male and one female in each cohort. Inclusion Criteria. Eligible CAB members in Aim 1 will: 1) Identify as Black or African American; 2) Aged 18-65; 3) currently a resident of Louisville and Cincinnati metro areas; 4) report misuse of stimulants and opioids in the last 30-days. Exclusion Criteria. The purpose of this study is to develop a culturally adapted intervention for Black Americans; thus, the sample will intentionally exclude individuals who do not identify as Black or African American. Individuals are also excluded if they do not want to be audio-recorded, since a main component of the study is recording focus groups. Aim 1 will occur in Louisville.

Aim 2:

Participants: Eligible participants for Aim 2 (n = up to 48-60; defined by approximately 3 focus groups of n = approximately 8-10 participants per group [depending on retention attrition across the from screener to appointment, and overall] in both Louisville and Cincinnati totaling approximately 6 total groups) are aged 18-65 and will be recruited to have approximately 50% male and female members overall but not specific to age cohorts. More groups may be necessary to reach maximum recruitment at each site (n = 30) if there is an issue with no-shows to previous groups. We will recruit until maximum is achieved. Inclusion Criteria. Inclusion criteria for Aim 2 are identical to Aim 1, except participants are asked if they have used stimulants and/or opioids in the past six months instead of opioids and stimulants in the past 30-days. Exclusion Criteria. Exclusion criteria for Aim 2 are identical to Aim 1, with the aforementioned exception regarding stimulant and/or opioid use in the past six months. Additionally, participants who participated in Aim 1 will not be eligible to participate in Aim 2.

Rationale:

The THRIVE project will recruit in two stages, a CAB for the development of the culturally adapted harm reduction intervention (n = approx. 8), and a group of n = approx. 48 – 60 to pilot the intervention. Based on census data from the states of Kentucky and Ohio, we expect that approximately 7.95% of the sample will identify as LGBTQ+. For the CAB, members will be Black adults stratified by age and gender across four cohorts to have gender and generational representation during the development of the intervention. Specifically, one self-identified woman and man from each of the following cohorts will comprise the targeted eight-person board: born 1996-2006; born 1985-1995; born 1974-1984; born 1960-1973. Selection rationale is to target Black adults across age and gender given disproportionate rates of relative overdoses among this population in Kentucky and Ohio, the current study's catchment areas. The purpose of this study is to develop a culturally adapted intervention for Black Americans; thus, the sample will intentionally exclude individuals who do not identify as Black or African American. These individuals will have lived experience relevant to this study, meaning, they will have misused opioids and stimulants in the past 30-days. The CAB will hear the harm reduction intervention and suggest adaptations and data about harm reduction through a semi-structured focus group. Co-PIs will then adapt the intervention based on these comments and test it with the CAB in a second visit before piloting.

For pilot the intervention, participants will be self-identified Black women and men from 18-65 years old to pilot the developed culturally relevant opioid overdose education and distribution of Fentanyl test strips and Narcan. Rationale for selection criteria is to again develop a representative sample of Black adults in the catchment areas in efforts to pilot a opioid overdose harm reduction approach among a uniquely at-risk underrepresented and under-served population still showing increases in opioid-related overdoses despite overall population overdose decreases. Given the aforementioned purpose of the THRIVE study, Inclusion criteria includes: 1) identifies as Black or African American, 2) resides in Louisville, KY or Cincinnati, OH, 3) between the ages of 18 – 65, 4) reports misuse of opioids and stimulants in the past 30-days (Aim 1) or opioids and/or stimulants in the past six months (Aim 2).

The current study targets a minority population and is aligned with NIH's call for inclusion of racial and ethnic minorities in human subjects research.

Attachments

Attach Type	File Name
StudyPopulation	Study Population.pdf

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:				
Black/African American:	34	34		

Latinx:				
Native Hawaiian/Pacific Islander:				
White:				
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:				

If unknown, please explain why:

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)

ADDITIONAL INFORMATION:

- ☐ 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

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**

- ☒ 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

Attach Type	File Name
Informed Consent/Parental Permission	Aim 1 UK Consent to Participate_clean.pdf
Informed Consent/Parental Permission	Aim 2 UK THRIVE Consent_SiteUC_clean.pdf
Informed Consent/Parental Permission	Aim 2 UK THRIVE Consent_siteUK_clean.pdf

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](#).

All participants will be recruited from Jefferson County in KY (UK PI) and Hamilton County in OH (UC PI). Recruitment will include: 1) advertising flyers on social media sites; 2) collaborating with local community organizations to identify potential participants; 3) distributing flyers at health clinics; 4) distributing flyers at restaurants, bus stops, and other frequented areas in the catchment area; 5) canvassing in neighborhoods with large percentage of Black residents; and 6) contacting previous research participants who have consented to being contacted for future study opportunities. Recruited participants will be screened to assess eligibility (see "study demographics" section). Potential participants in both aims will be screened in one of four ways: 1) interested persons can call or email study personnel using the contact information provided on flyers and online advertising and study personnel will complete the screening questionnaire over the phone using online screener in Qualtrics, 2) potential participants can access the QR code on flyers and be directed to the screener on Qualtrics to complete electronically and study personnel will call participants to verify the entered information 3) participants from previous research who have provided consent to be contacted for future studies will be contacted directly to ask about interest in participating in the current study and if interested, will complete the screening questionnaire over the phone using the online Qualtrics screener, and 4) participants recruited via neighborhood canvassing will complete the screening questionnaire with study personnel in-person using the online screener in Qualtrics. Eligible participants will be scheduled for study visits after completing the screener.

Participants in both aims will provide written informed consent at participant's first study visit after being thoroughly informed about the study's purpose, procedures, risks and benefits, and what the participant's involvement would entail. Due to the group nature of the study visits, consent will describe thoroughly the limitations to confidentiality and the expectation that information shared in the research process is not shared outside of the study visit. Participants will also be encouraged to address any complaints to study personnel and the PIs to be addressed by the PIs. Complaints related to distress that influences that participants willingness to participate will result in the participant being withdrawn from the study and referred to local providers as necessary. Participants will also be clearly notified that they can withdraw from the study without penalty. Participants will also receive with their copy of the consent form, the toll-free number to contact Office of Research Integrity (ORI) for questions or additional concerns related to their rights as a research human subject.

Aim 1 will use the UK aim 1 consent since only the Louisville site will recruit for aim 1. Aim 2 will consent participants in Louisville (UK site consent) and Cincinnati (UC site consent).*

***modification to protocol submitted to IRB January 2025, requested that the AIM 1 study visit two focus group include individuals in the study visit two group that may not have been present in study visit 1 for a total group size of up to n = 8. Original protocol detailed that group 1 and 2 would have the same individuals, but this was impacted by no-shows to the first study visit. To maintain good science for the adapted intervention intervention developed in Aim 1, research team needs to include as many intended cohorts to the aim 1 adaption phase. Thus, given this change in the protocol, research team members will inform participants present at Aim 1 study visit 1 that also attend study visit 2, that new participants will be present that were not present at time 1. This will occur during the scheduling period for study visit 2, by phone (attached script), to all participants retained from visit 1. The no-shows from visit 1 who attend visit 2 will also be informed of the protocol change. All participants attending study visit 2 will be consented with the new

consent form outlining the current information pertaining to the updated protocol.**

modification to protocol submitted in February 2025 pertain to changes in Aim 2 time commitment, eligibility requirements (less restrictive), screening and advertising (due to eligibility changes), QI/QA considerations as requested by funder for this aim, and total number of groups. These changes occurred before enrollment of any participants to Aim 2.

modification to protocol in April 2025 includes adding a Cincinnati data collection site, a direct phone number for participants to reach study staff, and inclusion criteria change to opioids and/or stimulants, which are all noted in the consent form.

