IRB Approval
2/8/2024
IRB # 46591
IRB2

IMPORTANT NOTE: You will not be able to change your selections for "Which IRB" and "Protocol Process Type" after saving this section. If you select the wrong IRB or Protocol Process Type, you may need to create a new application.

For guidance, see:

- Which IRB?
- Which Protocol Process Type?
- "Getting Started"

Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions prior to saving your selections.

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.

Modification Request Section

0 unresolved comment(s)

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

Select One:

- (•) This modification does not increase risk to study participants.
- ( ) This modification may or will increase risk to study participants.

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

( ) Yes (•) No

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

( ) Yes (•) No

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

For each proposed modification, include a justification.

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

Update Study Personnel: Add Chamblin. She has completed required trainings and is NOT authorized to consent.

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

Prescription Medications: Pharmacodynamics and Interaction Effects

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.

Prescription Medication Interactions

Anticipated Ending Date of Research Project: 12/31/2024

Maximum number of human subjects (or records/specimens to be reviewed) 72

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:	Sharon	Room# & Bldg:	845 Angliana Avenue
Last Name:	Walsh	Speed Sort#:	40508
Middle Name	L		
Department:	Behavioral Science - 7H150	Dept Code:	7H150
PI's Employee/Student ID#:	00058631	Rank:	Professor
PI's Telephone #:	8592576485	Degree:	PhD
PI's e-mail address:	sharon.walsh@uky.edu	PI's FAX Number:	8592575232
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	1/18/2022
		RCR Trained:	Yes

Do you, the PI, 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.

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 55

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 these resources:
NIH Diversity Policy
FDA Diversity Guidance

Volunteers will be approximately 72 persons who are screened for the study, with up to 18 (up to 6 pilot phase participants and 12 main phase, fully randomized participants) completing the protocol. We anticipate starting recruitment on December 1, 2018, and finishing recruitment by December 1, 2020.
Inclusion criteria:
- ages 18-55 years old
- healthy adult male and female participants as determined by physical exam, 12-lead ECG, blood chemistries and routine urinalysis
- recreational (non-medical) opioid use within the past year
- recreational (non-medical) sedative use within the past year
- must be using an effective form of birth control
- literate and able to provide informed consent
- able and willing to follow the protocol

Exclusion criteria:
- physical dependence on any drug requiring medical management (e.g., opioids, sedatives, alcohol)
- seeking treatment for substance use disorder
- liver function tests exceeding 3x the normal limit
- known hypersensitivity to any of the study drugs
- any psychiatric disorder that would interfere with study participation
- any medical condition that is clinically significant or requires ongoing prescription medication
- acute medical illness unresolved (e.g., infection)
- women who are pregnant or lactating
- current seizure disorder, chronic pain, asthma or other respiratory disorders that may increase risk of respiratory depression, history of head injury, hypertension, or history of cardiovascular disease or abnormal ECG
- HIV-positive patients if they are not symptomatic with AIDS-defining illness (e.g., opportunistic infections, T-cell less than 200/mm3)
- anyone unable to fulfill the protocol requirements based on investigator judgment
- currently under parole or probation with urine testing requirements
- inability to tolerate the pain stimuli during training, reporting no pain/discomfort from cold water test

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, 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:	4	2		
Latinx:	3	1		
Native Hawaiian/Pacific Islander:				
White:	40	20		
American Arab/Middle Eastern/North African:				
Indigenous				

People Around the World:				
More than One Race:				
Unknown or Not Reported:	1	1		

If unknown, please explain why:

The volunteers in the "Other" category represent individuals reporting more than one race

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

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

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

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

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

Other Resources:

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

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

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

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

○ Yes ◉ No

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

Examples of such conditions include:

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

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

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

Additional Resources:

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

Consent/Assent Tips:

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

How to Get the Section Check Mark

1. You must:

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

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

Check All That Apply

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

Attachments

Attach Type	File Name
Informed Consent/HIPAA Combined Form	46591 Screening Consent - Prescription Med Interactions v10.0 Jun 13 2023 (f).pdf
Informed Consent/HIPAA Combined Form	46591 Main Study Consent - Prescription Med Interactions v9.0 Jun 13 2023 (f).pdf

Informed Consent Process:

Using active voice, 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

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.

Prior to obtaining informed consent, each potential subject must have an expired breath alcohol content (BAC) of 0.00 and not appeared intoxicated (nodding, appearing sedated). Sharon L. Walsh, Ph.D. or her designated staff will obtain consent for this project. There are two consent forms for this project: a screening consent and the main study consent. Designated staff may conduct and sign the informed screening consent with the volunteer. However, the volunteer will meet with the investigator, senior staff member, or co-investigator on an outpatient basis prior to admission to review all experimental procedures and allow the volunteer ample time to ask questions regarding the protocol before signing the study consent form. There is no time limit on this process. The investigator will inform the volunteer that this is not a treatment program and signing the consent form does not obligate them to participate. Each subject will receive a copy of his/her informed consent document.

Participants may also be consented via Zoom. All consenting procedures will be identical to an in-person consent, except the PI will be present via Zoom (instead of the same room). The participant will be screened by in-person research staff (e.g., participants provided photo ID, negative breathalyzer samples and protocol-appropriate urine samples; staff confirmed participants were not intoxicated). Research staff will provide the a copy of the hardcopy (paper) consent form to the participant, which will be verified on camera by the PI. This process allows for a thorough discussion and exchange of information with the participant, a method to ensure the participant's identity, and documentation of the consent itself.
Subjects may ask study personnel questions about the study procedures or make complaints at any time. All staff will be aware to contact Drs. Walsh and/or Lofwall about any subject concern or complaint as it arises. Phone numbers for the PI and staff, as well as the Office of Research Integrity, are included in the consent form. It is expected that providing a phone number and contact information for the PI may offer a safe, confidential and reliable channel for participants to express problems, concerns or questions and obtain study information.

☐ 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.

Request for Waiver of Signatures

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

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

Select the option below that best fits your study.

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

Option 1

Describe how your study meets these criteria:

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

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

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

Option 2

Describe how your study meets these criteria:

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

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

Option 3

Describe how your study meets these criteria:

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

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

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

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

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

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

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

To add an individual via the below feature:

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

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

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Adams	Christian	Medical Supervisor	SP	N	N	MD	P	Y	12/21/2022	Y	N	09/20/2023	N	Y
Allen	Timothy	Medical Supervisor	SP	N	N	MD	P	Y	12/04/2023	Y	N	09/20/2023	N	Y
Anderson	Danielle	Medical Supervisor	SP	N	N	MD	P	Y	05/31/2023	Y	N	10/18/2022	N	Y
Andrews	Lelia	Data Collection	SP	Y	N		P	Y	01/20/2023	Y	N	01/19/2023	N	Y
Atwater	Chelsea	Medical Supervisor	SP	N	N	MD	P	Y	10/25/2023	Y	N	11/10/2022	N	Y
Babalonis	Shanna	Co-Investigator	DP	Y	Y	PhD	P	Y	02/21/2023	Y	N	11/06/2018	N	Y
Bailey	Rebecca	Project Assistance/Support	SP	N	N		P	Y	09/08/2022	Y	N	10/12/2022	N	Y
Batsel-Thomas	Sandra	Medical Supervisor	SP	N	N	MD	P	Y	05/03/2021	Y	N	09/20/2023	N	Y
Brown	Paul	Project Assistance/Support	SP	N	N		P	Y	09/08/2023	Y	N	10/12/2021	N	Y
Buckler	Regan	Project Assistance/Support	SP	N	N	RN	P	Y	04/14/2021	Y	N	04/30/2021	N	Y
Cady	Corissa	Project Assistance/Support	SP	N	N		P	Y	06/05/2023	Y	N	07/20/2023	N	Y
Camper	Zenith	Project Assistance/Support	SP	N	N	RN	P	Y	02/08/2023	Y	N	02/09/2023	N	Y
Chamblin	Lisa	Project Assistance/Support	SP	N	N		P	Y	08/02/2022	Y	N	02/08/2024	N	Y
Chang	Loui	Data Collection	SP	Y	N		S	Y	06/05/2023	Y	N	06/06/2023	N	Y
Chilton	Elizabeth	Project Assistance/Support	SP	N	N		P	Y	09/28/2023	Y	N	08/04/2023	N	Y
Cobb	Susan	Project Assistance/Support	SP	N	N		P	Y	04/18/2021	Y	N	07/15/2020	N	Y
Cooley	Andrew	Medical Supervisor	SP	N	N	MD	P	Y	12/29/2023	Y	N	03/29/2021	N	Y
Cooley	Andrew	Medical Supervisor	SP	N	N	MD	P	Y	12/29/2023	Y	N	03/29/2021	N	Y
Davis	Miranda	Data Collection	SP	Y	N		P	Y	08/31/2022	Y	N	09/23/2022	N	Y
Dowden-Kruger	Melinda	Project Assistance/Support	DP	N	Y		P	Y	02/21/2023	Y	N	08/07/2019	N	Y
Fanucchi	Laura	Medical Supervisor	SP	Y	N		P	Y	01/24/2022	Y	N	08/02/2021	N	Y
Forenback	Denece	Project Assistance/Support	SP	N	N	RN	P	Y	12/07/2023	Y	N	03/09/2021	N	Y
Fuller	Grayson	Data Collection	SP	Y	N		P	Y	03/15/2023	Y	N	03/16/2023	N	Y
Gamble	Bethanie	Data Collection	SP	N	N		P	Y	10/03/2022	Y	N	10/12/2022	N	Y
Gayhart	Sarah	Data Collection	SP	N	N		P	Y	09/21/2023	Y	N	11/07/2018	N	Y
Gibson	Pamela	Project Assistance/Support	SP	N	N	RN	P	Y	07/27/2023	Y	N	02/01/2024	N	Y

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Gonzalez-Lozano	Evelyn	Data Collection	SP	Y	N		P	Y	08/04/2021	Y	N	08/18/2021	N	Y
Hamm	Anna	Data Collection	SP	N	N		P	Y	03/29/2023	Y	N	08/28/2018	N	Y
Harris	Shontel	Project Assistance/Support	SP	N	N		P	Y	09/06/2021	Y	N	10/12/2021	N	Y
Hash	Matthew	Project Assistance/Support	SP	N	N		P	Y	01/26/2024	Y	N	03/03/2020	N	Y
Hatton	Kevin	Co-Investigator	SP	Y	N	MD	P	Y	10/14/2021	Y	N	08/27/2018	N	Y
Hawthorne	James	Medical Supervisor	SP	N	N	MD	P	Y	05/09/2023	Y	N	09/20/2023	N	Y
Hays	Lon	Medical Supervisor	SP	N	N	MD	P	Y	11/08/2023	Y	N	09/20/2023	N	Y
Humphries	Timothy	Project Assistance/Support	SP	N	N	RN	P	Y	02/21/2023	Y	N	03/06/2023	N	Y
Hunt	Cassandra	Project Assistance/Support	SP	N	N		P	Y	03/15/2021	Y	N	08/28/2018	N	Y
Islam	Mohammed	Medical Supervisor	SP	N	N	MD	P	Y	10/12/2023	Y	N	09/20/2023	N	Y
Kroupa	Spencer	Project Assistance/Support	SP	N	N		P	Y	06/07/2023	Y	N	07/20/2023	N	Y
Kunzelman	Wyatt	Data Collection	SP	Y	N		P	Y	09/12/2023	Y	N	09/12/2023	N	Y
Lester	Clark	Medical Supervisor	SP	N	N	MD	P	Y	07/05/2022	Y	N	11/10/2022	N	Y
Lester	Clark	Medical Supervisor	SP	N	N	MD	P	Y	07/05/2022	Y	N	11/10/2022	N	Y
Leung	Steve	Medical Supervisor	SP	N	N	MD	P	Y	10/16/2021	Y	N	10/29/2020	N	Y
Lofwall	Michelle	Co-Investigator	SP	Y	N	MD	P	Y	06/29/2023	Y	N	08/27/2018	N	Y
Mandal	Anjana	Project Assistance/Support	SP	N	N		P	Y	12/22/2021	Y	N	08/29/2022	N	Y
Mandal	Prabin	Project Assistance/Support	DP	N	N		P	Y	06/27/2022	Y	N	08/29/2022	N	N
Maynard	Marshall	Project Assistance/Support	SP	N	N		P	Y	06/16/2022	Y	N	08/29/2022	N	Y
Meadows	Amy	Medical Supervisor	SP	N	N		P	Y	08/11/2021	Y	N	08/28/2018	N	Y
Min	James	Medical Supervisor	SP	N	N	MD	P	Y	10/23/2023	Y	N	09/20/2023	N	Y
Nieto	Alayne	Project Assistance/Support	SP	N	N	RN	P	Y	05/16/2022	Y	N	06/14/2022	N	Y
Nuzzo	Paul	Study Coordinator	SP	Y	N		P	Y	01/30/2023	Y	N	08/02/2021	N	Y
Oros	Sarah	Medical Supervisor	SP	N	N	MD	P	Y	02/16/2023	Y	N	03/05/2021	N	Y
Perpar	Justin	Data Collection	SP	Y	N		P	Y	10/26/2022	Y	N	10/26/2022	N	Y
Quarles	Allison	Project Assistance/Support	SP	N	N	RN	P	Y	11/16/2021	Y	N	11/30/2021	N	Y
Rakesh	Gopalkumar	Medical Supervisor	SP	N	N	MD	P	Y	09/15/2022	Y	N	10/12/2022	N	Y
Ross	Dorothy	Project Assistance/Support	SP	N	N		P	Y	11/03/2023	Y	N	08/28/2018	N	Y
Shelton	Charles	Medical Supervisor	SP	N	N	MD	P	Y	04/05/2023	Y	N	11/10/2022	N	Y
Shelton	Charles	Medical Supervisor	SP	N	N	MD	P	Y	04/05/2023	Y	N	11/10/2022	N	Y
Stamper	Brady	Project Assistance/Support	SP	N	N		P	Y	06/05/2023	Y	N	07/20/2023	N	Y
Stephens	Tonya	Project Assistance/Support	SP	N	N	RN	P	Y	09/01/2023	N	N	02/01/2024	N	Y
Swain	Audrie	Project Assistance/Support	SP	N	N		P	Y	01/28/2024	Y	N	08/29/2022	N	Y
Thompson	Tamra	Project Assistance/Support	SP	Y	N		P	Y	09/28/2022	Y	N	10/12/2022	N	N
Tuttle	Teresa	Project Assistance/Support	SP	N	N	RN	P	Y	02/25/2023	Y	N	03/06/2023	N	Y
VanMeter	Connor	Data Collection	SP	Y	N		P	Y	10/10/2022	Y	N	10/12/2021	N	Y
Vessels	Victoria	Data Collection	SP	Y	N		P	Y	05/03/2022	Y	N	08/28/2018	N	Y
Vincent	Sylvia	Data Collection	SP	N	N		P	Y	01/30/2024	Y	N	11/07/2018	N	Y
White	Jessica	Project Assistance/Support	SP	N	N	RN	P	Y	02/23/2023	Y	N	02/01/2024	N	Y
Yadon	Rachele	Medical Supervisor	SP	N	N	MD	P	Y	01/21/2022	Y	N	03/05/2021	N	Y
AbouAhmed	Amira	Data Collection	SP	N	N		P	N	10/22/2019		Y	04/29/2022	N	N

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Adams	Elizabeth	Project Assistance/Support	SP	N	N	RN	P	N	10/22/2020		Y	04/29/2022	N	N
Ali	Nur-Ur-Sahar	Data Collection	SP	Y	N		P	N	08/06/2020		Y	07/23/2021	N	N
Allen	Nicola	Project Assistance/Support	SP	N	N	RN	P	N	10/29/2020	N	Y	02/03/2023	N	Y
Bradley	Robin	Project Assistance/Support	SP	N	N		P	N	05/24/2019		Y	07/22/2022	N	N
Britch	Stevie	Data Collection	SP	Y	N		P	Y	07/29/2022	Y	Y	07/20/2023	N	N
Broome	Bibi	Data Collection	SP	N	N		P	Y	03/21/2023	Y	Y	04/29/2022	N	Y
Brown	Vickie	Project Assistance/Support	SP	N	N		P	N	02/14/2020	N	Y	03/06/2023	N	Y
Browning	Christopher	Project Assistance/Support	SP	N	N		P	Y	09/18/2023	Y	Y	10/26/2022	N	Y
Clark	Katie	Project Assistance/Support	SP	Y	N		P	Y	10/10/2022	Y	Y	07/20/2023	N	Y
Devine	Amber	Project Assistance/Support	SP	N	N		P	Y	11/23/2021	N	Y	06/13/2023	N	N
Dugan	Joseph	Project Assistance/Support	SP	N	N		P	N	05/30/2019		Y	10/12/2021	N	N
Elder	Katherine	Project Assistance/Support	SP	N	N		S	N	01/19/2021	Y	Y	10/12/2022	N	Y
Evans	Rachel	Project Assistance/Support	SP	N	N	RN	P	Y	05/21/2023	N	Y	02/01/2024	N	N
Fancher	Joshua	Data Collection	SP	Y	N		P	Y	01/17/2023	N	Y	03/06/2023	N	N
Farrell	Carla	Project Assistance/Support	SP	N	N		P	N	04/07/2019		Y	04/04/2022	N	N
Finch	Megan	Project Assistance/Support	SP	N	N		P	Y	08/08/2022	Y	Y	07/20/2023	N	N
Foltz	Denise	Project Assistance/Support	SP	Y	N		P	Y	02/02/2023	Y	Y	05/17/2023	N	Y
Garnett	Kimberly	Project Assistance/Support	SP	N	N	RN	P	Y	09/07/2021		Y	04/29/2022	N	Y
Garton	Jackson	Data Collection	SP	Y	N		P	Y	09/24/2021		Y	10/12/2021	N	N
Gevedon	Teresa	Medical Supervisor	SP	N	N		P	Y	06/01/2022	Y	Y	05/11/2021	N	Y
Gifford	Mariah	Project Assistance/Support	SP	N	N	RN	P	Y	09/04/2021		Y	04/29/2022	N	Y
Hamilton	Rebekah	Project Assistance/Support	SP	N	N	RN	P	N	10/31/2020		Y	06/15/2022	N	N
Holbrook	Kathryn	Project Assistance/Support	SP	N	N		P	N	12/12/2018		Y	03/10/2021	N	N
Hurt	Amber	Data Collection	SP	Y	N		P	Y	06/14/2021		Y	06/15/2022	N	N
Jones	Dowana	Data Collection	SP	N	N		P	Y	04/18/2021		Y	04/29/2022	N	Y
Knight	Stephanie	Project Assistance/Support	SP	N	N	RN	P	N	10/20/2020		Y	04/29/2022	N	Y
Lewis	Russell	Data Collection	SP	Y	N		P	Y	02/16/2021		Y	07/12/2022	N	N
Mann	Shannon	Project Assistance/Support	SP	N	N		P	N	01/21/2021		Y	11/30/2021	N	N
Minix	Kathleen	Project Assistance/Support	SP	N	N	RN	P	Y	04/12/2021		Y	04/29/2022	N	Y
Nadim	Amina	Project Assistance/Support	SP	N	N		S	Y	02/16/2021		Y	06/15/2022	N	Y
Napier	Janice	Project Assistance/Support	SP	N	N	RN	P	N	10/27/2020		Y	06/13/2023	N	Y
Neltner	Matthew	Medical Supervisor	SP	N	N		P	Y	03/09/2021	Y	Y	03/05/2021	N	Y
Rayapati	Abner	Medical Supervisor	SP	N	N		P	Y	04/19/2021	N	Y	07/20/2023	N	N
Redmon	Nancy	Project Assistance/Support	SP	N	N		P	Y	08/24/2022	N	Y	02/03/2023	N	N
Rice	Linda	Project Assistance/Support	SP	N	N		P	Y	09/10/2021	Y	Y	04/29/2022	N	N
Roads	Andrew	Medical Supervisor	SP	N	N		P	Y	05/11/2022	N	Y	10/12/2021	N	Y
Ross	James	Project Assistance/Support	SP	N	N		P	Y	04/27/2022	Y	Y	07/20/2023	N	N
Rudd	Triana	Project Assistance/Support	SP	N	N		P	Y	09/16/2021	N	Y	02/01/2024	N	N

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Rudd	Trinity	Project Assistance/Support	SP	N	N		P	N	09/22/2020	Y	Y	06/13/2023	N	N
Silverstein	Lily	Project Assistance/Support	SP	N	N	RN	S	Y	01/10/2022	Y	Y	02/01/2024	N	Y
Skaggs	Kylee	Project Assistance/Support	SP	N	N	RN	P	Y	11/01/2022	Y	Y	10/12/2022	N	Y
Smith	Kayla	Data Collection	SP	N	N		P	N	06/04/2019		Y	07/22/2022	N	Y
Smoot	Holly	Project Assistance/Support	SP	N	N	RN	P	Y	08/17/2021		Y	04/29/2022	N	N
Stanley	Catherine	Data Collection	SP	Y	N		P	Y	05/11/2021	N	Y	02/03/2023	N	N
Stiehler	Julie	Project Assistance/Support	SP	N	N		P	Y	04/15/2021	Y	Y	04/29/2022	N	Y
Tarr	Rebecca	Project Assistance/Support	SP	N	N	RN	P	N	10/08/2020		Y	07/20/2023	N	Y
Tarrence	Jacob	Data Collection	SP	Y	N		P	Y	04/20/2021		Y	01/11/2022	N	N
Tillery	Melanie	Project Assistance/Support	SP	N	N		P	Y	10/05/2021	Y	Y	06/15/2022	N	Y
True	Laura	Data Collection	SP	N	N		P	N	04/13/2020		Y	06/15/2022	N	N
Watts	Linda	Project Assistance/Support	SP	N	N		P	Y	11/10/2021	Y	Y	02/01/2024	N	N
Wengert	Brandon	Recruitment	SP	N	N		P	Y	04/11/2022	Y	Y	07/07/2021	N	Y
Wilson	Aimee	Project Assistance/Support	SP	N	N	RN	P	Y	06/22/2022	N	Y	10/12/2022	N	N
Woodson	Andrea	Data Collection	SP	N	N		P	Y	05/13/2021		Y	07/13/2022	N	N

RESEARCH DESCRIPTION

0 unresolved comment(s)

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

Pro Tips:

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

Background

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

Gabapentin and oxycodone are commonly used in combination for the treatment of chronic pain. Gabapentin is now widely misused/abused with studies indicating that gabapentin abuse is especially common among individuals with opioid misuse. The nature of gabapentin's abuse-related effects have been described in case reports and online as sedative-like and opioid-like, with descriptive reports including sedation, euphoria, talkativeness and increased energy. Despite their widespread co-administration both for licit and illicit purposes, no controlled psychopharmacological studies to our knowledge have directly examined the effects of oxycodone (or another opioid agonist) and gabapentin in combination. Moreover, few data are available on the pharmacodynamic profile of gabapentin when administered alone, and, despite its apparent abuse potential, it remains an uncontrolled drug in the U.S. under the Controlled Substances Act.

Objectives

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

1. Characterize the nature of the subjective effect profile of gabapentin
2. Examine the interaction between gabapentin and oxycodone
3. Assess the acute analgesic response to gabapentin and oxycodone, alone and in combination

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.

This study will first employ a quasi-randomized, double-blind, placebo-controlled, inpatient, within-subject design to ensure that all doses and combinations are safely tolerated. Gabapentin doses and the combination doses of oxycodone and gabapentin will be given in ascending order, but imposed on an otherwise randomized design for all other conditions. Up to six volunteers will complete the pilot phase, and a review of safety will be conducted before enrolling additional volunteers.

After completion of the pilot phase study, a fully randomized, double-blind, placebo-controlled, inpatient, within-subject design will be used utilized.

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

Volunteers will be recruited through newspaper and radio advertisement, local postings, online advertisements on forums such as ResearchMatch, Cragislist, BuildClinical, Facebook, by geo-fencing techniques, and word-of-mouth. Volunteers will make initial contact by phone, Facebook or BuildClinical with one of our staff who have completed the research training and HIPAA compliance web-based teaching modules. If the volunteer discloses information that would make him/her potentially eligible for the study, they will be invited to come in for a screening appointment. Screening is completed by one of our trained research assistants/research nurses/investigators at the Behavioral Science Research Building or the UK CCTS. Study investigators may interact with volunteers in any of these settings and appropriate cautions are in place to ensure privacy during the intake process. We will not use any biological samples or information collected for this study for future research studies, even if we remove the identifiable information.

Volunteers will be recruited through newspaper and radio advertisement, local postings, online advertisements on forums such as ResearchMatch, Facebook, BuildClinical, Craigslist, by geo-fencing techniques and by word-of-mouth. Volunteers will make initial contact by phone, Facebook, or BuildClinical with one of our staff who have completed the research training and HIPAA compliance web-based teaching modules. If the volunteer discloses information that would make him/her potentially eligible for the study, they will be invited to come in for a screening appointment. Screening is completed by one of our trained research assistants/research nurses/investigators at the Behavioral Science Research Building or the UK CCTS. Study investigators may interact with volunteers in any of these settings and appropriate cautions are in place to ensure privacy during the intake process. Our Facebook page template and study flyers have been approved by UK PR.

Attachments

Attach Type	File Name
Advertising	Facebook page - revised Dec 17 APPROVED.pdf
Advertising	Non-Dependent OPI Advertisements APPROVED.pdf
Advertising	Possible Accompanying Text APPROVED.pdf
Advertising	20183 Ad 1.pdf
Advertising	20183 AD 2.pdf
Advertising	20183 AD 5.jpg
Advertising	20183 AD 6.jpg
Advertising	20183 AD 3.jpg
Advertising	20183 AD 4.jpg
Advertising	20183-Ad 7.pdf
Advertising	BuildClinical Secure questionnaire.pdf
Advertising	RX Interactions Cards 6.1 - CLEAN COPY.pdf
Advertising	RX Interactions Flyer 6.1 - CLEAN COPY.pdf
Advertising	RX Interactions Digital Ads 6.1 - CLEAN COPY.pdf
Advertising	General - Card 1 _20183_C-FINAL-STAMPED.pdf
Advertising	General - Cards 2_20183_A-FINAL-STAMPED.pdf
Advertising	General - Cards 3_20183_B-FINAL-STAMPED.pdf
Advertising	General - Digital 1_20183_B-1-FINAL-STAMPED.pdf
Advertising	General - Digital 2_20183_C-FINAL-STAMPED.pdf
Advertising	General - Digital 3_20183_A-1-FINAL-STAMPED.pdf
Advertising	General - Digital 3_20183-1-FINAL-STAMPED.pdf
Advertising	General - Flyer 3 _20183_C-FINAL-STAMPED.pdf
Advertising	General Flyer 1_20183_A_Revised-STAMPED.pdf
Advertising	General Flyer 2_20183_B_Revised-STAMPED.pdf
Advertising	General - Card 1 _20183_C-FINAL.pdf
Advertising	General - Cards 2_20183_A-FINAL.pdf
Advertising	General - Cards 3_20183_B-FINAL.pdf
Advertising	General - Digital 1_20183_B-1-FINAL.jpg
Advertising	General - Digital 2_20183_C-FINAL.jpg
Advertising	General - Digital 3_20183_A-1-FINAL.jpg
Advertising	General - Digital 3_20183-1-FINAL.jpg
Advertising	General - Flyer 3 _20183_C-FINAL.pdf
Advertising	General Flyer 1_20183_A_Revised.pdf
Advertising	General Flyer 2_20183_B_Revised.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.

Screening and Admission: Subjects will answer questionnaires related to their drug use and health during screening. They will also undergo medical examination that includes a physical exam, electrocardiogram (ECG), and blood and urine chemistries. The number of screening visits may vary depending on the subjects' availability and staff scheduling. This study will enroll only non-physically-dependent, recreational sedative/opioid users who have prior non-medical experience with both opioids and sedatives in the past year; supervised urine samples must corroborate self-reports. Female participants will be tested at screening, on entry, at weekly intervals, and prior to each session for pregnancy. During screening, each subject will complete a cold pressor test (CPT), which will be performed during the main study (see description below). This is done during screening to ensure participants understand the procedure feels to determine if they want to proceed with the study AND in order to ensure that subjects exhibit an algesic (i.e. painful) response to this pain procedure. Subjects that are unable to tolerate the CPT or who report no pain during the CPT will be excluded from the study.

General Methods: After admission to the inpatient unit, a trained research staff person will familiarize the participant with the various computer tasks to ensure that they are comfortable with the tasks prior to study initiation. All experimental session procedures will be conducted with methods that have been previously used to study the effects of psychoactive drugs. Some physiological measures (e.g., heart rate, resting blood pressure, and oxygen saturation) will be collected using a Macintosh computer system that is interfaced with physiological monitoring equipment (DINAMAP) and will be monitored continuously throughout the sessions. Other physiological measures (e.g., respiratory rate) will be collected at regular intervals. These measures serve as both safety data and as study outcomes. An array of subjective and observer-rated measures, including but not limited to visual analog scales and Likert adjective checklists, are presented on a computer screen and a computer mouse is used to respond to questions. Smoking is allowed at any time with an escort, though only under supervised conditions, with the exception of 30 minutes prior to the start of the session and until the session is completed. A trained research staff will be present throughout the entire session.

Experimental Procedures: Prior to starting the experiment, subjects will participate in an initial active control test session during which the subjects will receive 30 mg oxycodone (oral). This session will serve as a "qualifying day" or responsiveness challenge which is intended to confirm that subjects are able to detect the active drug and report "liking" for the test agent (i.e., confirmation that the subject will provide a sensitive signal). If subjects fail to report any drug liking and identify the drug as placebo, they will not proceed further with dosing.

