Modification Request Form Instructions
University of Kentucky Institutional Review Board (IRB)

Use the attached 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 (Use the Protocol Violation Form)
- In emergency situations involving unanticipated problems involving risk to human subjects or others (Contact ORI staff immediately at 859-257-9428)
- 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 (e.g., Form V if prisoners are to be included as a new subject population).
- Use the *SP List template* from the IRB application General Information Sheet to request changes to study personnel (SP). Include currently approved SP and clearly mark changes.

  Please confirm new SP have completed the mandatory human subject protections training and all existing SP are up-to-date on training BEFORE you submit your modification request to ORI. See the Human Subject Protection (HSP) Training web page for frequently asked questions on training requirements.
- Update or submit, if necessary, an online financial disclosure form (per UK Administrative Regulation 7:2). Contact OSPA with questions or for help.
- Complete and attach a revised General Information Sheet (*Form A-Medical*; *Form A-Nonmedical*), Signature Assurance Sheet (Form Z) and other forms, as appropriate, if the PI is changing (please also consider whether HIPAA documents need revision).
- Include a summary of changes if the sponsor protocol or investigator brochure is modified.
- Secure UK Public Relations prior review for any print or media advertisements to the public.
- Have the PI sign on the line provided at the top of the attached form.
- Attach **two** copies – one marked and one clean – of all documents affected by the modification (i.e., consent form). On the marked copy, underline or highlight each change being made.
- Allow ample time for processing of this modification request. NOTE: changes may not be implemented prior to receiving IRB approval.
- Submit to: **IRBSubmission@uky.edu**

For questions, contact:
Office of Research Integrity (ORI),
Room 315 Kinkead Hall, 0057,
859-257-9428,
https://www.research.uky.edu/office-research-integrity

Modification Request Form

PI Name:		IRB Protocol #:	
Title of Study:			

PI Signature: _____ Date: _____

1. Address Change for Protocol Correspondence? ◯ Yes ◯ No

If yes, indicate new address: _____

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 your revised consent/assent documents **and any applicable HIPAA documents**.

5. Select 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.):

_____

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 (*Form T*)
  - ☐ Children age 17 or less (*Form W*)
  - ☐ Pregnant Women (*Form U*)
  - ☐ Prisoners (*Form V*)
  - ☐ Other vulnerable population
- ☐ Funding/Support (*some federal agencies have specific requirements – see guidance*)
- ☐ Study Personnel (*SP List Template*)
- ☐ Medical Device (*Form P*)
- ☐ Study Drug (*Form O*)

Other - Describe:

_____

_____

Form B: Research Description & Appendices
- ☐ Objectives
- ☐ Inclusion/Exclusion Criteria
- ☐ Subject Recruitment
- ☐ Procedures/Materials
- ☐ Research Procedures
- ☐ Grant Application
- ☐ Sponsor Protocol; Investigator Brochure

Forms C-F
- ☐ Consent Form (Form C-*Medical*; *Nonmedical*) or combined Informed Consent/HIPAA Form
- ☐ Assent Form (Form D-*Medical*; *Nonmedical*)
- ☐ Waiver of Informed Consent (*Form E*)
- ☐ Waiver of Documentation of Informed Consent (*Form F)*

Forms I-K
- ☐ HIPAA De-Identification Certification (*Form I*)
- ☐ HIPAA Waiver of Authorization (*Form K*)

Modification Request Form

PI Name:		**IRB Protocol #:**	
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REQUIRED: For each proposed modification, describe the currently approved procedures, forms, etc. and 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, Dr. Doe is a new faculty member who will be working with subjects on this protocol and she is authorized to obtain consent.

1. Currently Approved:

Proposed Revision:

2. Currently Approved:

Proposed Revision:

3. Currently Approved:

Proposed Revision:

4. Currently Approved:

Proposed Revision: