When to Submit an “Amendment”

After a study has been approved by the IRB, an Investigator should submit an “Amendment” Application when planning to implement any changes.

Any change in a protocol, regardless of how benign the change might seem, must be approved by the IRB BEFORE the Investigator implements it.

Common examples requiring an Amendment Application:
- Changing the research protocol in any way
- Changing or adding an instrument to the protocol
- Changing or adding recruitment methods or recruitment materials
- Changing or adding informed consent documents
- Adding or removing a Co-Investigator
- Adding a research site
- Increasing sample size
- Adding planned research activities not included in the approved proposal

An Investigator should NOT wait until it is time to submit a Continuing Review Application to submit an Amendment; an Amendment can be submitted at any time.

If the initial application was determined to meet the criteria for exemption from the regulations, contact your Program Coordinator or ORS to verify if an Amendment Application is required.

Steps to Submit an Amendment:

- Visit the “forms” page on the ORS website: http://www.utexas.edu/research/rsc/humansubjects/forms.html
- Access the link, “Amendment Form Application”: https://utdirect.utexas.edu/vr/IRBAmendment.WBX
- Enter your EID and password
- Input the study number or access the link, “list your studies,” to select the study
- Specify the type of Amendment
- Upload any accompanying revised documents and/or forms

The next IRB Full Board meeting is November 14, 2011
The deadline to submit paper copies is October 28, 2011.

QI Visits

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) expects the ORS to conduct Quality Improvement (QI) Visits to assess educational needs of the research community.

You may be contacted to discuss an open protocol. The visit lasts approximately one hour in order to provide any necessary education and to answer any questions Investigators may have about the IRB process.

A Friendly Reminder on Training

The IRB requires all Investigators and research personnel involved in human subjects research to complete the Collaborative Institutional Training Initiative (CITI) program. Access the instructions through the ORS website: http://www.utexas.edu/research/rsc/humansubjects/training/index.html

Remember to select either “Social/Behavioral Research Course” (Group 1) OR “Biomedical Research” (Group 4) as the curriculum.

Educational Workshops

Multi-discipline educational sessions and workshops are available to assist you with IRB submissions. The first hour of each session is a presentation; the second hour is a workshop along with a Q&A session. For more information and registration, visit http://www.utexas.edu/research/rsc/news/

Upcoming Topics:
- IRB Special Topics: Conducting Research Online
- IRB Special Topics: Using University Students as Subjects

IRB Consent Templates have been updated!

Please use the current templates from the IRB website.