IRB Reliance Request/Registration Form

The purpose of this form is to facilitate the decision making process in choosing the relied-upon IRB for cooperative research. The Office of Research Integrity (ORI) supports multi-site collaborations and will try to eliminate, where possible, multiple IRB reviews. The request will be considered by ORI and decisions will be made on a case-by-case basis.

You may be asked to submit a copy of the full protocol or other information to ORI to aid in the decision making process. The reliance arrangement must be approved by the ORI staff, and may involve consultation with UK Legal Counsel, the UK IRB Chair, and the UK Vice President for Research. IRB Reliance arrangements may also requires the completion of a detail agreement that clearly outlines the responsibilities of each site.

General inquiries/questions about IRB reliance and the University of Kentucky's policies and procedures may be submitted to: IRBReliance@uky.edu.

PLEASE NOTE: If the project meets criteria for an exempt application, there is a possibility that one or both institutions will require local IRB review.

I. UK PI/protocol information

1. University of Kentucky Principal Investigator:	
2. Title of Protocol:	
3. Sponsor (funding):	
Is UK the primary awardee?	Yes ☐ No ☐
4. Does this protocol include activities that fall under the purview of the FDA?	Yes ☐ No ☐
5. Briefly describe the study. Additionally, explain the roles and responsibilities of the UK researchers (ex. informing reviewing IRB of changes in research, consenting subjects, study team training and qualifications, using site-specific language in consents, etc.):	

II. Non-UK Site Information

1. Non-UK Site Principal Investigator:	

2. Institution Name:

Is the non-UK Institution accredited by AAHRPP? Yes ☐ No ☐

3. FWA #:

Has the site's FWA been extended to non-federally funded research?

Please note that the University of Kentucky has not extended its assurance to non-federally funded research and may choose not to report to OHRP serious or continuing non-compliance, terminations and suspensions of research that is not federally funded. Yes ☐ No ☐

4. Briefly describe the study. Additionally, explain the roles and responsibilities of the Reviewing Site's researchers (ex. providing IRB-approved documents, consenting subjects, reportable events determinations, continuing review, closure reports, etc.):

III. IRB Information

1. **Is there a preferred reviewing external IRB? If yes, please list name of the IRB.**	

2. Provide any other information you think is pertinent to the decision making process:

SITE PERSONNEL

List research personnel from UK:

Include the names of individuals from UK who will participate in human subjects research activities for this protocol. Also describe their role and indicate the date they completed human subjects protection training. You may attach additional sheets, as necessary.

Name:
Role:
Date training completed:

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Reliance Agreement
Signature Assurances

Study Title: _____

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 of the Reviewing/Relying IRB's and the UK IRB/Human Research Protection Program's (HRPP) policies, decisions, conditions, and requirements.
2. To accept responsibility for the scientific and ethical conduct of the research study.
3. To obtain prior approval from the Reviewing IRB before amending or altering the research protocol or implementing changes in the approved consent/assent form.
4. To report to the Reviewing/Relying IRB and the UK IRB, in accord with IRB and Institutional policies, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects. Each institution may have unique policies and procedures for reporting.
5. To complete, on request from the Reviewing IRB, the Continuation/Final Review Forms.
6. To notify the UK Office of Sponsored Projects Administration (OSPA) and the UK IRB of the development of any financial conflict of interest not already disclosed.
7. To verify that each individual listed as study personnel at UK for this application has completed the mandatory human research protections education (e.g. CITI).
8. To verify that each individual listed as study personnel at UK for this application possesses the necessary experience and qualifications for conducting the research activities in the role described for this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

SIGNATURE _____ DATE _____

Printed Name _____