Document Coversheet

Study Title: Integrated Outpatient Treatment of Opioid Use Disorder and Severe Injection Related Infections

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	10/14/2025
NCT Number:	NCT04677114
IRB Number:	60903
Coversheet Created:	2/26/2026

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.

60903

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

Integrated outpatient treatment of opioid use disorder and injection-related infections

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.

B-OPAT: buprenorphine treatment of OUD plus OPAT

Anticipated Ending Date of Research Project: 9/30/2026

Maximum number of human subjects (or records/specimens to be reviewed) 152

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:	Laura	Room# & Bldg:	845 Angliana Ave
Last Name:	Fanucchi	Speed Sort#:	9861
Middle Name	Chiara		
Department:	Internal Medicine & Divisions …	Dept Code:	7H361
PI's Employee/Student ID#:	10925504	Rank:	Associate Professor
PI's Telephone #:	859-323-1982	Degree:	MD, MPH
PI's e-mail address:	laura.fanucchi@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	1/17/2025
		RCR Trained:	Yes

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

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

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

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

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

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

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

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to 99

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: The proposed dates of enrollment are January 11, 2021 – December 31, 2026. It is anticipated that 400 potential subjects will need to be screened to enroll and randomize a total of 120 participants (60 per group). Inclusion criteria: Participants will be volunteer adult males and females, age 18 years or older, physically dependent on opioids meeting DSM-5 criteria for moderate-severe OUD who are hospitalized with SIRI (IE by Duke's criteria, osteomyelitis, septic arthritis, bacteremia, severe skin and soft tissue infections requiring IV antibiotics) and recruited from the inpatient hospital setting at UK Chandler and Good Samaritan hospitals. Participants must be accepting of BUP treatment, anticipated to be discharged home after medically stabilized, and have =5 days of IV antibiotics remaining at the time of medical readiness for discharge (as defined by the primary clinical team), and providing informed consent. Five days of IV antibiotic therapy remaining was chosen as a minimum amount of time for exposure to home IV antibiotics if randomized to the B-OPAT arm.
Exclusion criteria will include presence of stroke or cerebral mycotic aneurysms preventing aortic or mitral valve surgery, fungal IE, patients who require inpatient physical rehabilitation, current pregnancy, hypersensitivity or allergy to BUP, class III or IV heart failure, end-stage liver disease, end-stage renal disease, current suicidal ideation (answering 'yes' to item 4 or 5 on the CSSRS), other screening laboratory, medical, and/or psychiatric condition that may prevent the volunteer from safely participating in the study in the opinion of the investigator (e.g., benzodiazepine or alcohol dependence requiring medically supervised withdrawal), self-report of desire to inject into PICC line, pending legal action that could interfere with study participation, unsafe or unstable home environment precluding safe outpatient administration of IV antibiotics, and living more than a approximately 120-minute drive from Lexington, KY because of the intense outpatient component to the intervention.

Aim 2: The stakeholder sample will include approximately 50 key members of the inpatient and outpatient care teams involved in clinical care of Aim 1 participants as well as those involved in setting up and running the integrated outpatient care model.

Aim 3: Qualitative interviews will be conducted with 30 participants enrolled in the Aim 1 study (15 from each group). The inclusion criteria are 1) participation in the Aim 1 study, and 2) providing informed consent for the qualitative interview.

The provider sample for Aim 3 will include approximately 15 key members of the clinical care team and organization leaders from the hospital setting. Inclusion criteria are: 1) age 18 or older; 2) current employment at UKHealthCare; and 3) involved directly in the care of persons with OUD hospitalized with SIRI or involved in a leadership/administrative role in the hospital.

Attachments

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

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:				
Asian:				
Black/African American:	22	22		
Latinx:	10	10		
Native Hawaiian/Pacific Islander:				
White:	168	168		
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)

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

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

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

Other Resources:

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

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

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

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

◉ Yes ○ No

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

Examples of such conditions include:

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

Attachments

Attach Type	File Name
ImpairedConsent	BOPAT Form_T_2Bi.doc
ImpairedConsent	BOPAT IC Quiz.docx

PRISONERS

0 unresolved comment(s)

SECTION 1.

For studies involving **prisoners** or people at risk of becoming involuntarily detained during the research (e.g., subjects with substance abuse history), respond to the following items. For information on restrictions and regulatory requirements, see ORI's Research Involving Prisoners web page.

For research involving prisoners, the definition of minimal risk refers to the probability and magnitude of **physical** or **psychological** harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons.

Select the category below that best represents your research and explain why your research meets the criteria.

Prisoner Categories

- ○ **Category 1: My research involves the study of possible causes, effects, processes of incarceration, and of criminal behavior.** (Processes of incarceration can be interpreted broadly to include substance abuse research, half-way houses, counseling techniques, criminal behavior, etc.)
- ○ **Category 2: My research involves the study of prisons as institutional structures, or of prisoners as incarcerated persons.** (This category is usually used fairly narrowly – i.e., looking at prisoner diet, conditions of prison, etc.)
- ◉ **Category 3: My research involves the study of conditions particularly affecting prisoners as a class.** (This category is rarely used – e.g., vaccine trials, research on hepatitis, social and psychological problems such as alcoholism, drug addiction, sexual assaults. Minimal risk studies should not go under this category.)
- ○ **Category 4: My research involves the study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.** (Rare for research involving placebo or control groups to fall in this category because of the difficulty in justifying improvement of the health or well-being of the subject being given placebo or in a control group.) Note: Contact the Office of Research Integrity at (859) 257-9428 for more information.
- ○ **Epidemiologic Research Involving Prisoners [See also SECTION 3 below]**

Explain what condition(s) will be studied and provide rationale for each:

Opioid Use Disorder and Serious Injection Related Infections – while we are not recruiting and enrolling prisoners in this study (all recruitment and enrollment is in the hospital and current incarceration is exclusionary), our volunteers may become prisoners after enrollment because they may be picked up on old warrants and incarcerated or be involved in activities that result in prisoner status starting after discharge from the hospital while the study is ongoing.

SECTION 2.

When an IRB is reviewing a protocol in which a prisoner will be a subject, the IRB must find and document justification that six additional conditions are met. Describe in the space provided how each condition applies to your research.

NOTE: If your study **only** involves epidemiologic research, you may insert "N/A" in each of the text boxes in this section (Section 2). Your response to Section 3 will determine appropriateness for "N/A" answers here.

Condition 1. Advantages acquired through participation in the research, when compared to the prisoners' current situation, are not so great that they impair their ability to weigh risks.
Describe the possible advantages that can be expected for prisoner participants:

Prisoners are often not allowed to continue medications for Opioid Use Disorder treatment in our experience working with prisoners receiving medical care at UKHC. Thus, staying in the study has the potential benefit of helping volunteers to be able to stay on their prescribed FDA-approved medication for Opioid Use Disorder, and/or be connected with ongoing treatment after incarceration, that has been shown to decrease overdose and all-cause mortality.

Condition 2. Risks are the same as those that would be accepted by non-prisoners.
Describe the possible risks that can be expected for prisoner participants and justify that they are the same as for non-prisoners:

Other prisoners may be jealous/envious that participants are getting treatment for Opioid Use Disorder that relieves withdrawal and craving. There is a similar experience in non-prisoner populations whereby people often have difficulty accessing MOUD treatment and may be envious/jealous. Some people (both prisoners and non-prisoners) may try to steal the medication. There are no data to support that these risks are higher in prisoners than for non-prisoners.