☐ 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.

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. [i](#)

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: [i](#)

Last Name	First Name	Responsibility In Project	Role	A C	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Beard	De'Asia	Data Collection	SP	Y	N		P	Y	01/09/2024	Y	N	02/04/2025	N	Y
Mizelle	Destin	Data Collection	SP	Y	N		P	Y	10/18/2023	Y	N	02/04/2025	N	Y
Peterson	Rayven	Data Analysis/Processing	SP	N	N		P	Y	08/20/2024	Y	N	08/07/2025	N	Y
Smith	Adrienne	Data Collection	SP	Y	N	PhD	P	Y	07/08/2024	Y	N	11/07/2024	N	Y
Stevens-Watkins	Danelle	Consultant/Advisor	DP	Y	N	PhD	P	Y	08/12/2025	Y	N	06/14/2024	N	Y
Wheeler	Paris	Co-Investigator	DP	Y	N	PhD	N	Y	03/03/3000		N	11/15/2024	N	Y

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).

Rates of drug overdoses have increased exponentially among Black Americans,^{2,19-23} such that drug poisoning death rates among Black residents of Kentucky and Ohio now exceed the rates of White Americans.⁴⁻⁵ These drug overdoses are primarily driven by the presence of fentanyl and its illicitly manufactured analogs in the drug supply,² as it has been detected in counterfeit prescription pills, heroin, cocaine, methamphetamine, and other drugs.²⁴⁻²⁵ Fentanyl and its illicitly manufactured analogs are the leading cause of drug related mortality across the US³ and have disproportionately impacted Black communities in Kentucky and Ohio. Specifically, rates of overdose deaths among Black residents of Louisville, KY have increased tenfold from 2011-2021, compared to a three-fold increase among White residents.²⁶ As a result, the drug poisoning death rate among Black individuals in Kentucky now exceeds the rate among White individuals (61.2 vs 52.5 out of 100,000, respectively⁴). Similarly in Hamilton County, OH, despite an overall decrease in overdose related emergency department visits, the highest increase in the rate of overdose deaths was among Black residents from 2020-2021.⁵ Further, as of 2021, overdose rates in Ohio were highest among Black residents (53 per 100,000), compared to 49 per 100,000 among White residents.⁶ In both Kentucky and Ohio, the landscape of the overdose phenomenon is characterized by co-use, whether intentional or unintentional, of opioids and stimulants. In Kentucky, nearly half of opioid related deaths involved stimulants such as cocaine or methamphetamine, and Black individuals had the highest rate of stimulant involvement in drug poisoning deaths.⁴ In Hamilton County, Ohio, cocaine (41%) and methamphetamine (19%) were the second and third most common substances involved in drug overdoses after fentanyl.⁶ Reducing overdose mortality among people who use opioids and/or stimulants is critical in addressing health disparities among Black individuals, as intentional and unintentional co-use of opioids and stimulants such as cocaine, is associated with greater history of overdose compared to either substance alone.⁷ This risk is also due to high risk of fentanyl compounds in stimulants, such as cocaine, leading to mounting rates of overdose.²⁷

Harm reduction is an evidence-based approach that equips people who use drugs with health-promoting skills, resources, and information to help improve well-being and potentially save lives.²⁸ Harm reduction includes a constellation of strategies aiming to minimize the negative consequences of drug use,²⁹ such as overdose education and naloxone distribution (OEND) and testing one's drug supply for potential adulterants (FTS). In particular, OEND and FTS are critical points of intervention with a strong evidence base that will be integral to reducing overdoses among Black communities. OEND programming includes education about opioid overdoses, and use of naloxone to reverse an overdose, and distribution of naloxone. It has been a pillar of the overdose response efforts utilized since the onset of the opioid crisis and is associated with improved overdose knowledge, attitudes toward naloxone, and efficacy of administering naloxone to reverse an overdose.³⁰⁻³² FTS are lateral flow immunoassays that are used to detect the presence of fentanyl in one's drug supply.³³⁻³⁴ Interventions implementing use of FTS have demonstrated that participants who detect presence of fentanyl in their drug supply are more likely to employ further harm reduction behaviors such as reducing the amount they use, using in the presence of another, or using with Narcan on hand.⁹⁻¹⁰ Thus, both OEND and FTS are modifiable behavioral skills with high impact on behavior change and reduction in overdose risk. However, there are significant racial disparities in the use of these harm reduction approaches.

Among people who use illicit opioids, Black Americans report lower rates of naloxone training, possession of naloxone, and use of naloxone during opioid use compared to Whites and Hispanics.¹¹ Despite concerted efforts to improve naloxone kit distribution after the onset of the COVID-19 pandemic, increases in the ratio of overdose rates to naloxone kit distribution were not statistically significant among Black neighborhoods relative to White and Latino neighborhoods.³⁵ Black individuals are also less likely to have used FTS compared to other races.¹² There are several modifiable barriers that contribute to these disparities, including stigma, medical mistrust, practical knowledge, and access to transportation.³⁶⁻³⁷ Identifying methods to address these barriers and improve access to and use of Narcan and FTS among Black Americans is critical to mitigating disproportionate overdose risk. Importantly, simply increasing distribution of naloxone and FTS in Black communities is insufficient; rather, culturally appropriate and community engaged approaches are needed to address inequities in overdose mortality.³⁸⁻³⁹ Community engaged approaches are collaborative and address health disparities by centering topics important to the community and work with community advisory boards (CABs) to integrate knowledge with action to pursue social change.⁴⁰ Numerous studies have demonstrated the efficacy of community-based approaches in developing tailored interventions for improving health outcomes among underserved target populations.⁴¹⁻⁴⁴ However, few community-based interventions have been developed to reduce overdose risk among Black adults. Thus, we will utilize empirically supported community engaged methods to establish a CAB comprised of individuals with lived experience of opioid and stimulant use to inform the development of a culturally adapted intervention to increase Narcan and FTS use.

Objectives

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

Aim 1: To culturally adapt a harm reduction intervention for opioid overdose among Black American adults in Kentucky and Ohio using a community engaged approach. We will recruit a community advisory board (CAB) of individuals with lived experience of opioid and stimulant use, with expected equal representation across age groups and genders. Co-PIs will modify the original (HRC) Overdose Prevention and Naloxone Manual¹⁴ to pull key information on opioid and overdose education and Narcan distribution and include education on use of FTS. The intervention will then be presented to the CAB members (approx. n = 8) at study visit 1, where Co-PIs will elicit feedback for further adaptation and collect data on this suggested feedback and on harm reduction. Co-PIs will utilize this feedback to culturally adapt the intervention, which will then be presented again to the CAB for final feedback in a separate session.

****Before Aim 2, new adapted materials will be sent via a modification for review and approval before implementation of the intervention in Aim 2.-----Included in February 2025 modification****

Aim 2: To examine the feasibility of the community engaged, culturally relevant adapted harm reduction intervention with Narcan and FTS distribution. We will pilot the culturally adapted harm reduction intervention from Aim 1 among a sample of approx. 48 – 60 Black adults in Louisville, KY and Cincinnati, OH. We will conduct pre- and post-tests measuring confidence using methods, willingness to use methods, willingness to share/teach interventions to others at-risk in their networks, overall knowledge of overdose and prevention/intervention techniques, and comfortability possessing FTS and Narcan. Focus groups will measure these topics as well.

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](#).

The overall study design is a mixed methods pilot developing and testing a culturally adapted intervention to enhance knowledge about and motivation to use harm reduction approaches. Given the preliminary nature of this pilot study designed to develop a tailored intervention, subjects will not be randomized and there will be no control group or placebo.

Aim 1 is a qualitative design in which we will conduct two focus group sessions with a group of approx. 8 Black adults who have used opioids and stimulants in the past 30 days. Participant target will be to have recruitment of 50% gender and age representation across four cohorts: born 1996-2006; born 1985-1995; born 1974-1984; and born 1960-1973; with one male and one female in each cohort. A semi-structured qualitative focus group format will be utilized for each focus group session to allow for flexibility in asking additional questions based on participant responses. Individuals are excluded if they do not want to be audio-recorded, since a main component of the study is recording focus groups. Aim 1 will occur in Louisville, KY and full study visits will be recorded.

Aim 2 is a cross-sectional mixed method design in which the culturally adapted intervention developed during Aim 1 will be piloted after IRB modification approval (submitted in February 2025) among approx. 48-60 Black adults residing in Louisville, KY and Cincinnati, OH. Each study site will recruit approx. three groups of approx. 8-10 participants to pilot the intervention, resulting in approx. 6 groups and approx. 48-60 participants. To prepare for issues regarding retention from screening to appointment time, we may have more than 3 groups per site in order to reach our maximum enrollment (24-30 participants per site). We will hold groups until we reach enrollment, thus, the group number total and participants per group is flexible. Eligible participants for Aim 2 are aged 18-65, report using opioids and/or stimulants in the past six months, and will be recruited to have approximately 50% male and female members overall but not specific to age cohorts. Participants will complete pre-and post-intervention quantitative measures assessing their motivation and comfort using Narcan and FTS. In addition, participants will also participate in a semi-structured qualitative focus group after completing the intervention session to assess harm reduction needs in their community, additional barriers participants expect with the adapted intervention, feasibility of the intervention, and perceived knowledge of opioid overdose and prevention and intervention tools gained from prior to the intervention to afterwards. Individuals are excluded if they do not want to be audio-recorded, since a main component of the study is recording focus groups.

Attachments

Attach Type	File Name
StudyDesign	References.pdf

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](#)

All participants will be recruited from Jefferson County in KY (Aim 1 and 2) and Hamilton County in OH (Aim 2). Recruitment methods will include approaches that have been demonstrated to be effective in reaching underserved populations who use substances in Jefferson County as part of previous NIH funded studies. These include: 1) advertising digital versions of flyers on social media sites (via personal Facebook, Instagram profiles with commenting disabled); 2) collaborating with local community organizations to identify potential participants; 3) distributing flyers at health clinics; 4) distributing flyers at restaurants, bus stops, and other frequented areas in the catchment area; 5) canvassing in neighborhoods with large percentage of Black residents; and 6) contacting previous research participants who have consented to being contacted for future study opportunities. Interested participants will be screened to assess eligibility. Potential participants in both aims will be screened in one of four ways: 1) interested persons can call (direct, secure university office line to UC PI) or email study personnel (direct, secure, UK-sponsored email address) using the contact information provided on flyers and online advertising and study personnel will complete the screening questionnaire over the phone using Qualtrics screener, 2) potential participants can access the QR code on flyers and be directed to the screener on Qualtrics to complete electronically and study personnel will call participants to verify the entered information 3) participants from previous University of Kentucky or University of Cincinnati drug use research who have provided consent to be contacted for future studies will be contacted directly to ask about interest in participating in the current study and if interested, will complete the screening questionnaire over the phone using Qualtrics screener, and 4) participants recruited via neighborhood canvassing will complete the screening questionnaire with study personnel in-person using Qualtrics screener. Eligible participants will be scheduled for study visits after completing the screener. Participants will provide written consent at participant's first study visit after being thoroughly informed about the study's purpose, procedures, risks and benefits, and what the participant's involvement would entail.

Participant eligibility criteria for Aim 1 are as follows: 1) Identify as Black or African American; 2) Aged 18-65; 3) currently a resident of Louisville metro area; 4) report misuse of stimulants and opioids in the last 30-days. Individuals are excluded if they do not want to be audio-recorded, since a main component of the study is recording focus groups.

Participant eligibility criteria for Aim 2 are as follows: 1) Identify as Black or African American; 2) Aged 18-65; 3) currently a resident of Louisville or Cincinnati metro areas; 4) report misuse of stimulants and/or opioids in the last six months. If participant completed Aim 1, they will not be eligible to participate in Aim 2. Individuals are also excluded if they do not want to be audio-recorded, since a main component of the study is recording focus groups.

****UK PR approved Flyers****

Attachments

Attach Type	File Name
Advertising	Miller-Roenigk_Aim 2 Flyer 2025-STAMPED.pdf
Advertising	Miller-Roenigk_Aim 2 Flyer 2025.pdf
Advertising	Aim 1 Sample Scripts.pdf
Advertising	Aim 1 Flyer.pdf
Advertising	Aim 1 SCREENER_trackedchanges.pdf
Advertising	Aim 1 SCREENER_clean.pdf
Advertising	LT_STAMPED_071024_Aim 1 Flyer[88].pdf
Advertising	Aim 2 Sample Scripts_tracked.pdf
Advertising	Aim 2 Sample Scripts_Clean.pdf
Advertising	Aim 2 SCREENER_trackedchanges.pdf
Advertising	Aim 2 SCREENER_CLEAN.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.

Aim 1: Study visits for Aim 1 will take place at Louisville research facility (LCCC). Study Visit 1 will be used to solicit feedback using a community engaged approach from up to n = 8 CAB members on culturally adapting the harm reduction intervention: the HRC's Manual. 14,7 Before Study Visit 1, the Co-PIs will make initial modifications to the manual to ensure relevancy on opioid overdose education and use of Narcan and FTS as intervention and prevention techniques. The first Study Visit will be conducted by the two Co-PIs and is expected to last approximately 90-minutes. Following informed consent, the CAB members will be presented with the modified HRC manual¹⁴ and will be asked to provide feedback and additional harm reduction data. Specifically, they will provide information on 1) how the manual could be changed to better serve Black individuals who use opioids and stimulants and 2) barriers, challenges, and strengths regarding utilization of harm reduction resources in Black communities. The 90-minute study visit will be conducted in-person and recorded using HIPAA compliant Zoom software. CAB feedback will be incorporated into an adapted version of the manual. Data collected in Study Visit 1 includes qualitative data examining factors of the harm reduction intervention that the CAB would like to see implemented and tracking the types of changes they are suggesting, as well as barriers, challenges, and strengths regarding utilization of harm reduction resources in Black communities.

