

CONTINUATION REVIEW/FINAL REVIEW

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

If you have any questions, please contact the Office of Research Integrity at 859-257-9428.



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

1. Status of the Research

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

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

*Possibility that review will move from Full to Expedited.

2. If subjects have been enrolled within the last year, and the IRB approved a consent/assent form for your study, attach one copy of the entire signed consent/assent form/HIPAA form for the last TWO subjects enrolled.

3. Informed Consent

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

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

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

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

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

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

Yes No

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

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

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

5. Subject Info To-Date

Our records for the previously approved IRB application indicate the **IRB approved estimate** of subjects to be enrolled (or records/specimens reviewed) is:

0

Enter the number of enrolled subjects (or records/specimens reviewed) that **have not been previously reported** to the IRB

0

Our records for the previously approved IRB application indicate the previous total # of subjects enrolled (or records/specimens reviewed) since activation of the study is:

0

The new total number of subjects enrolled (or records/specimens reviewed) since activation of the study: [?](#)

0

Please review the Project Info section for the IRB approved estimate of subjects to be enrolled (or records/specimens reviewed). If this new total exceeds your approved estimate of subjects to be enrolled (or records/specimens reviewed), please update the number in the field for Number of Human Subjects in the Project Info section.

6. Data and Safety Monitoring Board (DSMB)

Our records for the previously approved IRB application indicate:

This **study is monitored** by a Data and Safety Monitoring Board (DSMB): **N**

There is a Data and Safety Monitoring Plan: **N**

If yes, to any of the above, attach all documentation (i.e. summary report; meeting minutes) representing Data and Safety Monitoring activities that have not been previously reported to the IRB.

7. Since the most recent IRB Initial/Continuation Review Approval:

Have there been any **participant complaints** regarding the research?

Yes No

If yes, in the field below, provide a summary describing the complaints.

Have any **subjects withdrawn** from the research?

Yes No

If yes, in the field below, provide a detailed explanation.

Has any **new and relevant literature** been published since the last IRB review, especially literature relating to risks associated with the research?

Yes No

If yes, attach a copy of the literature as well as a brief summary of the literature including, if pertinent, the impact of the findings on the protection of human subjects.

Have there been any **interim findings**?

Yes No

If yes, attach a copy of **Interim Findings**.

Have **subjects experienced any benefits**?

Yes No

If yes, in the field below, provide a description of benefits subjects have experienced.

Have there been any **inspections/audits/quality improvement reviews** of your research protocol resulting in the need for corrective action in order to protect the safety and welfare of subjects?

Yes No

If yes, please attach documentation evidencing the outcome(s) and any corrective action(s) taken as a result.

Was an FDA 483 issued as a result of any inspections/audits?

Yes No

If yes, submit documentation using attachment button above.

8. Risk Level:

Our records for the previously approved IRB application show your research is:

Risk Level:

Has something during the course of your research changed the level of risk?

Yes No

If yes, go to the Risk Level section, mark the appropriate risk level, and in the field below, describe why the risk level has changed:

9. Funding/Support:

Our records for the **previously approved** IRB application indicate your research is being submitted to, supported by, or conducted in cooperation with the following external or internal agency(ies) or funding program(s):

- 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

Please **update the Funding/Support section of your IRB application** if needed, including the following attachments if they contain changes not previously reported to the IRB:

- A current copy of your **protocol if you are conducting industry/pharmaceutical research**;
- A current **Investigator Brochure** (submit a copy with all changes underlined).
- A **new or revised grant application** for this project.

Did your project receive extramural funding?

Yes No

If yes, please review and correct if necessary, the OSPA Account # information under the **Funding/Support section** of your IRB application.

If the project is externally funded, has the sponsor offered any of the research team enrollment incentives or other personal benefit bonuses? (e.g., cash/check, travel reimbursements, gift checks, etc.)

Yes No N/A

Note: It is University of Kentucky policy that personal benefit bonuses are not allowed. If these conditions change during the course of the study, please notify the IRB.

10. Project Information

Our records for the previously approved IRB application indicate your estimated project end date is:

07/31/2019

If you have a new estimated project end date, please go to the Project Info section and change the date in the field for Anticipated Ending Date of Research Project.

11. Study Personnel

Our records for the previously approved IRB application indicate the following individuals are study personnel on this project (if applicable):

Last Name	First Name
No records to display.	

Please review the individuals listed above and update your records as needed in the Study Personnel section of the E-IRB application, being sure that each individual listed has completed or is up-to-date on the mandatory human research protection training [see the policy on [Mandatory Human Subject Protection Training FAQs](#) (required every three years)].

12. Progress of the Research

To meet federal requirements the IRB is relying on your RESEARCH DESCRIPTION as a protocol summary and their expectation is that it is up-to-date. If the currently approved protocol (or research description) in your E-IRB application is outdated, please make applicable changes, and describe in the field below any substantive changes and explain why they are essential. If none, insert "N/A" in the text field below. If you are closing your study, you may use the space below to summarize the final status of the research.

Note: No changes in the research procedures should have occurred without previous IRB review. Approval from the IRB must

be obtained before implementing any changes.

Provide a brief **summary** of any **modifications approved** by the IRB since the last review (If none, insert "N/A" in the text field below.):

If you are conducting the study under your own IND/IDE (Investigator Sponsored), attach one copy of the most recent progress report sent to the FDA.

Attachments

13. Confidentiality/Security

Review your Research Description section and update the Confidentiality portion, if necessary, to describe measures for security of electronic and physical research records (e.g., informed consent document(s), HIPAA Authorization forms, sensitive or private data).

14. Subject Demographics

Our records for the previously approved IRB application indicate the following categories of subjects and controls are included in your research:

- 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
- International Citizens
- Normal Volunteers
- Military Personnel and/or DoD Civilian Employees
- Patients
- Appalachian Population

Please review the Subject Demographics section of your IRB application for accuracy, and note the following:

If during the course of your research 1) any prisoners have been enrolled, OR 2) subjects have been enrolled that became involuntarily confined/detained in a penal institution that have not been previously reported to the IRB, go to Subject Demographic section in your E-IRB application and mark "prisoners" in the categories of subjects to be included in the study, if it is not already marked.

Note: If either 1 or 2 above apply, and you have received funding from the Department of Health and Human Services (HHS), a Certification Letter should have been submitted to the Office for Human Research Protections (OHRP); prisoners and individuals who have become involuntarily confined/detained in a penal institution cannot continue participation in the research until OHRP issues approval. If the Certification has not been submitted, contact the Office of Research Integrity.

Based on the **total # of subjects** who have enrolled, complete the subject demographic section below:

Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:	<input type="text"/>	<input type="text"/>
Asian:	<input type="text"/>	<input type="text"/>
Black African American:	<input type="text"/>	<input type="text"/>
Hispanic/Latino:	<input type="text"/>	<input type="text"/>

Native Hawaiian/Pacific Islander:	<input type="text"/>	<input type="text"/>
White/Caucasian:	<input type="text"/>	<input type="text"/>
Other or Unknown:	<input type="text"/>	<input type="text"/>

If unknown, please explain why:

15. Research Sites

Our records for the previously approved IRB application indicate that you are conducting research at the following sites:

UK Sites

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

Schools/Education Institutions Schools/Education Institutions

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

Other Medical Facilities

- Bluegrass Regional Mental Health Retardation Board
- Cardinal Hill Hospital
- Eastern State Hospital
- Nursing Homes
- Shriner's Children's Hospital
- Other Hospitals and Med. Centers

- Correctional Facilities
- Home Health Agencies
- International Sites

Other:

If the above listed sites are not accurate, go to the Research Sites section of the E-IRB application to update the facilities at which research procedures have been or will be conducted.


If you are adding a new off-site facility, you may also need to update your E-IRB application Research Description, Research Sites, Informed Consent, and other affected sections as well as any documents which will list the off-site facility. Documents needing updating may include, but not limited to:

- Consent forms (attachment under Informed Consent section)
- Brochures (attachment under Additional Info section)
- Advertisements (attachment under Research Description section) ;
- Letter of support (attachment under Research Sites section)).

Please revise applicable sections and attachments as necessary.

16. Disclosure of Significant Financial Interest

Disclosure of Significant Financial Interest:

Our records for the previously approved IRB application indicate that you, your investigators, and/or key personnel (KP) have a [significant financial interest \(SFI\)](#) related to your/their responsibilities at the University of Kentucky (that requires disclosure per the [UK administrative regulation 7:2](#)): 

Yes No

If you need to update your records, please go to the PI Contact Information section and/or Details for individuals listed in the Study Personnel section to change your response to the applicable question(s).

17. Supplementals

To ensure the IRB has the most accurate information for your protocol you are expected to re-visit the E-IRB application sections and make corrections or updates as needed. At a minimum you are being asked to review the following sections for accuracy:

STUDY DRUG INFORMATION—Please review for accuracy.

STUDY DEVICE INFORMATION—Please review for accuracy.

RESEARCH ATTRIBUTES—Please review for accuracy.

OTHER REVIEW COMMITTEES -- Please review for accuracy.

If applicable, submit one copy of the entire **signed HIPAA Authorization form** for the same last TWO subjects enrolled.

[Attachments](#)