Condition 3. Procedures for selection are fair to all prisoners and are immune from intervention by prison authorities in prisons; control subjects must be randomly selected.

a) Describe how prisoners will be selected for participation:

N/A. We do not allow prisoners to enroll in the study – this is an exclusionary criterion. We are only requesting to allow volunteers who become prisoners after enrollment to continue to participate in the study because we believe that remaining in the study is beneficial to them – more so than automatically withdrawing them from the study. We have experience at UKHC whereby hospitalized prisoners are not allowed to continue medication treatment for OUD when they are discharged – e.g., UK doctors on the inpatient addiction consult service make outpatient follow-up appointments at UK's First Bridge Clinic to continue medication treatment for Opioid Use Disorder and the detention center refuses to bring the prisoner to the appointment (and they will transport for other kinds of medical care, like a cardiology appointment).

b) Describe what measures will be taken to prevent intervention by prison authorities in the selection process:

N/A - we are not recruiting or enrolling currently incarcerated individuals.

Condition 4. Parole boards cannot take into consideration a prisoner's participation in research. Informed consent must state participation will not impact parole.
Describe what measures are in place to ensure parole boards are not influenced by prisoners' participation in research and how prisoners will be told their participation (or refusal or withdrawal from) will not impact parole:

The informed consent will be modified to state that if someone becomes a prisoner, participating in the study will not impact parole.

Condition 5. For studies that require follow-up, provisions are made including consideration for the length of individual sentences; informed consent must reflect provisions for follow-up.
Describe what provisions have been made for follow-up and how this information will be relayed to the prisoner participants:

We will add into the consent that if someone becomes a prisoner after randomization that we will attempt to collect study measures by phone, phone+video, or in-person visits to the jail/prison/home incarceration setting as feasible or allowable given COVID-19 restrictions.

Condition 6. Information about the study is presented in a language understandable to prisoners.
Describe what efforts have been made to present information about the study in a language understandable to the prisoner population:

The study is not recruiting prisoners. It is only asking to allow already enrolled volunteers who later become prisoners to continue in the study. However, our informed consent procedures include a quiz with teach-back to ensure understanding.

SECTION 3. Epidemiologic Research Involving Prisoners
Only complete if applicable:

Effective June 20, 2003, DHHS adopted policy that allows waiver of the requirement for documenting applicability of a category (as found in Section 1 of this form) for certain epidemiologic research involving prisoners. This waiver applies to epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects.

☐ Check this box if your research meets all three criteria listed below, then provide justification in the space provided.

1. I request a waiver for meeting the category conditions under Section 1 of this form.
2. My research involves epidemiologic research intended to describe the prevalence/incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease; **and**
3. Prisoners are not the sole focus of my research.

Justify how the research presents no more than minimal risk and no more than inconvenience to the subjects:

SECTION 4. Prisoners are not the targeted population
Only complete if applicable:

Although prisoners may not be the target population for your research, a subject could become a prisoner during the course of the study (particularly if studying a subject population at high-risk of incarceration).

Note: If you did not receive IRB approval for involvement of prisoners, and a subject becomes a prisoner during the study, **all research activities involving the now-incarcerated participant must cease** until IRB approval has been issued for their continuation in the research. If you need IRB approval for a prisoner subject to continue participation in your research, select and complete the applicable category from Section 1, complete section 2 and this section, then submit for IRB review.

In special circumstances where it is in the best interest of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research prior to satisfying the requirements of Subpart C. However, subsequent IRB review and approval of this completed form is required.

☑ Prisoners are not a target population for my research, but a subject became a prisoner during the study and I am seeking IRB approval so the subject can continue participation in the research.

Explain the importance of continuing to intervene, interact, or collect identifiable private information during the participant's incarceration:

The treatments being studied may benefit prisoners – if we are not allowed to collect these data, then we will not able to generalize to persons who become incarcerated and incarcerated persons are often not allowed to continue on medication in the CJ setting. The risk of withdrawing after having enrolled is associated with potentially additional risk to the participant than being allowed to stay enrolled.

SECTION 5. Kentucky (KY) Department of Corrections (DoC) Approval

Review the following conditions and determine whether any apply to your study:

- active recruitment of participants from a correctional facility (prison, jail, or community corrections institution);
- active recruitment of individuals under community supervision from a state probation and parole office.

If any of the above conditions apply to your research, refer to the Kentucky Department of Corrections Policy and Procedures, Management Information and Research (Chapter 5) for information about submitting a proposal for DoC approval of research including the DoC approved Research Consent and Research Agreement (5.1.G.1).

If the Department of Corrections is directly involved in your research as a sponsor or otherwise, contact Office of Legal Counsel at 859-257-2936 or email at UKOfficeofLegalCounsel@uky.edu and ask to be connected with a research attorney for additional information.

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

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.

Aim 1: Sober, written informed consent will be obtained from all individuals both prior to screening and prior to enrollment and randomization. The screening consent form will provide the potential volunteer with information about the study (e.g., who is conducting it, contact information for the investigators and medical staff, how it is funded, where it will take place, the purpose of the study), about what will be required of the volunteer for screening (e.g., time commitment, urine samples), the risks to the subject (e.g., breach of confidentiality), the rights of the volunteer (e.g., confidentiality, voluntary participation) and the benefits of participating (e.g., possible enrollment in study, helping increase knowledge). The full study informed consent form will review the information in the screening consent and then provide further detail on what will be required of the volunteer for the study (e.g., time commitment, schedule of outpatient visits, urine samples), the risks to the volunteer of study participation (e.g., breach of confidentiality, risks of BUP and OPAT), and the benefits of participating (e.g. possibly leaving the hospital earlier, helping to increase knowledge) and study payment information. The informed consent documents will be explained thoroughly and signed. An informed consent quiz will be utilized to ensure participant understanding. The subject is given ample time to ask questions of the investigator at the time of consent and any time thereafter. Each subject will receive a copy of their informed consent documents and will sign a form indicating its receipt.

Participants are not a "vulnerable population" as defined by human subjects protection guidelines; that is, they are not minors, pregnant women, under legal coercion or restriction, or mentally impaired. They are competent, English-speaking, adults who provide their voluntary informed consent. In order to verify eligibility for participation in these studies, medical histories are compiled after consent by our recruiting staff from existing records, through interview with the subjects themselves by a study clinician, and through contacts with treatment and referral sources if warranted in a HIPAA-compliant manner. Urine specimens are collected prior to and throughout a subject's participation in the research protocol. These urine specimens are tested for the presence of a number of drugs of abuse (methadone, oxycodone, morphine, fentanyl, benzodiazepines, cocaine, barbiturates, methamphetamine, amphetamine, buprenorphine and marijuana). The testing ensures that research is conducted on subjects who use opioids and allows for assessment of recent opioid use (primary outcome measure) during study participation.

Aim 2: Cornell investigators (Co-Is Murphy and Kapadia) will contact potential participants over email after referral from the UK investigators, and invite them to participate in qualitative interviews at a mutually agreeable time. Co-Is Murphy and Kapadia or trained staff will obtain verbal consent for participation in these qualitative interviews.

Aim 3: A randomly selected sample of enrolled participants from Aim 1 will be approached for participation in qualitative interviews for Aim 3. This sample will be recruited after discharge from the hospital. The nature of the qualitative interviews will be explained by the research staff, including the voluntary and confidential nature, the structure and timing of contacts, the length of sessions, what is expected of participants, and the monetary stipend. Participation will be voluntary, and written consent will be given by each participant for interviews. In the event that a participant cannot travel to the study site and it is not possible to obtain written consent, verbal consent may be obtained by phone or video call.

The study will enroll approximately 15 healthcare providers. We anticipate including will include hospitalists, infectious disease physicians, nurses, case managers and hospital administration. Co-I Surratt will recruit providers, explaining the nature of the project, the commitment involved, the incentive stipend, and contact information for the research team. She will obtain informed consent for study participation.
If participants have any questions, concerns, or complaints about the study they will be directed to contact: Dr. Laura Fanucchi,

Principal Investigator, at 859-323-1982 or laura.fanucchi@uky.edu. Furthermore, if they have questions about their rights as a participant in research they will be directed to contact the Office of Research Integrity at the University of Kentucky 859-257-9428.

☐ Request for Waiver of Informed Consent Process

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

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

SECTION 1.

Check the appropriate item:

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

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

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

SECTION 2.

Explain how each condition applies to your research.

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

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

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

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

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

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

☑ Request for Waiver of Signatures

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

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

Select the option below that best fits your study.

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

○ **Option 1**

Describe how your study meets these criteria:

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

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

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

◉ **Option 2**

Describe how your study meets these criteria:

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

The research is limited to survey questions involving resources needed for clinical care and do not involve personal or health questions of the participant. There is minimal PHI collected and then records are fully de-identified prior to analysis and are reported in the aggregate.

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):

Phone script and verbal responses to questions.

○ **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.

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).

Hospitalizations for complications of opioid use disorder (OUD), like infectious endocarditis (IE) and other severe, injection-related infections (SIRI), have increased dramatically along with the opioid epidemic. Persons with OUD hospitalized with SIRI, often remain inpatient to complete prolonged intravenous (IV) antibiotic courses due to several assumptions such as 1) if outpatient, patients will inject illicit drugs into the IV catheter and will fail to complete prescribed antibiotic regimens, and 2) if inpatient, patients will not inject drugs because of the increased supervision and will complete the antibiotic regimen. No evidence supports these assumptions, and unfortunately, the inpatient stay is not only very costly to the healthcare system, but infrequently includes comprehensive OUD treatment. In contrast, outpatient parenteral antibiotic therapy (OPAT) via a peripherally-inserted central catheter (PICC) is the standard of care for continuing IV medications for patients without injection drug use (IDU) once medically stable, and is commonly used in treating infections requiring prolonged IV antibiotics. OPAT is cost-effective, associated with improved patient satisfaction, and with decreased risks of hospital-acquired infections. Development of innovative outpatient clinical models is urgently needed to improve the management and transition plan of persons with OUD and SIRI, given the costs and risks associated with prolonged hospitalizations.
We will conduct a randomized, parallel-group study where 120 patients hospitalized with OUD and SIRI will receive treatment with buprenorphine (BUP) and be randomized (1:1) to complete IV antibiotics in an innovative outpatient care model integrating OUD treatment with OPAT (n=60), compared to treatment as usual (TAU) (n=60), on the primary outcome of illicit opioid use over a 12-week post-hospital discharge study period. The study will also incorporate a comprehensive economic evaluation of the integrated outpatient care model as well as a qualitative investigation designed to examine key multi-level contextual barriers and facilitators to intervention implementation and assess the impact of these factors on implementation outcomes.

Objectives

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

Aim 1: Evaluate the integrated outpatient care model (B-OPAT: BUP treatment with OPAT) compared to TAU in patients with OUD and SIRI on the primary outcome of the proportion of urine samples negative for illicit opioids in the 12-weeks after hospital discharge, and on critical secondary outcomes including completion of recommended IV antibiotic therapy, self-reported number of days of illicit opioid abstinence, self-reported number of days without injection use of any drug, and retention in outpatient treatment.
Aim 2: Calculate the cost of implementing and running the integrated outpatient care model, and determine the relative value of the model from the healthcare sector and societal perspectives.
Aim 3: Using in-depth qualitative interviews, assess multi-level facilitators and barriers to: 1) intervention effectiveness in transitioning persons with OUD and SIRI from the inpatient to outpatient setting with a strategically selected sample of participants from Aim 1; and, 2) intervention adoption and implementation among key provider stakeholders from the healthcare team and organizational leaders in the healthcare setting.

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.

Aim 1: This study has a randomized, parallel-group design where 120 individuals hospitalized with opioid use disorder (OUD) and severe, injection-related infections (SIRI) will receive buprenorphine (BUP) treatment and be randomized (1:1) after stratification on the clinical injection-related infection subgroup, current moderate to severe stimulant use disorder, and gender to Group 1 – B-OPAT: complete IV antibiotics in an innovative outpatient care model integrating BUP treatment with outpatient parenteral antibiotic therapy (OPAT) (n=60), compared to Group 2 - treatment as usual (TAU) (n=60), on the primary outcome of illicit opioid use over a 12-week post-hospital discharge study period.

Aim 2: To inform the economic evaluation, the health economic team will conduct up to 50 qualitative interviews with stakeholders from the healthcare team involved in implementing and running the integrated care model, and providing clinical care to patients enrolled in the Aim 1 study.

Aim 3: Conduct in-depth qualitative interviews with a 30 participants (15 from the B-OPAT group, and 15 from TAU) from Aim 1 as well as with 15 key members of the hospital clinical care team and UKHealthCare leaders, including hospitalists, ID physicians, nurses, case managers, and administrators. These interviews will provide critical information to assess multi-level facilitators and barriers to intervention effectiveness to transition persons with OUD and SIRI from the inpatient to outpatient setting, and intervention adoption and implementation among key healthcare provider stakeholders and organizational leaders.

Attachments

Subject Recruitment Methods & Advertising

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

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

For additional information on recruiting and advertising:

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

For Aim 1, potential volunteers will be recruited from the inpatient setting via flyers requesting willingness to be contacted to learn more about the study. In addition, potential volunteers will be recruited through referral from inpatient services at UKHealthCare and approached in-person by research staff who have completed CITI HSP training. Research staff will ask permission to share information about the study with potential volunteers and offer the recruitment line or in-person information and screening. This is a similar procedure that has already been employed by the research team in several studies of hospitalized persons with OUD and SIRI (IRB Study 16-0019-F1V, PI: Fanucchi; and 16-1001-F1V, PI: Fanucchi). The Office of Research Integrity at the University of Kentucky will approve advertisements.
Aim 3: A randomly selected sample of enrolled participants from Aim 1 will be approached for participation in qualitative interviews for Aim 3. This sample will be recruited after discharge from the hospital.

For Aim 2, study investigators will assist with recruiting members of the clinical team via email or phone and ask willingness to be contacted by the Cornell investigators (Co-Is Murphy and Kapadia) to participate in qualitative interviews. We anticipate including hospitalists, infectious disease clinicians, addiction medicine clinicians and staff, clinicians and staff from the UK First Bridge Clinic (where the Aim 1 intervention takes place), and staff involved in providing outpatient IV antibiotics.