Study Visit 2 will occur approximately one month after the completion of study visit 1 and after Co-PIs incorporate feedback from study visit 1. The CAB (some initial participants, and some new participants given attendance and retention vs. attrition from time 1) will meet again at the LCCC to test-run the adapted harm reduction manual. Data collected at Study Visit 2 will include: qualitative data on the feedback on the quality of the intervention adaptations, the extent to which participants believe the intervention will be helpful in improving harm reduction practices among Black individuals, and additional changes they recommend prior to pilot testing, as well as additional barriers they expect with implementation of the adapted intervention. CAB will also be asked about additional harm reduction needs in their community, what they have noticed has been effective/ineffective regarding harm reduction in their community. CAB will also be asked about other adaptations they would consider. Study Visit 2 will last approximately 60-90 minutes and will be recorded using the same procedures as Study Visit 1. Participants will be offered FTS and Narcan. CAB will also receive first aid supplies at each study visit. Aim 1 participants will be compensated with a \$50 physical gift card (researcher loadable rewards card in Louisville; gift card in Cincinnati) for each study visit, earning up to \$100 over the course of the study. CAB will be asked to sign receipts of payment.

modification to protocol submitted to IRB January 2025, requested that the AIM 1 study visit two focus group include individuals in the study visit two group that may not have been present in study visit 1 for a total group size of up to n = 8. Original protocol detailed that group 1 and 2 would have the same individuals, but this was impacted by no-shows to the first study visit. To maintain good science for the adapted intervention intervention developed in Aim 1, research team needs to include as many intended cohorts to the aim 1 adaption phase. Thus, given this change in the protocol, research team members will inform participants present at Aim 1 study visit 1 that also attend study visit 2, that new participants will be present that were not present at time 1. This will occur during the scheduling period for study visit 2, by phone (attached script), to all participants retained from visit 1. The no-shows from visit 1 who attend visit 2 will also be informed of the protocol change. All participants attending study visit 2 will be consented with the new consent form outlining the current information pertaining to the updated protocol.

Before Aim 2, the new adapted materials will be sent via an IRB modification for review and approval before implementation of the intervention in Aim 2.sent Feb 2025

*note about intervention----intervention identical between sites, however, some slides pertain to KY vs. OH and will be presented at relevant site. OH specific slides: 4-5, 25, and 34; KY specific slides: 6-7, 26, and 35.

Aim 2: Participants will present to one Study Visit in Aim 2. Each research location (Louisville, KY and Cincinnati, OH) will have approx. three intervention groups (totaling approx. six groups) to pilot the intervention. Group number will be flexible to account for no-shows, which may require additional groups to reach enrollment of approx. 48-60 total, or 24-30 participants per site. Thus, more groups may be added to achieve enrollment. Each intervention group will have approximately 8 – 10 participants. Pilot sessions will last approximately 90-120 minutes. When scheduling, a series of times will be offered (one evening time, one weekend time, and one daytime) and the session will be scheduled at the time that is most convenient for the group. Each participant will complete a pre-test at Study Visit 1 prior to the intervention, participate in the intervention, then complete a post-test. After the intervention, they will participate in a recorded focus group. Data collected in Aim 2 will include qualitative and quantitative data. Data will be derived from the pre-test, post-test, and the focus group discussion after the intervention. The pre-test will collection impressions of Narcan and FTS, current willingness to use and share knowledge related to overdose, prevention (i.e., FTS), and intervention (e.g., Narcan), perceived knowledge of overdose and tools like FTS and Narcan, and confidence using these methods. The post-test will the same data after the intervention, as well as asking participants what they liked/would change about the intervention. The qualitative focus group discussion questions after the intervention will collect any additional harm reduction needs in their community, what have participants noticed has been effective/ineffective regarding harm reduction in their community, additional barriers participants expect with the adapted intervention, feasibility of the intervention, and perceived knowledge of opioid overdose and prevention and intervention tools gained from prior to the intervention to afterwards. The group interventions will be conducted in-person and recorded via HIPAA

compliant Zoom software to collect qualitative data. Participants will be offered FTS, Narcan, first aid supplies at the study visit. Participants will be compensated with a \$50 physical gift card for completion of the study visit (researcher loadable rewards card in Louisville; gift card in Cincinnati). Participants will be asked to complete a receipt of payment (UC and UK corresponding site receipts). Up to 4 research personnel will be present at study visit.

Additional notes pertaining to research procedures:

- In OH, the study team will obtain FTS and Narcan from the Hamilton County Health Department. In KY, FTS and Narcan through the Louisville Metro Health and Wellness Harm Reduction Outreach Services. These supplies will be provided to the research team at no cost and will include instruction on proper use to the research team.
- Notably, CAB will be consented as regular participants because in addition to feedback on the intervention for adaption, we will collect research data from them in the focus group, similar to aim 2 focus group data collected (see Focus Group topics attachments).
- Further, we will be recording participants and the data will be used in future publications. Thus, we will consent them.
- For Aim 1 and 2, transcripts will be transcribed using professional transcription service (Rev), who has confidentiality policies with customers to help ensure that data is prohibited from unauthorized use. Participants can opt to not say their name during recordings as an additional safeguard. Transcripts will be de-identified for storage and use by the research team.

Attachments

Attach Type	File Name
ResearchProcedures	UC site Aim 2 SensitiveHumanSubjIncentiveReceipt.pdf
ResearchProcedures	Aim 2 Focus Group Topics 2025_tracked.pdf
ResearchProcedures	Aim 2 Focus Group Topics 2025_Clean.pdf
ResearchProcedures	THRIVE Adapted Intervention AIM 2.pdf
ResearchProcedures	Aim 1 Focus Group Topics_tracked_changes.pdf
ResearchProcedures	Aim 1 Focus Group Topics_CLEAN.pdf
ResearchProcedures	Example Script to inform participants of Jan 2025 modification .pdf
ResearchProcedures	Aim 2 Post-Test.pdf
ResearchProcedures	Aim 2 Pre-Test.pdf
ResearchProcedures	THRIVE Payment Receipt.pdf

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.

Aim 1: Data collected in Study Visit 1 includes qualitative data examining factors of the harm reduction intervention that the CAB would like to see implemented and tracking the types of changes they are suggesting, as well as barriers, challenges, and strengths regarding utilization of harm reduction resources in Black communities. Data collected at Study Visit 2 will include: similar items discussions on adaptations and barriers as time 1 as well as qualitative data on the feedback on the quality of the intervention adaptations, the extent to which participants believe the intervention will be helpful in improving harm reduction practices among Black individuals, and additional changes they recommend prior to pilot testing, as well as additional barriers they expect with implementation of the adapted intervention. Participants will also be asked about additional harm reduction needs in their community, what they have noticed has been effective/ineffective regarding harm reduction in their community. The focus groups will be conducted in-person and recorded via HIPAA compliant Zoom software to collect qualitative data. Data will be transcribed by professional and confidential (i.e., policies to prohibit unauthorized use) transcription service (Rev), de-identified, and saved to the protected HIPAA compliant OneDrive folder.

Aim 2: Data collected in Aim 2 will include qualitative and quantitative data. Data will be derived from the pre-test, post-test, and the focus group discussion after the intervention. The pre-test will collection impressions of Narcan and FTS, current willingness to use and share knowledge related to overdose, prevention (i.e., FTS), and intervention (e.g., Narcan), perceived knowledge of overdose and tools like FTS and Narcan, and confidence using these methods. The post-test will the same data after the intervention, as well as asking participants what they liked/would change about the intervention. All pre- and post-test data will be collected as a hard copy, then data will be entered by study staff into shared protected OneDrive drive. The qualitative focus group discussion questions after the intervention will collect any additional harm reduction needs in their community, what have participants noticed has been effective/ineffective regarding harm reduction in their community, additional barriers participants expect with the adapted intervention, feasibility of the intervention, and perceived knowledge/motivations of opioid overdose and prevention and intervention tools gained from prior to the intervention to afterwards. The group interventions will be conducted in-person and recorded via HIPAA compliant Zoom software to collect qualitative data. Data will be transcribed by professional and confidential (i.e., policies to prohibit unauthorized use) transcription service (Rev), de-identified, and saved to the protected HIPAA compliant OneDrive folder.

Attachments

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.

Study Team: The study team is comprised of underrepresented diverse investigators with experience in substance abuse research among Black Americans. Drs. Brittany Miller-Roenigk (UK) and Paris Wheeler (UC) are early career investigators and will serve as Co-PIs for this study, exhibiting equal effort throughout the study process. The partnership and responsibilities between Co-PIs include collaborating in the development of the harm reduction intervention in Aim 1, supervising research personnel in Aim 2 and analysis and dissemination of pre- and post-test data. University of Kentucky's, Dr. Danelle Stevens-Watkins will serve as the Co-PI's research mentor. She has over twenty years of clinical experience with Black Americans, is a licensed psychologist in KY, and has over a decade of continuous NIH funding. The research mentor will provide research consultation on the study procedures and potential challenges (e.g., recruitment delays). Co-PIs will also meet with the research mentor to discuss study progress once monthly, with additional consultation as needed between meeting times. Other key research personnel will include student research assistants/and or postdocs at each study site. These individuals will be responsible for assisting with recruitment, facilitating group intervention in Aim 2 (lead group facilitators will be at least master's level/PhD student personnel), data entry and management, and other research-related tasks as needed in the Aims. Research assistants/personnel at each location will be named and added to the protocol as study progresses. PIs will ensure all data security and that the study is carried out in compliance with protocol.

The proposed locations for the proposed study are Louisville, KY and Cincinnati, OH. Dr. Brittany Miller-Roenigk will conduct and coordinate research activities and manage personnel in Louisville, KY, and Dr. Paris Wheeler will conduct and coordinate research activities and manage personnel in Cincinnati, OH. Facilities used in Louisville, KY include a rented space in downtown Louisville: The Louisville Central Community Center (LCCC). A private office will be used to store data, while LCCC private conference rooms will be used to facilitate intervention groups. LCCC staff will not be engaged in research activities in any capacity and will performing their normal job duties as LCCC staff and/or lease holders. Facilities in Cincinnati, OH include a private office of the Co-PI in Clifton Court Hall to store data, and a private conference room to facilitate group intervention. Additionally, a private room at a Cincinnati community area will be used for data collection in OH (Urban Minority Alcoholism and Drug Abuse Outreach Program [UMADAOP]). Aim 1 activities will occur in Louisville, KY with coordination of both Co-PIs and personnel from each research site, while Aim 2 activities will occur at each of the respective research sites.

Specifically, for Aim 1, both UK and UC Co-PIs will be involved in recruitment, consenting, data collection, adaption of intervention, and analysis. For Aim 2, UC and UK personnel (respective Co-PIs and research assistants) will recruit for their own three focus groups and pilot intervention in their responsible cities (Dr. Brittany Miller-Roenigk and TBD assistants in Louisville recruiting, data collection, and consenting and Dr. Paris Wheeler and TBD assistants in Cincinnati recruiting, data collection, and consenting). Each site will be responsible for approx. three pilots/focus groups. Then, Dr. Miller-Roenigk and Dr. Wheeler will participate in data analysis upon completion.

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?
- *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.

Foreseeable participant risks are minimal and likely limited to feelings of emotional distress related to discussing and hearing about opioid overdose. Participants will be provided counseling referral if they disclose a need after participating in our study. Co-PI at the University of Kentucky is also a licensed clinician, to assess any immediate crisis, though, crisis is not anticipated. No physical risks are anticipated. Minimal social risks are anticipated, as interventions will be given in a group format, and eligibility requirements require opioid and stimulant use (aim 1) and opioids and/or stimulants (aim 2). Limits of confidentiality will be discussed, but participants will be encouraged to keep identities and disclosures confidential. There are potential legal risks anticipated since some of THRIVE staff are mandated reporters. Under circumstances required by law, mental health professionals will have to report (e.g., disclosed abuse to children or the elderly/vulnerable adult, disclosed danger/harm to self or others). Limits to confidentiality will be explicitly detailed and

stated in the consent form and staff will ensure full understanding from clients before enrolling. The Co-PI at the University of Kentucky and the mentor at the University of Kentucky are licensed psychologists in Kentucky and will be notified immediately if there is a suspected reporting requirement so the appropriate reporting steps can occur in-person to ensure enrollee and other persons' safety. Foreseeable staff risks are not greater than risks they already incur as a function of their professional roles as graduate students, faculty, administrators at the University of Kentucky and University of Cincinnati, and licensed psychologists. These risks are anticipated to be minimal, such as minimal psychological risks including emotional distress from discussing opioid overdose. There are not anticipated social, physical, or legal risks anticipated.

Risks are reasonable in relation to the knowledge to be gained. We also have procedures to minimize risks to participants. Procedures to minimize and protect against risks include: 1) protecting the confidentiality of any information obtained during the THRIVE project, with explicitly disclosed limits to confidentiality, 2) VPN, password, and key protected data storing, 3) signed informed consent from enrolled participants for data collection and intervention, 4) locked access points for paper data storing at both sites. In the event of an adverse effect to personnel or enrollees, the Co-PIs will be notified immediately. The Co-PI(s) will immediately report this to the University of Kentucky and University of Cincinnati IRBs, to ensure the appropriate course of action to mediate the adverse effect occurs within a reasonable time.

Potential benefits for participating include access to life saving interventions to prevent overdose, which also has a public health benefit. Participants will have access to both Narcan and Fentanyl tests strips. Other benefits include learning about culturally appropriate interventions for opioid overdose, which will have a societal impact to reduce opioid-related overdoses. Thus, this study is critical in helping to prevent disproportional overdoses among Black Americans.

In sum, We anticipate minimal risk as a result of participating in the current project among participants and staff. The minimal risk, such as emotional distress, anticipated may result from discussing or hearing about opioid overdose. We anticipate that many participants and staff will find, however, participation in this project to be rewarding, such as developing and piloting a harm reduction approach to help minimize overdose among Black populations. The THRIVE project is designed in a way to improve education about opioid overdose and utilization of strategies to prevent and intervene with opioid overdose (i.e., fentanyl test strips and Narcan) in Louisville and Cincinnati, two areas with growing rates of overdose among Black adults.

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 should participants choose to not participate.