Experimental Sessions: During each session, subjects will receive two oral doses. All dosing will be double dummy – subjects will always receive two capsule preparations and each capsule will be a distinct color (ex: blue capsule for oxycodone; white capsule for gabapentin). None, one or both of the capsules will contain an active drug dose. A total of ten [including the active control test session described above] 7.5 hr sessions will be conducted including 30 min of baseline data collection. Dose conditions will include: 1) placebo, 2) oxycodone 20 mg, 3) oxycodone 40 mg, 4) gabapentin 600 mg, 5) gabapentin 1200 mg, 6) oxycodone 20 mg + gabapentin 600 mg, 7) oxycodone 20 mg + gabapentin 1200 mg, 8) oxycodone 40 mg + gabapentin 600 mg and 9) oxycodone 40 mg + gabapentin 1200 mg. Sessions will be at least 48 hrs apart to ensure adequate wash-out. Dosing will be staggered in order to align the peak response to both drugs. In this instance, the reported Tmax for gabapentin is estimated at ~2.5 hr and for oxycodone ~1.5 hr; therefore, gabapentin will be administered 1 hr before oxycodone.

Discharge & Follow-up Visit: Subjects will typically be discharged from the CCTS the day after they complete their final session. They may be discharged early for safety reasons (see below) or if they fail to comply with the protocol or the inpatient rules (e.g. verbal abuse of staff). They will be asked before they leave if they are interested in treatment for their substance abuse and offered referrals for treatment if they indicate interest. A follow-up visit will be scheduled within two weeks of discharge. The volunteers will be asked about their health status and drug use, any adverse events occurring since discharge; an observed urine sample will also be collected.

Attachments

Data Collection & Research Materials

In this section, please provide the following:

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

- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

During the screening phase of the study, data collected will include demographics, medical history, NEO, drug use history, results of laboratory tests (blood and urine chemistries and ECG), and results of urine drug screens.

Outcome measures collected during the inpatient phase of the study include physiological measures (e.g., pupil diameter, expired CO2, blood pressure, heart rate, respiration rate), subject-rated questionnaires (e.g., Visual Analog Scales for drug effects, Pharmacological Class Questionnaire, Street Value Questionnaire, Next-Day Questionnaire), responses to the Cold Pressor Test, and observer ratings.

Attachments

Resources

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

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

The study will take place at our laboratory and at the University of Kentucky CCTS Inpatient Unit. Screening procedures will largely be performed at our laboratory while enrolled patients will perform experimental procedures and reside at the CCTS. Experimental rooms at the CCTS are equipped with the necessary physiologic and computer equipment necessary for the study. There will be 24-hr nursing supervision of volunteers while in the hospital. Dr. Michelle Lofwall will be the primary medically responsible investigator and is an adult psychiatrist with ACLS certification who has worked extensively with individuals with substance use disorders both in clinical and research settings. The Psychiatry Attending Service will monitor subjects daily while they are inpatients. Dr. Walsh will provide oversight for the study. Overall, the study team and the resources described above are well equipped to protect the participants and successfully implement, carry out, and complete this study protocol.

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 for the subjects in this study are associated with drug administration. Typical side effects of oxycodone include nausea, vomiting, headache, dry mouth, itchiness, drowsiness, sweating, dizziness, stimulation, somnolence, lightheadedness, restlessness, euphoria, talkativeness, urinary retention, and constipation. More serious side effects may include allergic reaction and respiratory depression, but these are rare and unlikely to occur in a sample of volunteers who have experience using opioids. Common side effects of gabapentin include: dizziness, weakness, fatigue, ataxia, and somnolence. More serious side effects may include allergic reaction and increased risk of seizures (reported only at doses exceeding those proposed here). We have carefully chosen doses to minimize serious drug effects. The combination of these two drugs may have additive or synergistic effects, but doses have been carefully selected and safety outcomes are carefully monitored (see below).

During the screening process, it is possible that subjects may feel uncomfortable answering personal questions about their health, psychiatric, and drug use histories. Also during screening, participants will have blood drawn via venipuncture, which may cause soreness, bruising, pain, infection, possible fainting, and/or bleeding. Using sterile procedures and well-trained staff minimizes these risks. There is the risk that someone other than the research staff may see a subject's Protected Health Information.
There are no direct benefits to volunteers. There are potential indirect benefits to society including the knowledge regarding safety, abuse liability, and pharmacodynamics of oxycodone and gabapentin (two often co-prescribed and co-abused medications) alone and in combination. Volunteers will indirectly benefit from receiving a free medical evaluation and free meals. If subjects decide they would

like substance abuse treatment during the course of the study, we will assist them in finding treatment programs and getting them on the appropriate waiting lists. The amount of risk to which individual study volunteers are exposed to is low. Overall, the risk/benefit ratio appears favorable, and the conduct of this research seems well justified.

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).

This is not a treatment study. If volunteers express interest in treatment, they will be given referrals and not allowed to participate in this study.

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Records, Privacy, and Confidentiality

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

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

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

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

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

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

Sources of research material obtained from our volunteers during screening and study participation include: blood and urine specimens, expired breath samples for alcohol, ECG data, self reported information on physical and mental health, family history, drug and alcohol use history, demographic information, volunteer and study staff observation of drug effects, vital signs (e.g. temperature, blood pressure, heart rate), and other physiological measures. All this information is required to determine eligibility for the study, to ensure safety during the experimental sessions and for outcome measures. All research material will be obtained and discarded when necessary in a HIPAA-complaint manner. All materials will be collected specifically for the proposed study by trained staff. The principal investigator and medical team will have access to private health information about volunteers so that study eligibility can be determined. All data with personal health information is kept in a locked file cabinet that is separate from a locked file cabinet with de-identified volunteer data. Prior medical records may be obtained with volunteer consent if there is any question about the volunteers' health history. Each participant will sign a form that details the HIPAA-compliant manner in which research material is collected.

If in the course of the research study, the investigators discover something that could affect the health of a subject, the medical monitor will determine if it is in the best interest of the subject to disclose the finding. If the information is to be disclosed, a trained member of the research team or the medical monitor will inform the subject of the finding and advise them to follow up with a primary care doctor or other appropriate entity.

Identifying information will be stored in a separate locked file cabinet from all other data and codes that could link an individuals' Subject ID to their identity. Incidental materials containing subject identifiers will be shredded or incinerated. Electronic data will be stored on password-protected computers in password-protected files. Access to identifying information will only be available to key research personnel. In addition, a Certificate of Confidentiality will be obtained. Biological samples will be destroyed no later than after study completion but typically soon after discharge. Paper records will be locked and stored for a minimum of 7 years and destroyed through shredding or a professional destruction company.

