Review Details | Consultant Signature | Attachment(s) | Finish

Note: You are evaluating this protocol specific to your area of expertise; you are not the Primary Reviewer. Please note: you are being asked to voluntarily donate your services; you will not be compensated for your time, however your services are appreciated.

You are being asked to:

- assess the appropriateness of the research for the special population or culture, or local laws;
- assess the appropriateness of the proposed method of obtaining informed consent;
- analyze, in the context of special population or cultural acceptance, the potential benefits of the research in relation to the risk to participants
- identify other cultural or special population issues relating to the nature of the research that may be of concern (e.g., appropriate space for procedures, appropriate facilities for managing adverse events);
- verify that the translation of the consent form is accurate.
- Furthermore, if research is to be conducted at an international location, and you are aware of any local regulations, laws, or ethics review requirements for human subject protection that might apply to this research, please describe in the text box under the "Finish" tab, along with any other comments pertinent to your assessment based on this list.

Please review the Conflict of Interest Statement and Confidentiality Agreement below; by checking the box below you are affirming your agreement with it. A PDF copy of that agreement can be downloaded here.

For confidentiality purposes, we ask that after your review, you shred/destroy any protocol materials you have in paper, or return them to the Office of Research Integrity (ORI).

Consultant Conflict of Interest Statement and Confidentiality Agreement

CONFLICT OF INTEREST STATEMENT

U.S. Department of Health and Human Service (HHS) regulations [45 CFR 46.107(e)] stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. The University of Kentucky has the same requirement for IRB consultants.

To maintain the University of Kentucky IRB's independence from researchers and sponsors and to avoid a conflict of interest, IRB consultants either do NOT have or will disclose a conflicting interest. A conflict of interest involves any situation where an IRB consultant has any significant personal or financial interest.

Examples of a conflicting interest would be if the IRB consultant also is:

- Principal Investigator (PI);
- Co-Principal Investigator;
- Investigator receiving funding from the study, as listed in the study budget;
- In a supervisory role over the PI of the study; or
- Family member of PI

A conflict of interest is also whenever an IRB consultant has a significant financial interest in the research proposal. A financial interest is defined as anything of monetary value, including, but not limited to:

- salary or other payments for services (e.g., consulting fees or honoraria);
- equity interests (e.g., stocks, stock options or other ownership interests, excluding any interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the IRB member or his/her immediate family does not exercise control);
- intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does NOT include:

- Salary, royalties, or other remuneration from the University;
- Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- Income from service on advisory committees or review panels for public or non-profit entities; or
- An equity interest that when aggregated for the IRB consultant and the IRB consultant's spouse and dependent children, meets both of the following tests: Does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or,
- Salary, royalties or other payments that when aggregated for the IRB consultant and the IRB consultant's and dependent children over the next 12 months, are not expected to exceed $5,000.

Consultant recognizes that the protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. Therefore, consultant must consider conflict of interest issues in his/her deliberation of applications, and when appropriate, will recommend that researchers include suitable disclosure statements and relevant information related to conflicting interests in informed consent documents. Consultant is obligated to notify the IRB of any potential conflicts of interest consultant may have prior to any review on a protocol by protocol basis.

CONFIDENTIALITY AGREEMENT

Consultant may attend and/or review the University of Kentucky (UK) Institutional Review Board (IRB) protocol(s) to assist in the review of applicable protocols and will be exposed to certain confidential and possibly proprietary information during the review (hereinafter the "Confidential Information"); and UK is willing to allow the consultant to participate in the review so long as he/she agrees to maintain the Confidential Information in confidence.

In consideration of the mutual agreement set forth, the consultant is obligated by the following:

1. CONSULTANT shall receive **all** Confidential Information received or discussed in the review as confidential information. This obligation of confidentiality extends to all information in whatever form, in whatever form disclosed, including without limitation, oral and written disclosures, identities of participants, researchers, sponsors, and any information of any other type or nature revealed at the meetings.

2. CONSULTANT shall maintain the Information secret and confidential and, with the sole exception of discussions with the IRB and/or ORI staff as a part of the assessment process, shall not discuss it with or disclose it to third parties for any reason without prior written permission from UK.
3. The restrictions and obligations upon CONSULTANT under this Agreement concerning confidentiality shall expire five (5) years from the date on which the Information is first received by CONSULTANT and shall not apply to any portion of the Information which:
    a. is known to CONSULTANT prior to receipt thereof under this Agreement, as evidenced by competent proof;
    b. is disclosed to CONSULTANT in good faith by a third party who is in lawful possession of the Information and who has the right to make such a disclosure; or
    c. is or shall have become part of the public domain, by publication or otherwise through no fault of CONSULTANT;
    d. is independently developed by or for CONSULTANT by persons who did not have access to the information; or
    e. CONSULTANT is required by law to disclose, provided that CONSULTANT gives UK reasonable notice of its intent to disclose, such information.

☐ I agree to the University of Kentucky's Conflict of Interest and Confidentiality requirements.

Save

Review Details | Consultant Signature | Attachment(s) | Finish

--> Refer to this **Criteria for IRB Approval Checklist** as needed.
--> Refer to this **Elements of Informed Consent Checklist** as needed.
--> Refer to this **Reviewer Determinations Guidance** document for info about what each determination means.

Select Your Determination

- ○ Approve
- ○ Minor Revision
- ○ Full Review Required
- ○ Not Human Research
- ○ Withdrawn
- ○ Disapproved
- ☐ Serious/Continuing Non-compliance or Suspension/Termination.

Comments / Requested Revisions

☐ I am not aware of any *conflict of interest* that would prohibit me from reviewing and/or making a determination about the IRB application materials.

Save | Complete Review