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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](#)

Privacy and confidentiality will be ensured by storing data on an encrypted University of Kentucky and University of Cincinnati Shard encrypted OneDrive Folder accessed via password protected University VPNs (i.e., encrypted connection) on a password protected computer to ensure HIPAA compliance and data security. All hard copy data (i.e., signed consent forms and hard copy pre- and post-tests) will be stored in a locked file cabinet, in a locked office, within a locked building at the University of Cincinnati (for Dr. Wheeler of the University of Cincinnati's research involvement) and a rented space at the Louisville Central Community Center (LCCC) in Jefferson County (for Dr. Miller-Roenigk of the University of Kentucky's research involvement). Only project team members will have access to the data. Participant identities will be kept private from people outside of the project team. None of the members of the

University of Kentucky or University of Cincinnati IRB responsible for reviewing this project will have any association with the project procedures or treatment of enrollees. Both locations will have two locked points of entry (including a locked file cabinet, only accessible to research staff). Screener data will be collected via Qualtrics and entered in OneDrive folder, and data will only be accessible via project staff and via password protection. Qualtrics will be set to not collect local IP addresses to help secure online records. Data from paper copies will be entered in our shared OneDrive file. Focus groups from Aim 1 and 2 will be de-identified and The Co-PIs will be responsible for ensuring protections of data are maintained and communication with the University of Kentucky and University of Cincinnati IRB in the event of a data breach, though privacy and confidentiality are of the utmost importance, and we do not anticipate any breaches given our planned protections. Monitoring will occur on a monthly basis, with any program personnel and staff reporting any issues to the PIs immediately. All data will be identifiable by participant ID. The master list linking the participant ID to their name will be kept separate, in a locked file cabinet at the research sites.

All qualitative data from aims 1 and 2 will be collected via HIPAA compliant Zoom software. Digital recordings will then be sent to a professional transcription service (Rev) to be transcribed. Rev has confidentiality policies with customers to prohibit unauthorized use. Participants will be informed to not state their names on the recordings if they do not want their names available to the transcription service. Transcribed files will be de-identified and saved on the protected OneDrive folder for later analysis. Aim 2 is considered a clinical trial. Thus, aggregate demographic information will be reported in clinicaltrials.gov. No identifiable information or individual research data will be shared.

Participants in Louisville will be compensated via the UK loadable rewards card program. To load cards, participant ID numbers will be shared with University of Kentucky Accounts Payable to load the visa rewards cards through US Bank. No identifiable information will be shared externally due to CoC protections. For business protocol, first and last names will be stored internally within the PIs department at the University of Kentucky for card record keeping. No research data will be shared internally or externally for this process. Cards will be loaded within 24-hours, typically within the same business day of your participation.

Finally, this research is funded through CCTS, via an NIH cooperative agreement award class. All NIH studies automatically receive a certificate of confidentiality (CoC) to further protect data. This helps ensure that protection of identifiable information from disclosure.

*****Modification submitted in September 2025 details a change in hardcopy data storage for the Louisville-site. Data collection is complete for the study, so this change is to the protocol only describing data storage only. All digital data storage will remain the same as described in the section, as well as storage of Cincinnati-site data. In Louisville, upon approval of the modification request, all hard copy data (i.e., signed consent forms, receipts, hardcopy pre- and post-tests), will be moved with a lockbox from the Louisville Central Community Center by the UK PI, directly to the UK PIs on-campus office in Dickey Hall. This data will be stored in a locked file cabinet, in her locked office. Only project team members will have access to the data. Consents and receipts will be stored separate from research data (not in the same folders so pre- and post-test data cannot be linked to the names on the receipts or consents), and research data will be identifiable only by participant ID, with the linking master sheet stored separately. The linking hardcopy file, that links participant names to participant ID numbers, will be stored separately in the UK PI's office, in the locked file cabinet, within a separate lock-box in the file cabinet, accessible with a different key. Participant identities will be kept private from people outside of the project team. This location has two locked points of entry, only accessible to research staff. Transfer will occur in September 2025.

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.

Aim 1: CAB participants (up to n = 8) will be compensated with a physical \$50 gift card for each study visit, earning up to \$100 over the course of the study. Study visit 1 is the visit where the harm reduction intervention will be developed, and visit 2 will be the test run and any additional adaptations requested.

Aim 2: Each participant (n = approx. 48-60) will be compensated with a physical \$50 gift card for participating in the pilot intervention group.

This compensation amount is reasonable to not cause undue inducement yet can sustain motivation and commitment to the project. Specifically, \$50 will not lead to coercion to participate. Participants will also be notified in the consent form they can withdraw from the program at any point. Participants must complete study visit to receive compensation.

*Participants in Louisville will be compensated via the UK loadable rewards card program. To load cards, participant ID numbers will be shared with University of Kentucky Accounts Payable to load the visa rewards cards through US Bank. No identifiable information will be shared externally due to CoC protections. For business protocol, first and last names will be stored internally within the PIs department at the University of Kentucky for card record keeping. No research data will be shared internally or externally for this process. Cards will be loaded within 24-hours, typically within the same business day of your participation.

Costs to Subjects

Describe any research costs which participants may be responsible for if they participate in the study (e.g., urine, HIV test).

There will be no cost to participants to participate in this study.

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.



Data safety is a priority, so we have several safeguards in place to protect data. There is no Monitoring Plan, however, this study will have an initial and potentially second random quality assurance check through CCTS staff assigned to review project, given that this is a CCTS Pilot Funded study. Further, the proposed study will be approved by the UK IRB and UC IRB. Participants will provide informed consent for the study and several questions will be asked to ensure understanding. Participants will be able to withdraw from the study at any time if desired. Consent Forms will be stored in locked file cabinets in locked rooms at LCCC and the University of Cincinnati Clifton Court Hall, where only study staff will have access.

Privacy and confidentiality of all electronic data (entered pre- and post-tests, de-identified transcripts, participant trackers for scheduling purposes [will include screener data, name, and phone number]) will be ensured by storing data on an encrypted University of Kentucky and University of Cincinnati Shard drive and an encrypted OneDrive Folder accessed via password protected University VPNs (i.e., encrypted connection) on a password protected computer to ensure HIPAA compliance and data security. All hard copy data (i.e., signed consent forms, paper receipts, and hard copy pre- and post-tests) will be stored in a locked file cabinet, in a locked office, within a locked building at the University of Cincinnati and a rented space at the Louisville Central Community Center (LCCC) in Jefferson County. Only project team members will have access to the data. Consents and receipts will be stored separate from research data, and research data will be identifiable only by participant ID, with the linking master sheet stored separately. Participant identities will be kept private from people outside of the project team. None of the members of the University of Kentucky or University of Cincinnati IRB responsible for reviewing this project will have any association with the project procedures or treatment of enrollees. Both locations will have two locked points of entry (including a locked file cabinet, only accessible to research staff). Screener data will be collected via Qualtrics, entered in OneDrive, and data will only be accessible via project staff and via password protection. Qualtrics will be set to not collect IP addresses, and only identifiable information collected will be phone numbers. Data from paper copies will be entered in our shared OneDrive file. All qualitative data from aims 1 and 2 will be collected via HIPAA compliant Zoom software. Digital recordings will then be sent to a professional transcription service (Rev) to be transcribed. Rev has confidentiality policies with customers to prohibit unauthorized use. Participants will be informed to not state their names on the recordings if they do not want their names available to the transcription service. Transcribed files will then be de-identified and saved on the protected OneDrive folder for later analysis. Focus groups from Aim 1 and 2 will be accessible by research staff and the Co-PIs will be responsible for ensuring protections of data are maintained and communication with the University of Kentucky and University of Cincinnati IRB in the event of a data breach, though privacy and confidentiality are of the utmost importance, and we do not anticipate any breaches given our planned protections. Monitoring will occur on a monthly basis, with any program personnel and staff reporting any issues to the PI immediately in the Interim. Monitoring will include verification of correct entry into protected documents, audits of paper documents, audits of electronic documents to ensure compliance with this protocol, and regular trainings with staff to ensure proper use of VPN.

