

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 [Mandatory Human Subjects Protections 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,
www.research.uky.edu/ori

Modification Request Form

PI Name:		IRB Protocol #:	
Title of Study:			

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: