Attention Research Investigators

Office relocations are a part of life when working in a university setting. If you have relocated and have a new address that you wish to designate to receive IRB correspondence, please notify ORI.

You can either send a Modification Request Form for each protocol or send an itemized list of protocol numbers for which the change applies.

All Things Considered

Did you know that documents that accompany mail, electronic, or telephone surveys are considered part of the informed consent process? As such, documents like cover letters for survey research or telephone scripts require initial IRB approval as well as review and approval of any modifications. It is a challenge for researchers to keep track and ensure use of current, IRB approved versions of these documents. In an effort to help investigators keep track of currently valid versions, the ORI is now providing an approval stamp with the valid approval date on the cover letter or telephone script—just like a consent form.

Unlike the consent form, you are free to remove the stamp prior to posting or mailing the cover letter to potential participants. It is there simply to aid investigators and prevent initiating the consent process with an unapproved or invalid document.

In addition, documenting a location pathway at the end of a document is a “best practice” tip to help investigators keep track of the numerous documents required for each protocol (e.g., D:/Research/Cover Letters/IRB#85-0321-F1V cover-letter version 1.doc).

Continuation Review—3 Cues to Use

Federal and institutional regulations require the IRB to conduct “substantive” continuing review of previously approved research projects at intervals appropriate to the degree of risk, but not less than once per year. ORI will send Continuation Review (CR) request reminders to the Principal Investigator (PI) before the IRB approval period expires (e.g., approximately 12 weeks, 8 weeks, and 4 weeks prior).

Another reason to notify ORI if the PI’s address should change.

The PI must submit a CR report for studies as long as the research remains open to new subjects; is active for long-term follow-up; and/or requires analysis of data with identifiers. For many research protocols, the CR review must be conducted via Full Review Mechanism. Getting assigned to an agenda could take a couple of weeks, so plan accordingly. If the review results in requests for more information or required revisions, the process can come precariously close to the IRB approval end date. Last minute CR submissions can result in lapse of approval.

In order to allow both the IRB and Investigator time for any resulting dialogue and deliberation, respond to the 1st CR reminder notice. If you cannot get the CR materials to ORI by the deadline date provided on the form, contact either Karen Larson (257-3038 or Karen.Larson@uky.edu) or Gail Cadwallader (257-6071 or gcc@uky.edu) for medical reviews or Pam Stafford (257-1639 or pastaf3@email.uky.edu) for the non-medical IRB.

Visit the ORI CR process page for additional guidance and tips.

To remove your name from our mailing list, please click here.
Questions or comments? E-mail us at sbelin0@uky.edu.
Office of Research Integrity (ORI)

For a full listing of updates, see ORI’s What’s New webpage.