For Aim 3, the study will enroll approximately 15 healthcare providers as key stakeholders. We anticipate including will include hospitalists, infectious disease physicians, nurses, case managers and hospital administration. Co-I Surratt will recruit providers, explaining the nature of the project, the commitment involved, the incentive stipend, and contact information for the research team. Potential volunteers will be recruited from the inpatient setting via flyers requesting willingness to be contacted to learn more about the study. The Office of Research Integrity at the University of Kentucky will approve advertisements, and they will be reviewed by UK Public Relations.

Attachments

Attach Type	File Name
Advertising	BOPAT Flyer_Fanucchi 2.8.2021 PR edit CELAN.pdf
Advertising	BOPAT Flyer_Fanucchi 2.8.2021 PR edit STAMPED.pdf
Advertising	B-OPAT Flyers_Clinicians_Revised 2-20-24-STAMPED.pdf
Advertising	B-OPAT Flyers_Clinicians_Revised 2-20-24-CLEAN.pdf
Advertising	B-OPAT Flyers_Patients_Revised 2-20-2024-STAMPED.pdf
Advertising	B-OPAT Flyers_Patients_Revised 2-20-2024-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.

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

Aim 1: Randomized, parallel-group design in which hospitalized patients with OUD and SIRI are initiated onto BUP and randomized (1:1) to complete IV antibiotics and receive OUD treatment in an integrated outpatient care model (B-OPAT: BUP treatment with OPAT) versus TAU.

Attachments

Attach Type	File Name
ResearchProcedures	BOPAT eIRB - Research Procedures 12 09 21.docx
ResearchProcedures	BOPAT eIRB - Research Procedures 12 09 21_h.docx

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.

See attachments

Attachments

Attach Type	File Name
DataCollection	Econ Interview Guide_BOPAT Inpatient_short.docx
DataCollection	Econ Interview Guide_BOPAT.docx
DataCollection	Interview guides_qual_V2_11 24 20.pdf
DataCollection	PROPr-BOPAT_1-10-2021.pdf
DataCollection	CIWA-Ar.pdf
DataCollection	BTQ.pdf
DataCollection	BOPAT eIRB - Data collection.docx
DataCollection	ASI_Lite.pdf
DataCollection	C-SSRS-Baseline.pdf
DataCollection	MINI_v5_002006.pdf
DataCollection	briefpainR.pdf
DataCollection	ClinicalOpiateWithdrawalScaleR.pdf
DataCollection	DSM IV_V_Substance UseDisorders - add to MINI.docx
DataCollection	NMOS+CLAF-BL_8-12-20.docx
DataCollection	NMOS+CLAF-FU_8-12-20.docx
DataCollection	2. PC-PTSD-5 (IASP-Adapted).pdf
DataCollection	TLFB-general substance use.doc
DataCollection	SOWS opiate patient form wex.pdf

Resources

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

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;

- Resources for communication with subjects, such as language translation/interpretation services.

Center on Drug and Alcohol Research (CDAR)
The present physical facilities available to support the conduct of this work are substantial and largely provided by CDAR and the University of Kentucky. These existing CDAR facilities include the Straus Behavioral Science Research Facility, and Medical Behavioral Science Building (additional faculty office space, office space for other administrative support including purchasing, budget, grants management officer). All faculty have at least one fully equipped office with desktop computers and printers; affiliated Clinical faculty have additional offices in their home departments.
The Straus Behavioral Science Research Facility with its Straus and First Bridge outpatient clinical opioid addiction treatment services is centrally located, one mile off of the main UK campus at 845 Angliana Avenue. This location is ideal because it is within a short drive to the hospital and has easy access to the interstate. This research and outpatient clinical treatment facility also has a large private parking lot and there is ample and easily accessible parking for volunteers during clinic and research visits. Moreover, it is located two blocks from the public transportation lines and is convenient for subjects who rely on public transportation. This facility and clinic is equipped with numerous faculty, staff and investigator offices, interview rooms, a day room, two large labs, four exam/interview rooms, a ventilated, OSHA-approved, DEA-approved smoking room for marijuana and tobacco smoking studies, a bioprocessing area, cold storage for biological samples (including -70 freezer and refrigerated centrifuge), secure, DEA-approved Schedule I drug storage room, a urine toxicology testing site, and three unisex bathrooms for supervised urine collection. There are physicians, a nurse practitioner, a licensed therapist and a peer support all working within the clinic to provide evidence-based comprehensive opioid use disorder treatment employing pharmacotherapies (e.g., buprenorphine) with individual as well as group therapy. The laboratories have physiological monitoring devices and computer systems for data collection. This clinic site has experience conducting randomized research trials in this population of medically complicated patients with OUD and injection-related infections. This site and investigators is also familiar and well-versed in collecting the required research outcomes. This facility also has food preparation and storage areas and a large day room for participants to relax (under supervision) while awaiting data collection activities. Dr. Lofwall, our nurse practitioner and research nurse provide medical oversight to all volunteers. This research team has successfully completed clinical trials and several outpatient substance abuse-related protocols at this facility.
There are locked filing cabinets available for the storage of subject records on-site. A copier, fax, shredder, phone and internet connections are all in place. The Straus Facility is fully equipped with an integrated network system with supporting servers for computer back-up. It has a centralized recruiting database, computer support (including hardware and software) for the data management and statistical support staff, and is integrated with the UK hospital's patient laboratory results and scheduling data base system. Study data are stored on a Macintosh Mini computer with a 2.0 GHz Intel Core 2 Duo processor, 4 GB RAM, and 300 GB hard disk. The computer runs OSX 5.8 operating system and OSX 10.5 Server software. Access to the server is protected by a dual-password system, which requires access to the University of Kentucky system and a unique password to access the data folders. Data are backed-up on an hourly basis to a local external hard disk with 1TB of space using Apple Time Machine and then backed-up weekly off-site to an encrypted external disk system at the Department of Behavioral Science.

UK HealthCare
UK HealthCare (annual operating budget of $1.1 billion) encompasses the University of Kentucky's clinical enterprise and affiliated teaching hospitals: the Albert B. Chandler Hospital, a 600-bed acute care hospital and Level I trauma center; Kentucky Children's Hospital, a 210-bed full-service, tertiary care facility housing the only Level III neonatal intensive care unit in the area; and UK Good Samaritan Hospital, a 302-bed acute care community hospital facility. This study will recruit from the UK Good Samaritan and Chandler Hospitals.
The UK Addiction Consult and Education Service has a dedicated workroom in Chandler Hospital (H802) that facilitates clinical collaboration and provides workspace with computers, printer, fax, and locked file cabinets to physicians, a nurse practitioner, nurse navigator, social worker, and peer support specialist.

Additional Clinical Resources
HIV positive status does not exclude study participation. Participants will be referred to the UK Bluegrass Care Clinic (Co-I Thornton is the Medical Director) for treatment of HIV if needed. Pregnant women will be excluded and referred for OUD treatment and appropriate prenatal care services in the UK PATHways program that provides integrated obstetric and addiction treatment to pregnant women. Individuals who cannot give their voluntary informed consent will not be enrolled. Volunteers not qualified to participate are offered treatment referrals. All participants are told during screening that this is a research study and that, if enrolled, there will be a chance that they receive assignment to be discharged once medically stable to complete IV antibiotics at home OR to treatment as usual. There are alternative treatment options at UK and the surrounding community including OBOT programs, methadone treatment in licensed opioid treatment programs, and residential treatment. Potential subjects would be free to choose those options rather than participate in this project and staff will provide information and linkage to those if requested.

Weill-Cornell Medical College, Department of Healthcare Policy and Research
Investigators from Weill-Cornell Medical College will conduct the economic analysis and calculate the cost of implementing and running the integrated outpatient care model (B-OPAT), and determine the relative value of the model from the healthcare sector and societal perspectives. Per the terms of the Data Transfer and Use Agreement, Weill-Cornell investigators will receive de-identified datasets generated from the B-OPAT study. Weill-Cornell investigators will obtain verbal consent from healthcare stakeholders (not patients) for qualitative interviews to inform the economic evaluation. The notes from the qualitative interviews will be maintained on a secured server at Weill-Cornell.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.

- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

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

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

The primary risks associated with participation in this research are those related to BUP administration and treatment group assignment.

Risks of BUP: BUP is prescribed for its FDA-indicated use for opioid dependence treatment (DSM-IV nomenclature was in place at the time of original approval, equivalent now to OUD from DSM-5), and its risks are well-documented. Subjects are carefully screened to exclude those with potential increased risk of adverse effects to BUP, such as those with comorbid current severe alcohol or benzodiazepine use disorder who need inpatient medical detoxification. During study participation, subjects remain under careful medical observation and are monitored. Participants will receive a thorough description of the potential side effects of BUP during the informed consent process and will be asked about side effects during follow-up doctor visits. Only doses in the therapeutic range that are FDA-approved are prescribed in the study.
Common side effects of BUP include headache, insomnia, opioid withdrawal signs and symptoms (nausea, sweating, vomiting, diarrhea, nervous/anxious, asthenia, lacrimation), rhinitis, pain, and constipation. More serious side effects include allergic reaction, hepatitis/hepatic failure, pancreatitis, fungal eye infections and death. Case reports of hepatitis/hepatic failure have occurred primarily among patients who have injected buprenorphine, taken other medications metabolized by the liver, and have underlying hepatic disease (e.g., hepatitis B and C). Increases in ALT and AST values among hepatitis C positive patients taking BUP were increased by less than 10 IU with no clear clinical adverse effects; thus, hepatitis C positive status is not a contraindication to taking BUP, and it is not exclusionary in this study. Acute pancreatitis was reported after BUP injection, and fungal eye infections have occurred after buprenorphine pills were injected that had been initially placed in ones' mouth. In the latter cases, the mouth was the likely source of the fungus. Lastly, BUP-related deaths have occurred. These have occurred primarily in association with use of other central nervous system depressants (e.g., alcohol and benzodiazepines) and with intravenous use of BUP.
The Food and Drug Administration has recently written that all opioids can have additional risks and interactions with other medications. For instance, opioids can interact with certain medicines that increase the effects of serotonin, a chemical in the brain. These medications include antidepressants and migraine medicines, and the interaction may cause a serious central nervous system reaction called serotonin syndrome. Subjects will be warned that if they take an opioid along with a serotonergic medicine, they should seek medical attention immediately if they develop symptoms such as agitation; hallucinations; rapid heart rate; fever; excessive sweating; shivering or shaking; muscle twitching or stiffness; trouble with coordination; and/or nausea, vomiting, or diarrhea. Symptoms generally start within several hours to a few days of taking an opioid with another medicine that increases the effects of serotonin in the brain, but symptoms may occur later, particularly after a dose increase. Taking opioids may lead to a rare, but serious condition called adrenal insufficiency in which the adrenal glands do not produce adequate amounts of the steroid hormone, cortisol, particularly during stressful conditions.
The risk of serious adverse effects to BUP is low, especially using our screening procedures to exclude those currently alcohol/benzodiazepine/barbiturate dependent who need inpatient detoxification, regular doctor visits, and 24-hour on-call medical coverage for any acute problems. In addition, a prescription for naloxone is provided as part of standard clinical care for patients with OUD.

Risks of OPAT: The main difference between Group 1 (B-OPAT) and Group 2 (TAU) is that Group 1 will receive between 5 days – 6 weeks of OPAT. We anticipate that subjects will complete an average of 3 weeks of outpatient IV antibiotics based on our pilot study. OPAT is a standard method of providing prolonged courses of intravenous antibiotic therapy in a home environment. The risks of OPAT include problems with the peripherally inserted central catheter (PICC) such as infection and blood clots, as well as antibiotic-related toxicities. There are several clinical activities that will occur in the inpatient setting prior to discharge, and the primary team will perform these activities as part of standard clinical care: 1) infectious disease consultation to include recommended antibiotic dose, duration, and laboratory monitoring during OPAT, 2) PICC placed, 3) patient education regarding self-administration of IV antibiotics and proper PICC care at home (e.g. instructions on bathing, keeping the dressing clean and intact), 4) insurance approval for OPAT 5) prescription for the home IV antibiotic course, 6) home infusion arranged to deliver antibiotics to the patient's home, 7) delivery of supplies for weekly PICC line dressing changes, 8) appointments scheduled after discharge as indicated (e.g., primary care, infectious disease, cardiology, cardiovascular surgery, dental), and 9) confirmation that the patient has a reliable method to be reached by the clinical team. The OPAT nurse expert (TBN) will assist the inpatient primary team in ensuring all of these activities are completed. The OPAT nurse expert will coordinate with the CDAR nurse navigator (TBN), who will confirm that all of the above activities have been completed, and that the subject has been notified of appointments for follow up at CDAR.
For Group 1 (B-OPAT), in the outpatient setting, subjects will be seen twice weekly at CDAR while they are receiving IV antibiotics at home through the PICC. The PICC will be checked by a study nurse or study clinician at each visit for problems (e.g. redness or tenderness, dressing needing to be changed), and the subject will be asked about any problems with the PICC line and compliance with the antibiotic dosing schedule at home. PICC line concerns will be discussed with the OPAT nurse expert, and with the home infusion company, and the subject may be brought to the infectious disease clinic for evaluation if needed. Required labs for antibiotic monitoring will be drawn at CDAR and the results will be reviewed by Dr. Fanucchi (Co-PI), and by Dr. Thornton (Co-I, Infectious

Disease) if there are any clinical concerns. Subjects will attend a follow-up appointment with an infectious disease specialist within 4 weeks after discharge as part of standard clinical follow up of the severe injection-related infection.

The risks of PICC line insertion (which will occur in the hospital and is ordered by the primary clinical team) include bleeding, infection, injury to artery, vein, nerve, or tendon in the arm, pain at the insertion site, blood clot, and blockage of the catheter requiring medication to clear or replacement of the catheter. UKHealthCare has a dedicated PICC team in the hospital that is very experienced and conducts a separate procedure written informed consent with the patient prior to insertion. These risks are reviewed in detail with the patient during informed consent. The PICC line will be removed as an outpatient after completion of IV antibiotics and by a qualified study nurse or clinician. The risks of removing the PICC line include possible air embolism and breakage of the catheter. The risk of air embolism is minimal with a PICC (compared to shorter central venous access catheters) due to the placement within the upper arm and the length of the catheter. To further decrease the risk of air embolism, subjects are placed supine and asked to hold the breath or hum continuously during the procedure. The likelihood of catheter breakage is also minimal. The PICC is inspected after removal and if there is a concern of breakage, the patient is sent for x-ray (the catheter is radio-opaque). If there is catheter remnant present, the study clinician will consult with interventional radiology and/or vascular surgery to determine if surgical removal of the remnant is required.
Group 2 (TAU) will likely also receive PICCs as they are commonly utilized in the hospital setting to minimize the need for frequent needles sticks for phlebotomy or peripheral IV catheter placement. There is also a possible risk that a research subject in either group may use the PICC line to inject opioids or other drugs, but participants will be receiving evidence-based medical treatment for their OUD, and we expect that the risk of PICC line misuse is low based on our preliminary data where subjects reported that the PICC line did not increase cravings or desire to use, and that their desire to inject in the PICC line was essentially zero. On screening, potential subjects will be asked specifically about desire to inject in the PICC, and those reporting desire to inject in the PICC, will be excluded.

There is also a risk of not completing recommended IV antibiotic therapy. This is a risk that occurs clinically and is not specifically tied to the research procedures, but is an important one to discuss nonetheless. This may occur if a subject leaves the hospital early against medical advice (AMA), leaves a post-discharge facility (e.g., such as a residential treatment facility which may happen in TAU), or is lost to follow up after discharge with the PICC line. While relatively uncommon, this does occur clinically in a small number of cases. It is important to note that 100% of subjects in both groups of the pilot study done by the same team of investigators (UK IRB: 16-1001-F1V, PI: Fanucchi) completed their antibiotic regimen. The research and clinical teams will make every effort to ensure subjects complete recommended courses of IV antibiotic therapy. The hospital has clinical protocols in place that are activated if, for example, a patient leaves AMA before completing their treatment. For example, patients who choose to leave the hospital AMA may be offered oral antibiotics (if there is an oral option that may treat the infection, though an IV regimen would be considered standard of care), and follow up in the infectious disease clinic. In OPAT as part of standard clinical care, several contact numbers are obtained from patients (and confirmed prior to discharge) to minimize the chances of loss-to-follow-up with a PICC line. If patients on OPAT with a PICC line are lost to follow up as defined by: 1) missing scheduled appointments, 2) not able to be reached by the involved home health or home infusion agencies, 3) not able to be reached with all available contact numbers, 4) and 3 days have passed with no successful contact made with the patient, local law enforcement is then contacted to do a home safety check on the patient and potentially bring the patient to the emergency room to have the PICC line removed. With regard to our research approach, participants may continue in research assessments, and study clinicians will continue to assess medical stability and recommend readmission to the hospital if needed.

Risks of research assessments: The behavioral and physiological assessment procedures employed in these studies are relatively benign. During the screening process, it is possible that subjects may feel uncomfortable answering personal questions about their health, psychiatric and drug use histories. However, they may stop answering questions at any point. There is also the risk that others may see a subject's Protected Health Information (PHI). PHI is considered individually identifiable health information transmitted or maintained in any form (electronic means, on paper or through oral communication) that relates to the past, present or future physical or psychiatric health conditions of an individual that may be used or disclosed.

Risks of qualitative interviews: Psychological stress may occur among some participants when discussing medical and substance use histories. Participants are instructed that they may choose not to answer such questions.
Volunteers in clinical trials involving BUP have benefited from receiving the medication and counseling services because those studies demonstrated decreased illicit opioid use. It is likely that volunteers in our study will directly benefit from receiving the medication. Volunteers in Group 1 (B-OPAT) may also benefit from being able to leave the hospital earlier than they would have if they were not participating in the study. The major benefits derived from this research are of a scientific nature, which should benefit society at large in the long run particularly if results are positive regarding the efficacy and cost-effectiveness of providing OPAT supported with intensive outpatient OUD treatment compared to TAU. Volunteers may receive no direct benefit from participating in the qualitative interview component of the study. Nevertheless, volunteers may find satisfaction in sharing their experiences and opinions about the intervention with an impartial interviewer, and in doing so, may contribute to improved interventions and standard of care for other patients. The individuals who may benefit from this research are opioid dependent individuals with severe infections associated with IDU, the same individuals who are participating in these studies. The degree of risk to which individual study volunteers are exposed as a consequence of their research participation is low. In contrast, the potential and probable benefits to be derived by society, in general and by opioid dependent individuals, specifically, appear to be considerable. Consequently, the risk/benefit ratio seems quite favorable and the conduct of this research seems well justified.
Providers may receive no direct benefit from participating in the stakeholder interviews, however, this project is expected to generate important information about the organizational and systems level barriers that interacted with the intervention to hinder adoption and participation, and the organizational factors that negatively or positively influenced implementation. Providers may benefit from the opportunity to share their opinions and experiences with intervention delivery for themselves, their patients and their organization, and may find satisfaction in contributing to research that will improve patient care.

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).

Participation is voluntary, and refusal to participate is without consequence. If volunteers do not want to participate, we can give them a list of clinics/facilities that offer treatment for opioid use disorder and websites that help locate treatment providers as well. Most potential volunteers will have received consultation in the hospital from the UK Addiction Consult and Education Service and will be provided linkage to ongoing substance use disorder treatment after hospital discharge.

Back to Top

Records, Privacy, and Confidentiality

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

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

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

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

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

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

The new data security compliance requirements under 28 CFR Part 202 are in effect as of 10/6/25. For any questions please contact Sara Poll, UK's Research Security Administrator, researchsecurity@uky.edu

Aim 1: Sources of research material obtained from our volunteers during screening and study participation include: urine specimens; self-reported information gathered from the volunteer about their personal and their family psychiatric and medical, demographic information, self-report of medication diversion/misuse, and illicit drug use; study staff observation of drug effects (e.g., opioid withdrawal symptoms), vital signs (blood pressure, pulse), the electronic medical record (e.g., for confirmation of the SIRI inclusion criteria), the state prescription drug monitoring program (e.g. for confirmation of buprenorphine prescriptions), and medical records from other facilities (e.g. for urine test results and possible hospital admissions at other facilities). All sources of research material will be obtained in a HIPAA-compliant manner and are collected specifically for the proposed clinical trial by study staff. The principal investigator and medical team will have access to private health information about volunteers so that determination of study eligibility can be determined. All data with personal health information are kept in a locked file cabinet separate from other volunteer data without identifiable private health information.

Aim 2: The qualitative interviews conducted to inform the economic evaluation will gather information on the resources needed to launch and run the integrated outpatient care model. Interviews are not recorded; notes will be stored on a password-protected, secured server at Weill Cornell.

Aim 3:The in-depth qualitative interviews will gather information on patient satisfaction with the experimental B-OPAT intervention, identify targets that might increase retention, and explore any substantial barriers and potential adaptations to enhance acceptability by patients. The in-depth interviews will also provide rich data on: when patients experienced the most difficulties during hospitalization and the outpatient transition, participant perspectives and priorities related to outcomes, and the most important elements of the treatment model from the patient perspective. The qualitative interviews will be conducted by Co-I Surratt, who is experienced with interviewing persons with OUD, and has extensive training in protections of human subjects. The interviews will be digitally audio-recorded; no names will be used in any of these audio recordings. Each transcribed interview will be labelled with a unique number, and no participant identification information will appear on the interview transcript. Audio files of completed interviews will be electronically uploaded to a password-protected central server accessible only to study staff.

Aim 3: The one-time in-depth interview sessions with participating health care providers and leadership are designed to elucidate critical information on the multi-level barriers to implementing the experimental intervention, be they provider- or systems-level issues. Qualitative interviews will focus on attitudes and experiences of delivering care to patients with OUD and SIRI, structural or organizational barriers to implementing the treatment model, and challenges for scalability. Interview data will be collected by Co-I Surratt, who has experience with qualitative interviewing with healthcare providers and extensive training in protections of human subjects. The interviews will be digitally audio-recorded; no names will be used in any of these audio recordings. Audio files of completed interviews will be electronically uploaded to a password-protected central server accessible only to study staff. All self-

report data are new data to be collected solely for the purposes of this research project and will be reported in aggregate only.
A Certificate of Confidentiality will be obtained from the NIH. The following PHI will be collected as part of this project: names (individual, employer, relatives, etc.), address, telephone number, Social Security number, dates (birth, admission, discharge), medical record numbers, psychiatric and physical health history, drug use history, results from psychiatric and physical health screening, and electronic health record data.

All documentation that contains PHI is kept apart from research data. Files will not contain the name of the subject. Instead, each subject will be assigned a unique identifying number. Data containing volunteer names (e.g., health records) are kept separately from coded data. Crosswalk tables that link PHI with the research record numbers will be kept separately from both the research data and PHI file. All volunteer PHI is confidential and will be protected according to the guidelines established by the Health Information Portability and Accountability Act (HIPAA). An “Authorization to use and disclose PHI for research purposes” approved by the IRB will be obtained. All electronic files (except for data entered via REDCap described below) will be stored on the HIPAA-compliant Center on Drug and Alcohol Research (CDAR) server that is located in the data center of the UK hospital and is behind the firewall. The server is password protected and only assigned staff are granted access. The server is backed-up each night. Encrypted laptops will be used for data collection. The specific files are also password-protected. All personal identifiers are encrypted when the data are uploaded.

Some data collection will utilize REDCap, which is a secure web-based application for building and managing online surveys and databases. The application is trademarked by the Vanderbilt CTSA; however, the data is housed on local servers with in-house control. REDCap is implemented as a secure web server (HTTPs) located within IPOP behind a firewall on UK’s network. Accounts are created using the mc/ad domain account generated by UK and is used for authentication purposes. This login process requires individual password protection for investigators. Investigators can assign additional users of REDCap to their Projects/Surveys and define permissions for each user. User rights issued include the ability to invite participants for survey responses, creation of calendar events, import or export of data-which can be further secured by enabling export of data as a full data set or as deidentified only, ability to build reports, lock or unlock records when entry is completed, create records, rename records, edit records, or delete records, or determine if an electronic signature is required for certain events. In addition, each user can be given an expiration date which will remove access to that individual user. When investigators are logged onto REDCap to enter data into their case report forms, a vulnerability to hacking the account while open is of concern; however, all data is encrypted when transmitted to the REDCap server. Portable devices are not at risk because nothing is downloaded onto the device, a secure web based connection is used for all data collection. Data storage on portable devices is not a security concern for REDCap administration, but appropriate measures should be taken when exporting data from REDCap. To assist investigators, REDCap has an email function that offers greater security for large attachments that contain sensitive data. Each recipient receives an email containing a unique downloaded URL, along with a second follow up email with the password for downloading the files. The file is stored securely and removed from the server upon the specified expiration date.

All written documents, including PHI, will be stored in locked cabinets at the Center on Drug and Alcohol Research at 845 Angliana Avenue. Paper documents that contain PHI will be stored separately from research data. Offices are locked and building entry is protected by badge access. Key access will be limited to study personnel.

The study will maintain all data for at least six years. The investigator will retain signed documents (e.g., signed consents) and IRB records for at least six years after study closure as outlined in the Study Closure SOP.
The Co-PIs will screen all potential volunteers to ensure they meet medical inclusion/exclusion criteria. Because participation is voluntary, subjects can withdraw at any time if they find the study procedures undesirable. Dr. Fanucchi and Dr. Lofwall will train all staff on this project, and all staff involved in these studies will complete all of the appropriate trainings (i.e., HSP, GCP, RCR).

Because several of the assessments will take place in the hospital setting, interviews will take place in private rooms (e.g., private inpatient rooms) with a sign placed on the door indicating ‘research interview in progress, do not disturb except for emergency.’ All research urine drug screens will be processed at CDAR and the results will not appear in the patient’s electronic record (nor will they be available to anyone outside of the research team). Subjects in both groups will receive instructions related to appropriate use and care of the PICC, as well as be informed about the risks of using the PICC line for purposes other than indicated (e.g., injection of illicit substances). This information will also be included in the consent form.
Volunteers will meet with Dr. Fanucchi (or another study clinician) weekly during the inpatient phase, and with Dr. Lofwall (or another study clinician) between 1-2 times weekly during the outpatient phase for assessment and evaluation of medication tolerability, adverse events and unanticipated problems. If for some reason the volunteer cannot make their scheduled appointment in any given week, the study staff will attempt to make phone contact with the volunteer in order to try to reschedule the subject; study medical staff may talk to the subject by phone if there are any concerns and may schedule extra in-office visits as clinically necessary. Dr. Thornton (Infectious Disease, Co-I) is available to assist Dr. Fanucchi and Dr. Lofwall with any concerns related to the PICC line or the infection that may arise during study participation.
All volunteer information and data are confidential and never released to anyone outside of the project purview without the volunteer’s written authorization. The identity of participants is never revealed in research reports. All intake documentation that contains PHI is handled separately from the actual data collected during the study. Files will not contain the name of the subject. Instead, each subject will be assigned a unique identifying number. Data containing volunteer names (e.g., health records) are kept separately from coded data so that the two cannot be joined. All volunteer PHI is confidential and will be protected according to the guidelines established by the Health Information Portability and Accountability Act (HIPAA). An “Authorization to use and disclose PHI for research purposes” approved by the IRB will be obtained. All written documents, including PHI, will be stored in locked cabinets at the site. Key access will be limited to study personnel. Electronic information will reside on a stand-alone, password-protected computer. Electronic transmission via e-mail or FAX with volunteer PHI will have a statement of confidentiality. During the conduct of this project, we will maintain an active concern for providing proper protection of the welfare and rights of the research volunteers.
Medical risks are minimized by thorough screening medical examinations, standardized induction and maintenance dosing procedures, medical exclusion criteria, provision of naloxone prescriptions, and ongoing regular doctor visits and 24-hour 7 day per week medical

on-call coverage. Precipitated withdrawal is minimized due to the induction procedure that includes initiation of BUP dosing in the presence of opioid withdrawal. The use of split BUP dosing on induction day (initial 4 mg dose followed by another 4 mg dose 1-2 hours later) is well-tolerated with rapid relief of opioid withdrawal and is recommended practice (SAMHSA TIP 63, 2018). The doses of BUP to be administered are within the therapeutic dose range indicated by the FDA-approved drug label and published federal guidance (TIP 63). All participants, regardless of completing or not completing the study, are offered assistance with finding ongoing treatment in the community after the study ends in order to further decrease the risk of relapse and ongoing illicit drug use and diversion.

Qualitative interviews: Co-I Surratt will serve as the primary interviewer and is experienced in recognizing signs of discomfort or unwillingness to answer questions and will move on to other topics when necessary. The interviews will be conducted in clinical care settings that will also have medical and behavioral health providers on site should any acute distress require immediate attention. For healthcare stakeholder interviews, we will ensure that data collection occurs at provider convenience to minimize burden, and ensure that the provider can stop at any time during the interview. The investigators have established procedures to ensure confidentiality to participants, and the instrumentation, study procedures and consent forms are subject to regular Institutional Review Board (IRB) oversight. No information will be shared with authorities or any other persons. To protect against any risk to confidentiality from the provider interviews, only minimal identifying information will be collected.

