Please mark the applicable box(es) under each section:

Section I. (refer to Criteria for IRB Approval checklist on the back of this page, if necessary)

- A. The criteria for IRB approval are met.
- B. The criteria for IRB approval are not met (criterion/criteria specified in the comments section).

Section II.

Any previously approved research categories requiring documented determinations:

- A. are not affected by this modification request;
- B. are affected by this modification request (requested revisions specified in the comments section apply).

Examples:
- eligibility for expedited review (Form A-1);
- waiver of informed consent (Form E);
- waiver of documentation of informed consent (Form F);
- FDA regulated medical device (Form P);
- FDA regulated drug or biologic (Form O);
- decisionally impaired/challenged (Form T);
- pregnant women (Form U);
- fetuses &/or neonates (Form U);
- prisoners (Form V);
- children (Form W);

Section III. Significant new findings (e.g., from scientific literature; a procedural change; PI disclosure of financial interest; privacy/confidentiality issues, etc...) that might relate to a subject’s willingness to continue participation need to be relayed to the subject.

- No
- Yes If yes (check one):
  - A. PI’s proposal for communicating the information to subjects is appropriate.
  - B. PI’s proposal for communicating the information to subjects is not appropriate – describe revisions needed in “Comments/Requested Revisions” below (e.g., revise consent document & re-consent subjects; send letter to subjects).

Section IV. IRB Determination:

- (1) Approved (I.A and II.A above apply [if II.B applies, specific findings have been met and appropriately documented]; if III.B. is true, approval cannot be issued until resolved)

- (2) Approval Pending Minor Revisions – non-substantive materials requested. Subsequent expedited review of PI response (see “Comments/Requested Revisions” below).

- (3) Approval Deferred – substantive clarifications or modifications regarding the protocol or informed consent document(s) required. Subsequent review at convened meeting. PI not required to attend.

- (4) Approval Deferred – substantive clarification or modification regarding the protocol or informed consent document(s) required. Subsequent review at convened meeting. PI attendance required.

- (5) Disapproved – Determination made at a convened meeting.
Comments/Requested Revisions
Please specify which forms are needed, if any, to appropriately document required determinations (e.g., Form E for waiver of informed consent). Attach additional pages, if necessary:

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

______________________________
Reviewer Printed Name

______________________________
IRB Reviewer Signature Date
CRITERIA FOR IRB APPROVAL
University of Kentucky Institutional Review Board

1. • Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (achieved from research interventions).
   • Risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk.
   • When possible, risks to subjects are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes.
   • The research proposal addresses the likelihood of harm and magnitude of harm (encompassing potential physical, psychological, social, and/or economic risks to the subjects).
   • The research is likely to achieve its proposed aims.
   • The importance of the knowledge expected to result is clear.

2. • Subject selection is equitable (in relation to:)
   - Objectives of the research;
   - The setting in which the research is to take place;
   - The special problems of research involving special populations;
   - Recruitment methods
   - Inclusion/exclusion criteria

* If N/A for any of #3 below, “Form E” (a request for waiver/alteration of the informed consent process) must be completed by the PI and the criteria met.

3. • Adequate provisions are in place for seeking informed consent from each prospective subject (“subject), or the prospective subject’s legally authorized representative (“subject’s LAR”).
   • The proposed consent process provides the subject/subject’s LAR with sufficient opportunity to consider whether to participate.
   • The proposed consent process minimizes the possibility of coercion or undue influence.
   • The information to be relayed during the consent process is in a language understandable to the subject/subject’s LAR.
   • The information being communicated during the consent process does not include exculpatory language through which the subject/subject’s LAR waives or appears to waive any of the subject’s legal rights.
   • The information being communicated during the consent process does not include exculpatory language through which the subject/subject’s LAR releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

** If N/A for #4 below, “Form F” (a request for waiver/alteration of documentation of informed consent) must be completed by the PI and the criteria met.

4. • The provisions for documenting informed consent/assent are appropriate.

5. • The research proposal describes adequate provisions for protecting the privacy of subjects.

6. • The research proposal describes adequate provisions for maintaining confidentiality of the data.

7. • The credentials and/or described qualifications of the research staff/investigators are representative of the appropriate expertise needed to perform their responsibilities in the study.

8. • The research setting (e.g., location of research, facilities, drug/device controls & accounting) supports adequate safeguards for protection of human subjects.

9. • Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence (e.g., children, prisoners, adults with impaired consent capacity).

10. • For greater than minimal risk research or NIH funded/FDA regulated clinical investigations, adequate provisions are in place for monitoring the data collected to ensure safety of subjects. Where applicable, the following may be considered in evaluating whether the data and safety monitoring is adequate:

11. • If the proposal is a multicenter study in which the lead PI or UK is the coordinating institution, the plans for communication among sites are adequate to protect the participant (e.g., consider communication of protocol modifications, data and safety monitoring reports, and unanticipated problems).

12. • Proposed payment to participants and/or cost to subjects for participation is appropriate.

13. • If PI/research staff conflict of interest is identified, the conflict of interest in relation to human research protections is appropriately minimized or managed (e.g., limit who obtains informed consent; add disclosure(s) in informed consent)

14. • Review and approval by other committees/units, as applicable for medical research (e.g., RDRC, IBC, RSC, MCC PRC), has been conducted.

15. • Approval from external institutions has been obtained from an authorized official.

16. • A signature assurance sheet signed by the Principal Investigator and his/her Department Chairperson (or appropriate equivalent) is on file.