Subjects will be carefully screened (history and physical examination, routine labs including CBC and LFTs, urinalysis, ECG, and psychiatric assessments) to exclude those with a risk of adverse events. Those at increased risk may have histories that include a personal or family history of seizure or head injury associated with more than a brief loss of consciousness, hypertension, psychosis, etc. During sessions, subjects remain under careful observation. Vital signs will be collected multiple times daily throughout the dosing period. Dr. Walsh has substantial experience in testing psychoactive substances in human subjects. Female subjects will be given pregnancy tests weekly and before each session to ensure that we do not administer any potentially harmful agents to a pregnant woman. To protect confidentiality, all research subjects are identified by a subject identification code (Subject ID) consisting of their

initials and sequentially assigned subject numbers on all forms and data files, and not by their names. Actual subject names and corresponding subject IDs are kept in a locked master file separate from the actual data collected during the study. All personal and experimental information is kept locked and is accessible only to key personnel involved in the research. Risks of allergic reaction or serious respiratory depression are mitigated due to the volunteers' history of opioid use. However, should an allergic reaction occur, diphenhydramine will be available for oral administration. During test sessions when opioids are administered, if respiratory rate drops below 10 breaths/min accompanied by sedation, volunteers are verbally prompted to breathe. In our experience, physical (e.g., gentle shaking) and verbal stimulation is often sufficient to prompt breathing and restore a normal respiratory rate. During test sessions, nurses are instructed to check and record oxygen saturation and respiratory rate before each drug administration as follows: If respiratory rate falls below 10 breaths/min or oxygen saturation is less than 95%, REPEAT and count breaths for 60 seconds. If either oxygen saturation or respiratory rate remains outside parameters, HOLD the study medication and call the study physicians. If the patient is unresponsive, call code team. Naloxone and supplemental oxygen may be administered based on physician evaluation. If oxygen saturation falls below 90, any subsequent dosing is terminated and participants remain under continuous monitoring until resolved. The study takes place within a fully functional hospital with emergency code response available. We do not anticipate needing to employ these interventions but they are available in the event of an emergency.

Because we are exploring possible synergistic or additive effects of oxycodone and gabapentin, this study includes a quasi-randomized, double-blind, placebo-controlled pilot phase to ensure that all dose conditions are safely tolerated before moving to a fully randomized dose order. Up to six volunteers will participate in the pilot phase, and a full safety assessment will be made in order to determine if dose adjustment is necessary for the full study.

All participants who are discharged early will have a follow-up appointment within two weeks. The entire study could be halted for a few reasons: any serious adverse event related to the study drug(s) resulting in death would halt the study and any serious adverse event related to the study drug that results in hospitalization would result in halting the study and spur a review with the FDA and IRB before proceeding.

UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Do you confirm that you will retain all IRB-related records for a minimum of 6 years after study closure?

◉ Yes ○ No

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.

Participants will be paid for each screening visit at the rate of $50/visit. If only a urinalysis is required, subjects will be paid $15.

For the main inpatient study phase, participants will receive a base pay of $60/night regardless of whether or not they complete the study. They will receive a bonus of $60/night if they complete the entire study, but not in the case of early departure or dismissal. If the volunteer completes the study, depending on their length of stay, they may receive a maximum of approximately $3,600 (for 30 study nights). The study team and others have successfully employed this compensation structure before.

There will be one follow up visit after discharge from the inpatient unit, and they will be paid $25 for this visit.

Costs to Subjects

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

There will be no cost to volunteers for participation in the current study. Cost of research-related harm will be the subjects' responsibility.

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.

Medical Safety Monitoring: Volunteers undergo a rigorous screening process to determine their eligibility and safety of their participation. In addition, our well-trained and vigilant research and medical staff, and the carefully considered medication dosing and safety criteria all serve as precautionary measures to ensure the safety of volunteers. The principal investigator, Sharon L. Walsh, Ph.D., will be the primary person responsible for monitoring the safety of this project, executing the DSMP and complying with all

reporting requirements. Our medical staff, including Dr. Lofwall and CCTS nursing staff, will conduct careful medical monitoring. We have an experienced anesthesiologist, Kevin Hatton, M.D. consulting on this project as an additional safety precaution. Volunteers will have daily contact with a physician and CCTS nurses while they reside as inpatients. The safety monitoring of each volunteer is discussed on an ongoing basis among medical and scientific staff, including our study statistician, Paul Nuzzo. This process has been successful in protecting volunteers and the integrity of the scientific outcomes. Any minor adverse events will be discussed among all study staff, documented in the subjects' medical charts through progress notes and medical logs along with any intervention required (e.g. headache requiring Tylenol). Any severe adverse events, whether study related or not, will be reported to the UK IRB and the FDA within 24 hours or as required.

Data Monitoring: Data are collected using a computerized data collection and management system, which eliminates data entry errors. Data files for experimental tasks and physiological measures from each experimental session will be manipulated and combined into a single electronic spreadsheet for each volunteer that can then be used for analysis. Any data manipulation is conducted twice and compared with the original manipulation to ensure accuracy. Research assistants will minimize missing data and adjust potential data collection errors based upon paper questionnaires. All data requiring hand entry (e.g., urinalysis results, pupil diameter) will be double entered by two separate staff members and comparison macros conducted to ensure accuracy. The data are stored on password-protected computers in password-protected files. Data files do not contain PHI. A computer file linking the unique number with the subjects' name will be kept on a stand-alone, password-protected computer available only to the study investigators. All paper copies of the collected data will be stored in locked file cabinets separate from any identifying information. To ensure data integrity and validity, all questionnaires will be explained to volunteers and time for questions and clarifications will be given. Trained research assistants will be present when participants are answering questionnaires to ensure that volunteers are staying on task, paying attention, and to be able to answer any questions from the volunteers should they have questions about the tasks.

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

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

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

Information and samples collected for this study will NOT be used or shared for future research studies, even if identifiable information is removed.

