Kentucky State University
Office of Research and Innovation
400 E Main St, Frankfort KY, 40601
ORI@KYSU.EDU (502) 597-5997

Modification Request Form

Kentucky State University • **Institutional Review Board (IRB)**

PI Name: _____ **IRB #:** _____

Instructions

Use this form to request IRB approval of the following:

- Proposed changes to your current IRB-approved protocol.
- A proposed change which impacts an individual subject but does not change the overall protocol (i.e., exception and deviation).

Do NOT use this form:

- To report a change to the currently approved protocol which has already been implemented without prior IRB approval.
- In emergency situations involving unanticipated problems involving risk to human subjects or others (contact ORI staff immediately at 502-597-6530).
- To close a study or to report that a study has been completed (contact ORI).

Please be sure to…

- Revise consent and assent forms, as needed, based on the proposed changes.
- Complete and attach appropriate forms.
- If you are adding new study personnel, confirm that all new members have completed the mandatory human-subject-protections CITI training BEFORE you submit your modification request.
- Have the PI sign on the line provided at the top of the form (next page).
- Attach two copies – one marked and one clean – of all documents affected by the modification (i.e., consent form). On the track-changes copy, underline or highlight each change being made.
- Allow ample time for processing this modification request. NOTE: changes may not be implemented prior to receiving IRB approval.

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PI Signature

Date

Modification Details

1. **Address change for protocol correspondence?** ○ Yes ○ No
   If yes, indicate new address:

2. **Study Title:**
   Title change? ○ Yes ○ No
   If yes, indicate new title:

3. **Is this a one-time request for a deviation from the currently approved protocol, or an exception to the currently approved enrollment criteria?**
   ○ Yes ○ No

4. **Consent / Assent Form change?** ○ Yes ○ No
   If yes, be sure changes are reflected in all revised consent/assent documents and any applicable HIPAA documents.

5. **Check one:**
   ○ This modification does NOT increase risk to study participants.
   ○ This modification may or will increase risk to study participants.

6. **Is this modification request due to an Unanticipated Problem or Adverse Event?**
   ○ Yes ○ No

7. **In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?**
   ○ Yes ○ No
   If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

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8. Changes Made To — check all that apply and attach appropriate documents

Form A: General Information Sheet

- ☐ Anticipated Project End Date
- ☐ Estimated # of Subjects
- ☐ Subject Population
- ☐ Vulnerable Subject Population
  - ☐ Impaired Consent Capacity
  - ☐ Children age 17 or less
  - ☐ Pregnant Women
  - ☐ Prisoners
  - ☐ Other vulnerable population
- ☐ Funding / Support
- ☐ Study Personnel
- ☐ Other – Describe: _____

Form B: Research Description & Appendices

- ☐ Objectives
- ☐ Inclusion / Exclusion Criteria
- ☐ Subject Recruitment
- ☐ Procedures / Materials
- ☐ Research Procedures
- ☐ Grant Application
- ☐ Sponsor Protocol; Investigator Brochure
- ☐ Waiver of Informed Consent
- ☐ Waiver of Documentation of Informed Consent

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Describe Each Modification

REQUIRED: For each proposed modification, describe the currently approved procedures, forms, etc., then summarize the proposed change, addition, etc. Include a justification for the modification request. Add additional sheets if necessary.

Example

Currently Approved: study staff as listed on attached SP List Template.
Proposed Revision: add Jane Doe, MD, as co-investigator. Dr. Doe has completed human-subject-protections training, is a new faculty member who will work with subjects on this protocol, and is authorized to obtain consent.

1 Currently Approved

Proposed Revision

2 Currently Approved

Proposed Revision

3 Currently Approved

Proposed Revision