Aim 2 is considered a clinical trial. Thus, aggregate demographic information will be reported in clinicaltrials.gov. No identifiable information or individual research data will be shared.

Participants in Louisville will be compensated via the UK loadable rewards card program. To load cards, participant ID numbers will be shared with University of Kentucky Accounts Payable to load the visa rewards cards through US Bank. No identifiable information will be shared externally due to CoC protections. For business protocol, first and last names will be stored internally within the PIs department at the University of Kentucky for card record keeping. No research data will be shared internally or externally for this process. Cards will be loaded within 24-hours, typically within the same business day of your participation.

Other protections will include UK and UC required trainings to be completed by all research staff. Data will be secured daily and any necessary transportation of data between research sites will occur with locked hard-cover brief cases moved directly from protected site 1 to protected site 2.

*****Modification submitted in September 2025 details a change in hardcopy data storage for the Louisville-site. Data collection is complete for the study, so this change is to the protocol only describing data storage only. All digital data storage will remain the same as described in the section, as well as storage of Cincinnati-site data. In Louisville, upon approval of the modification request, all hard copy data (i.e., signed consent forms, receipts, hardcopy pre- and post-tests), will be moved with a lockbox from the Louisville Central Community Center by the UK PI, directly to the UK PIs on-campus office in Dickey Hall. This data will be stored in a locked file cabinet, in her locked office. Only project team members will have access to the data. Consents and receipts will be stored separate from research data (not in the same folders so pre- and post-test data cannot be linked to the names on the receipts or consents), and research data will be identifiable only by participant ID, with the linking master sheet stored separately. The linking hardcopy file, that links participant names to participant ID numbers, will be stored separately in the UK PI's office, in the locked file cabinet, within a separate lock-box in the file cabinet, accessible with a different key. Participant identities will be kept private from people outside of the

project team. This location has two locked points of entry, only accessible to research staff. Transfer will occur in September 2025.

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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

The information that will be used or shared with other approved researchers include de-identified transcripts and de-identified pre- and post-test data in aggregate form (excel file, or SPSS file). There will be no risk to participants regarding additional use. Secondary researchers will be informed of the University of Kentucky, University of Cincinnati, and CCTS/CCTST/NIH privacy and confidentiality protections and will be required to comply with these procedures outlined in this IRB application. Further, all secondary researchers will be required to show completion of the Human Subjects Protections and RCR or equivalent CITI trainings. Consistent with human subjects survey research it is expected that data will be used for up to ten years after the conclusion of the study. This research does not involve biological specimens. All publications will present aggregate data and will not be identifiable. Aim 2 is considered a clinical trial. Thus, aggregate demographic information will be reported in clinicaltrials.gov. No identifiable information or individual research data will be shared.

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-Initiated 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)**

Drugs are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

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](#)).

See [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)**

Medical devices are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.

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

- ☐ 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:

Dr. Paris Wheeler and her approved research staff will conduct Cincinnati sites research activities in Cincinnati at the University of Cincinnati (LOS attached) given that this is a collaborative award. As additional site in OH for only data collection, research personnel will utilize private space by appointment at Urban Minority Alcoholism and Drug Abuse Outreach Program. UC is relying on the UK IRB.

Dr. Miller-Roenigk and her approved research staff of the University of Kentucky will conduct research in Louisville at the Louisville Central Community Center (LOS attached).

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

Dr. Paris Wheeler and her approved research staff will conduct Cincinnati's research activities (recruitment and groups in OH as detailed in our research protocol) in Cincinnati at the University of Cincinnati given that this is a collaborative award. She will recruit, consent, and engage participants at this research site.

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:

This is a CCTS collaborative award with the University of Cincinnati funded through cooperative agreement with NCATS and NIH. I am the PI at UK, Dr. Paris Wheeler is the PI at the University of Cincinnati. I (Dr. Miller-Roenigk) will oversee research activities in Louisville, and she (Dr. Paris Wheeler) will oversee research activities in Cincinnati, as detailed in our protocol. IRB reliance is fully enacted and documentation is included in attachments. Any reporting needing to occur will happen to the UK IRB and our sponsor.

Initially, we were getting a data use agreement since we had separate IRBs. Now that our funder has informed us of a single IRB requirement before enrolling participants, we completed the reliance process (UK reviewing IRB, UC relying IRB), instead of the use agreement.

Attachments

Attach Type	File Name
-IRB Authorization Agreement	UKY IRB 96815 UK Comm Plan_Revised (Wheeler).pdf
-IRB Authorization Agreement	UKY IRB 96815 SMART_UC_ (002).pdf
-Letter of Support & Local Context	Local Context Form (Wheeler).pdf
-Letter of Support & Local Context	LCCC Signed LOS.pdf
-Letter of Support & Local Context	UC Facilities Signed LOS.pdf
-Letter of Support & Local Context	Thrive - Letter of Support.pdf

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.

Contact the Clinical Research Support Office (CRSO) if your study provides clinical services (e.g., labs, biopsies, tissue samples, physical exams, PT, counseling) regardless of payer (grant, federal, UK, industry)), utilizes UKHC space, or meets the NIH definition of a clinical trial (thereby requiring registry with CT.gov) as your study will need to be entered in OnCore to ensure appropriate regulatory tracking and billing. Visit [CRSO FAQs](#) for more information; requests for CCTS/CRSO services can be submitted via their [service request form](#). For other questions, you can contact the CRSO Director, Jessica Heskell, at jhesk2@uky.edu.

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

Does your research study involve one or more human subjects prospectively assigned into one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes?

☒ 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

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*](#)

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

*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-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:

This project is supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1TR001998. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. This pilot grant was awarded internally through above mechanism, by a collaborative pilot award through UK CCTS and the University of Cincinnati CCTST.

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.):

This project is supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1TR001998. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. This pilot grant was awarded internally through above mechanism, by a collaborative pilot award through UK CCTS and the University of Cincinnati CCTST.

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	Miller-Roenigk Letter of Agreement.pdf
GrantContract	Approved Proposal.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

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	
Danelle	Stevens-Watkins	Other Signee	Educational, School and Counseling Psych		06/07/2024 12:46 PM	View/Sign
Brittany	Miller-Roenigk	Principal Investigator	Educational, School and Counseling Psych		06/10/2024 04:29 PM	View/Sign
Laurie	McCubbin	Department Authorization	Educational, School and Counseling Psych		06/07/2024 01:29 PM	View/Sign

Other Signee's Assurance Statement

☒ This is to certify, that at the request of the Principal Investigator (PI), I have reviewed this research protocol and agree it is appropriate per departmental/college policy and/or procedures and I will support the PI as needed.

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)**

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.

