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 require the completion of a detail agreement that clearly outlines the responsibilities of each site.

For any general inquiries/questions about IRB reliance and the University of Kentucky's policies and procedures please see the FAQs section on the ORI Reliance website. Any further inquiries or questions 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. Initial Reliance Determination Questions				
Is the protocol non-exempt (i.e., the protocol does not meet any exemption criteria as defined by 45 CFR 46.104)?	**Yes**	☑	**No**	☐
Will the protocol receive Federal Funding (i.e., NIH, HHS, etc.)?	**Yes**	☑	**No**	☐
Are Study Personnel from the proposed Relying Institution intervening, interacting, consenting, and/or viewing identifiable participant information?	**Yes**	☑	**No**	☐
Does the Reviewing IRB require single IRB (if so, please attach the letter from the institution stating this)?	**Yes**	☑	**No**	☐
Will the protocol receive funding from the:				
FDA?	**Yes**	☑	**No**	☐
DoD?	**Yes**	☑	**No**	☐

II. UK PI/Protocol Information	
University of Kentucky Principal Investigator:	
Title of Protocol:	
Sponsor (funding):	
Is UK the primary awardee? **Yes** ☑ **No** ☐	
What is the Risk Assessment Level?	(Level 1) Not greater than minimal risk.
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.):	

III. Non-UK Site Information	
Non-UK Site Principal Investigator:	
Institution Name:	

Is the non-UK Institution accredited by AAHRPP?

Yes ☑ **No** ☐

If no, please answer the following questions:
Has the institution's HRPP/IRB been cited in the last three years by FDA or OHRP?

N/A ☑ **Yes** ☐ **No** ☐

Can the institution's HRPP/IRB leadership attest that it has completed its own internal quality review process (i.e., use of AAHRPP's Evaluation Instrument for Accreditation to conduct a self-assessment, completion of the US FDA's self-evaluation checklist for IRBs or ECs, or an equivalent process)?

N/A ☑ **Yes** ☐ **No** ☐

4. Please submit to irbreliance@uky.edu this institution's HRPP/IRB policies and/or procedures regarding the following*:

- **a. Initial Review**
- **b. Continuing Review**
- **c. Adverse Event/Unanticipated Problem/Protocol Violation Review**
- **d. Reporting of serious/continuing noncompliance, unanticipated problems involving risks to subjects or others, suspension or termination of research**

***Please note, upon review, additional policies/procedures may be requested by UK's HRPP staff.**

Federalwide Assurance (FWA) Number: *If the institution does not have an FWA, please type N/A in the space provided.	
List the research sites that will be relying on the Reviewing IRB.	
Briefly describe the study. Additionally, explain the roles and responsibilities of the Site's Reviewing researchers (ex. providing IRB-approved documents, consenting subjects, reportable events determinations, continuing review, closure reports, etc.):	

IV. IRB Information	
Is there a preferred reviewing external IRB? If yes, please list name of the IRB.	
Provide any other information you think is pertinent to the decision-making process:	

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:

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. Please see the PI Responsibilities, Sections VII & VIII for a detailed list which includes, but is not limited to the following:

- To accept responsibility for the scientific and ethical conduct of the research study.
- To obtain prior approval from the Reviewing IRB before amending or altering the research protocol or implementing changes in the approved consent/assent form.
- 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.
- To complete, on request from the Reviewing IRB, the Continuation/Final Review Forms.
- 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.
- 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).
- 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 _____

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Based on the information provided above, the University of Kentucky Office of Research Integrity Reliance Team has determined that a Single IRB is:

Needed ☑ Not Needed ☐

Reliance Team Member Signature _____ DATE _____

Printed Name _____