To protect against any risk to confidentiality from the qualitative interviews, digital audio recordings will be erased immediately following transcription. All transcribed and printed data forms will be coded with unique identifiers. Data containing volunteer names (e.g., health records) are kept separately from coded data so that the two cannot be joined. All volunteer PHI is confidential and will be protected according to the guidelines established by the Health Information Portability and Accountability Act (HIPAA). An “Authorization to use and disclose PHI for research purposes” approved by the IRB will be obtained. All written documents, including PHI, will be stored in locked cabinets at the site. Key access will be limited to study personnel. Electronic information will reside on a stand-alone, password-protected computer. Electronic transmission via e-mail or FAX with volunteer PHI will have a statement of confidentiality. During the conduct of this project, we will maintain an active concern for providing proper protection of the welfare and rights of the research volunteers.

☑ **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.

Subjects will be paid for their participation. Specifically, subjects will receive $25 for screening and informed consent and $50 for the initial assessment. The remaining payments occur after discharge and will be checks as described: $25 for each short outpatient research assessment (weeks 1-3 of each outpatient month), $50 for each longer monthly outpatient research assessment, $50 for each monthly follow up visit, and $250 as a bonus if all research assessments are completed. Payments occurring while participants are hospitalized will be in cash, and payments occurring while participants are outpatients will be checks. In the event that it is a hardship for participants to cash/deposit checks, payments may be made in cash. For the qualitative interviews, subjects (both research volunteers and health system stakeholders) will be offered a $25 stipend for their time to participate in each in-depth interview, which is anticipated to last between 60 - 90 minutes. Assistance with transportation expenses to attend visits related to study participation may be provided.

We follow the UK business procedure E-9-1 (https://www.uky.edu/ufs/sites/www.uky.edu.ufs/files/bpm/E-9.pdf) Compensation to Research Subjects or Survey Participants documentation requirements.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a subject will not know what is “standard” – and thus not covered by the sponsor/study – unless you tell them.

Buprenorphine treatment is standard outpatient clinical care for opioid use disorder that Medicaid, Medicare and commercial insurances cover (e.g, KY Medicaid pays for buprenorphine prescriptions and the associated visits). Volunteers’ are responsible for payment for this buprenorphine treatment. If Medicaid is their insurer – they will not have any copays. However, if they have another insurance, they may have deductibles and copays. If they have no insurance, they will be billed. This will be explained to participants in the informed consent form. Likewise, the infectious disease and hospital clinical care are all standard care that will be billed to the patient/their insurance. There are no other costs to participate in the study. This study will undergo indemnification review by UK legal to develop a plan code that will carefully distinguish between research and clinical care costs.

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.

The study will randomize 120 subjects with OUD and SIRI to one of two treatment models; one that completes IV antibiotics via OPAT and one that completes IV antibiotics according to treatment as usual. The study uses BUP for its FDA-approved indication of treating opioid use disorder within the therapeutic dose range as described on the FDA-approved medication label. The frequency of doctor visits and urine drug test monitoring are within the range or exceed the amount recommended for outpatient OUD treatment. The study uses OPAT according to standard protocols to safely provide IV antibiotics on an outpatient basis.

It is a clinical trial because it "… is a prospective study to test the effect of a biomedical or behavioral intervention in human subjects." It best fits the criteria for a Phase II clinical trial because it is evaluating the efficacy of providing OPAT with BUP compared to treatment as usual. Phase III clinical trials typically involve hundreds to thousands of subjects. This study randomizes a smaller number of subjects (n=120), is not blinded, and is not multisite; however, given the complexity of the underlying medical illnesses in the study patient population, we propose to convene a DSMB. Both Dr. Michelle Lofwall, Co-PI and Dr. Sharon Walsh, Co-I, have extensive experience working on studies requiring a DSMB.
The MPIs, Laura Fanucchi, MD, MPH, and Michelle Lofwall, MD will be responsible for monitoring the safety and effective implementation of this project, executing the DSMP including reporting to the DSMB. Prior to initiation of the study, the detailed DSMP including DSMB roster will be submitted to NIDA for review. The initial plan for the DSMB membership is as follows: the Chair will be Kevin Hatton, MD who is Professor of Anesthesiology and Surgery, Division Chief for Anesthesiology Critical Care Medicine at the University of Kentucky. Dr. Hatton has extensive clinical experience caring for hospitalized patients with opioid use disorder and injection-related complications. He also collaborates with researchers in studies of opioid and other substance use, with a primary role to evaluate and maintain research subject safety. William Stoops, Ph.D., Professor of Behavioral Science and Psychiatry, Director of the Regulatory Knowledge and Support Core of the Center for Clinical and Translational Science, and Interim Director of the Clinical Research Support Office at the University of Kentucky, will serve as a member of the DSMB. Dr. Stoops is PI of several NIH-funded projects, all of which involve enrollment of participants with substance use disorders, and has extensive experience convening and serving on DSMBs. Takako Schaninger, MD is Associate Professor of Medicine in the Division of Infectious Diseases at the University of Kentucky and will serve on the DSMB. Dr. Schaninger has extensive experience managing patients with severe injection-related infections in the inpatient and outpatient settings via outpatient parenteral antimicrobial therapy.

There will be an initial DSMB meeting prior to enrolling patients and subsequent DSMB interim reviews thrice yearly of study progress and study logs (e.g. including logs of participant completion/withdrawal, adverse event logs, protocol violation log). The MPIs are responsible for complying with the reporting requirements. Methods for monitoring adverse events (AEs) will include observations by the research staff and spontaneous report by the volunteers. All AEs occurring during the course of the study will be collected, documented and reported to the Co-PIs and Co-Investigators, the DSMB and our IRB. The occurrence of AEs will be assessed for the duration of participation and during follow-up visits or as long as needed. Each week a study investigator will review the AE forms from the previous week for events that were reported as new or continuing. The study investigators will follow all AEs to the point of a satisfactory resolution. Volunteers may be withdrawn from the study if the either PI determines it is the best decision in order to protect the safety of the subject.

All AEs will be assessed to determine if they meet criteria for a serious adverse event (SAE). While not expected to occur as a result of this research project, Serious Adverse Events, as defined by the FDA, will be systematically evaluated for the duration of participation. Any SAE, will be reported to the IRB, the DSMB, and to the designated NIDA project officer. The initial SAE report will be followed by submission of a completed SAE report. In the event that a volunteer either withdraws from the study or the investigator decides to discontinue a volunteer due to an SAE, the volunteer will have appropriate follow-up medical monitoring. Monitoring will continue until the problem has resolved or stabilized with no further change expected.

Back to Top

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

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

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

N/A

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

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

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

Cultural and Language Consultants:

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

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

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

Local Requirements:

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

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

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

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

HIV/AIDS Research

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

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

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

PI-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:

Weill Cornell Medical College

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

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

Attachments

Attach Type	File Name
-Letter of Support & Local Context	LOS_Fayette_County_Detention_Center.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 Heskel, 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:

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.):

NIDA

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

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.

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	
David	Moliterno	Department Authorization	Internal Medicine		09/09/2020 07:45 PM	View/Sign
Laura	Fanucchi	Principal Investigator	Internal Medicine & Divisions - Infectio		09/08/2020 10:16 AM	View/Sign

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.

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.

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.