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
🔗	ApprovalLetter	ApprovalLetter.pdf		0.073	kke304	9/16/2025 4:31:56 PM
🔗	Stamped Consent Form	Aim 1 UK Consent to Participate_clean.pdf		0.173	kke304	9/16/2025 4:31:55 PM
🔗	Stamped Consent Form	Aim 2 UK THRIVE Consent_SiteUC_clean.pdf		0.088	kke304	9/16/2025 4:31:55 PM
🔗	Stamped Consent Form	Aim 2 UK THRIVE Consent_siteUK_clean.pdf		0.086	kke304	9/16/2025 4:31:55 PM
🔗	Advertising	Miller-Roenigk_Aim 2 Flyer 2025.pdf	Aim 2 Flyer	1.217	bmi230	4/25/2025 2:50:59 PM
🔗	Advertising	Miller-Roenigk_Aim 2 Flyer 2025-STAMPED.pdf	Aim 2 Flyer Stamped	1.258	bmi230	4/25/2025 2:50:27 PM
🔗	-Letter of Support & Local Context	Thrive - Letter of Support.pdf	UMADAOP Letter of Support	0.325	bmi230	4/23/2025 3:47:48 PM
🔗	Informed ConsentParental Permission	Aim 2 UK THRIVE Consent_siteUK_clean.pdf	Aim 2 UK THRIVE Consent_SiteUK_clean	0.079	bmi230	4/23/2025 12:44:43 PM
🔗	Informed ConsentParental Permission	Aim 2 UK THRIVE Consent_SiteUC_clean.pdf	Aim 2 UK THRIVE Consent_SiteUC_clean	0.081	bmi230	4/23/2025 12:43:23 PM
🔗	ResearchProcedures	UC site Aim 2 SensitiveHumanSubjIncentiveReceipt.pdf	Aim 2 THRIVE UC Site Receipt	0.099	bmi230	2/20/2025 1:41:17 PM
🔗	StudyPopulation	Study Population.pdf	Figure 1 Protocol Supplement	0.339	bmi230	2/5/2025 12:53:05 PM
🔗	ResearchProcedures	THRIVE Adapted Intervention AIM 2.pdf	Thrive Intervention AIM 2 (PDF) presented as PowerPoint	2.099	bmi230	2/5/2025 12:42:49 PM
🔗	ResearchProcedures	Aim 2 Focus Group Topics 2025_Clean.pdf	Aim 2 Focus Group Topics_Clean	0.035	bmi230	2/5/2025 12:13:53 PM
🔗	ResearchProcedures	Aim 2 Focus Group Topics 2025_tracked.pdf	Aim 2 Focus Group Topics_tracked changes	0.035	bmi230	2/5/2025 12:13:34 PM
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🔗	Advertising	Aim 2 Sample Scripts_Clean.pdf	Aim 2 Sample Scripts_Clean	0.047	bmi230	2/5/2025 12:05:05 PM
🔗	Advertising	Aim 2 Sample Scripts_tracked.pdf	Aim 2 Sample Scripts_tracked changes	0.058	bmi230	2/5/2025 12:04:42 PM
🔗	ResearchProcedures	Example Script to inform participants of Jan 2025 modification .pdf	Example Phone script to inform Aim 1 time 1 participants of jan 2025 modification	0.014	bmi230	1/14/2025 2:19:14 PM
🔗	Informed ConsentParental Permission	Aim 1 UK Consent to Participate_clean.pdf	AIM 1 UK THRIVE Consent to Participate	0.167	bmi230	1/8/2025 3:57:23 PM
						1/8/2025

ResearchProcedures	Aim 1 Focus Group Topics_CLEAN.pdf	Aim 1 Focus Group Topics_Clean	0.031	bmi230	1:45:45 PM
ResearchProcedures	Aim 1 Focus Group Topics_tracked_changes.pdf	Aim 1 Focus Group Topics_tracked	0.073	bmi230	1/8/2025 1:45:23 PM
-Letter of Support & Local Context	Local Context Form (Wheeler).pdf	Reliance documentation - local context	0.173	bmi230	11/15/2024 9:24:35 AM
-IRB Authorization Agreement	UKY IRB 96815_SMART_UC_(002).pdf	Reliance documentation - site agreement	0.169	bmi230	11/15/2024 9:23:29 AM
-IRB Authorization Agreement	UKY IRB 96815 UK Comm Plan_Revised (Wheeler).pdf	Reliance documentation - communication plan	0.304	bmi230	11/15/2024 9:22:42 AM
Advertising	LT_STAMPED_071024_Aim 1 Flyer[88].pdf	Aim 1 Flyer_UK PR STAMPED	1.250	bmi230	7/10/2024 1:12:09 PM
Advertising	Aim 1 SCREENER_clean.pdf	Aim 1 Screener_Clean	0.024	bmi230	7/10/2024 12:31:18 PM
Advertising	Aim 1 SCREENER_trackedchanges.pdf	Aim 1 Screener_Highlighted	0.037	bmi230	7/10/2024 12:30:56 PM
Advertising	Aim 1 Flyer.pdf	Aim 1 Flyer	1.215	bmi230	7/10/2024 12:30:13 PM
Advertising	Aim 1 Sample Scripts.pdf	Aim 1 Sample Scripts	0.031	bmi230	7/10/2024 12:29:31 PM
-Letter of Support & Local Context	UC Facilities Signed LOS.pdf	UC Facilities signed LOS	0.087	bmi230	6/10/2024 10:09:50 AM
GrantContract	Approved Proposal.pdf	Approved Grant Proposal	0.388	bmi230	6/7/2024 10:26:25 AM
GrantContract	Miller-Roenigk Letter of Agreement.pdf	Miller-Roenigk Wheeler Letter of Agreement CCTS	0.433	bmi230	6/7/2024 10:26:09 AM
-Letter of Support & Local Context	LCCC Signed LOS.pdf	Letter of Support	0.155	bmi230	6/7/2024 10:19:47 AM
ResearchProcedures	THRIVE Payment Receipt.pdf	THRIVE Payment Receipt	0.011	bmi230	6/7/2024 9:48:43 AM
ResearchProcedures	Aim 2 Pre-Test.pdf	Aim 2 Pre-Test	0.017	bmi230	6/7/2024 9:39:14 AM
ResearchProcedures	Aim 2 Post-Test.pdf	Aim 2 Post-Test	0.028	bmi230	6/7/2024 9:39:01 AM
StudyDesign	References.pdf	Background Citations	0.079	bmi230	6/7/2024 9:31:31 AM

No comments

Data Analytic Plan

Quantitative data in THRIVE Aim 2 Clinical Trial:

Analyzed using SPSS v.31 univariate testing for descriptive statistics to assess means and standard deviations for scores on outcome variable scales for both pre- and post-testing among participants ($n = 57$):

- Change in participant confidence using harm reduction techniques (Fentanyl Test Strips [FTS] and Narcan) from baseline to post-intervention (approximately 2 hours)
- Change in participant willingness to use harm reduction techniques (FTS and Narcan) from baseline to post-intervention (approximately 2 hours)
- Change in participant comfort to possess harm reduction techniques (FTS and Narcan) from baseline to post-intervention (approximately 2 hours)
- Change in participant confidence describing how to use harm reduction techniques to others (FTS and Narcan) from baseline to post-intervention (approximately 2 hours)
- Change in participant willingness to teach others how to use harm reduction techniques (FTS and Narcan) from baseline to post-intervention (approximately 2 hours)
- Change in participant knowledge of how overdose occurs from baseline to post-intervention (approximately 2 hours)
- Change in perceived knowledge/confidence of how to prevent and intervene with an overdose from baseline to post-intervention (approximately 2 hours)

Additional analyses for publication include significance testing (e.g., t-tests) to compare the scores on the pre- and post-tests to examine significant difference in outcomes from pre- to post-intervention, thematic analyses to examine trends from qualitative focus groups.