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

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

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

Cultural and Language Consultants:

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

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

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

Local Requirements:

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

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

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

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

HIV/AIDS Research

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

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

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

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

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

PI-Sponsored FDA-Regulated Research

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

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

This study will be covered under IND # 69,214 (Sponsor: Sharon Walsh, Ph.D.). Dr. Walsh, the Principal Investigator, has been conducting FDA-regulated research for 20+ years. She has held several INDs throughout this period and currently holds three active INDs. She has also served as Principal Investigator for numerous privately sponsored studies in which the IND was held and sponsored by a private company. Through this extensive experience, she is familiar with the submission of INDs, amendments, reporting requirements for adverse events, annual progress reporting requirements and recordkeeping requirements. She is also familiar with Good Clinical Practice guidelines, has participated in numerous related training over the years, and has trained and managed a multi-disciplinary staff on regulatory affairs, confidentiality issues, reporting requirements, data management, data quality assurance, data storage, and human subjects' protections.

IRB policy requires mandatory training for all 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.)

If yes, check below all that apply and attach the applicable document(s):

☐ HIPAA De-identification Certification Form
☐ HIPAA Waiver of Authorization

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

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

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

◉ Yes ○ No

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

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Oxycodone, Gabapentin

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:

69,214

IND Submitted/Held by:

Sponsor: ☐	Held By:		
Investigator: ☑	Held By:	Sharon L. Walsh, Ph.D.	
Other: ☐	Held By:		

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

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

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

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

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

Attach Type	File Name
Study Drug Form	Study Drug Form (26 Aug 2019).pdf
Study Drug Form	FDA IND Approval (19 May 2004).pdf

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

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

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

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

○ Yes ◉ No

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

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

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

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

○ Yes ○ No

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

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

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

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

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

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

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

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

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

Attachments

RESEARCH SITES

0 unresolved comment(s)

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

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

UK Sites

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

UK Robert Straus Research Facility

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

Attachments

Attach Type	File Name
-Individual Investigator Agreement	Grant Proposal.pdf

B) Is this a multi-site study for which **you are the lead investigator or UK is the lead site**? ○ Yes ◉ No

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

C) 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)

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

	For additional requirements and information:
☐ Academic Degree/Required Research	
☑ Alcohol/Drug/Substance Abuse Research	• 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 "Specimen/Tissue Collection...") • Collection of Biological Specimens (look up "Specimen/Tissue Collection...") • Community-Based Participatory Research (look up "Community-Engaged...") • Data & Safety Monitoring Board (DSMB) *For Medical IRB: Service Request Form for CCTS DSMB • Data & Safety Monitoring Plan • Deception* *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process" • Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF) • Genetic Research (look up "Specimen/Tissue Collection...") • Gene Transfer • HIV/AIDS Research (look up "Reportable Diseases/Conditions") • Screening for Reportable Diseases [E2.0000] (PDF) • International Research (look up "International & Non-English Speaking") • NIH Genomic Data Sharing (GDS) Policy (PDF) • Planned Emergency Research Involving Waiver of 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
☑ CCTS-Center for Clinical & Translational Science	
☑ Certificate of Confidentiality	
☑ Clinical Research	
☐ Clinical Trial - Phase 1	
☑ Clinical Trial	
☐ Collection of Biological Specimens for internal banking and use (not sharing)	
☐ Community-Based Participatory Research	
☐ Deception	
☐ Educational/Student Records (e.g., GPA, test scores)	
☐ Emergency Use (Single Patient)	
☐ Gene Transfer	
☐ Genetic Research	
☐ GWAS (Genome-Wide Association Study) or NIH Genomic Data Sharing (GDS)	
☐ 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	

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

Other:

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]
- 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

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.):

National Institute on Drug Abuse

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 and attach form
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

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

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

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

Approval Letter Details:

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

Additional Materials:

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

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

Protocol/Other Attachments

Attach Type	File Name
Other	20183 Adverse Events Log - 06.12.2023.pdf
Other	46591 Progress Report 2023 - 06.12.2023.pdf
Protocol	Example Screening Measures.pdf
Protocol	Example Session Questionnaires.pdf

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

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

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

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

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

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

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

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
Carl	Leukefeld	Department Authorization	Behavioral Science	09/07/2018 06:59 AM	View/Sign
Sharon	Walsh	Principal Investigator	Behavioral Science	09/06/2018 01:34 PM	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). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to 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.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.081	jlkear0	2/8/2024 10:10:48 AM
	Stamped Consent Form	46591 Screening Consent - Prescription Med Interactions v10.0 Jun 13 2023 (f).pdf		0.279	jlkear0	2/8/2024 10:10:48 AM
	Stamped Consent Form	46591 Main Study Consent - Prescription Med Interactions v9.0 Jun 13 2023 (f).pdf		0.411	jlkear0	2/8/2024 10:10:48 AM
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	AddInfoProduct	20183 Adverse Events Log - 06.12.2023.pdf	Adverse Events Log dated 12JUN2023	0.628	mmdo225	6/26/2023 2:50:35 PM
	Informed ConsentHIPAA Combined Form	46591 Main Study Consent - Prescription Med Interactions v9.0 Jun 13 2023 (f).pdf	46591 Main Study Consent - Prescription Med Interactions v9.0 Jun 13 2023	0.351	mmdo225	6/13/2023 9:40:30 AM
	Informed ConsentHIPAA Combined Form	46591 Screening Consent - Prescription Med Interactions v10.0 Jun 13 2023 (f).pdf	46591 Screening Consent - Prescription Med Interactions v10.0 June 13 2023	0.229	mmdo225	6/13/2023 9:38:36 AM
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AdditionInfoConsiderations	Oxycodone HCl package insert (mallinckrodt).pdf	Package Insert Oxycodone	0.121	mco256	8/28/2018 8:56:07 AM

Protocol Changes

Protocol Number: 46591

No Changes
There are no recorded changes tracked for this protocol.

Study Personnel Changes:

Status	PPIdentity	ProtocolID	PersonID	RoleInProtocol	IsContact	LastName	FirstName	Email	DeptCode	RoomBuilding	SpeedSort	PhoneNum	DeptDesc	AuthorizedConsent	ResponsibilityInProject	Degree	Rank	StatusFlag	IsRemoved	ModBy	ModDate	SFI	IsPIRN	MiddleName
Updated	816932	94290	00007063	SP	N	Chamblin	Lisa	lmcham2@uky.edu						N	Project Assistance/Support			P	N	mmdo225	2/8/2024 9:13:31 AM	N		

No comments