New & Improved Modification Form

Based on recommendations and suggestions from the research community, the Office of Research Integrity has revised the IRB Modifications Request Form. The revised instructions clarify when to use the form and direct the investigator to applicable attachments. The form itself provides a more comprehensive menu of modifications and hyperlinks to required or related documents.

Consent Conundrums

Emergency Contact Numbers

During September/October 2007, at the request of the Institutional Review Board (IRB) the Office of Research Integrity (ORI) conducted an internal assessment for quality improvement purposes for greater than minimal risk research which involved calling the phone number(s) listed in the consent document under the “What Happens if you get Hurt or Sick During the Study?” section. The purpose was to determine the response time, whether an actual person answered or a machine, whether the caller was routed around, and whether the individual(s) answering were aware of the protocol and were able to competently respond to questions related to injury/problems.

The IRB learned from this Quality Improvement (QI) initiative that overall, more attention is needed regarding the emergency contact information provided in the informed consent document. It is therefore recommended that investigators evaluate their procedures for handling calls from subjects who believe they may be hurt or sick as a result of participation in the study. Also, for greater than minimal risk research, the IRB recommends the consent document(s) include one (or a combination) of the following as a contact for subjects to use in case of illness or injury during his/her study participation:

1. a dedicated pager number;
2. a dedicated cell phone number;
3. other reliable 24-hour contact option at your discretion, and/or
4. as deemed necessary, in addition to one or more of the above, referral to 911 for an emergency.

Investigators may modify existing consent documents in response to the above recommendation via a Modification Request Form [http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#MR_form] to the IRB along with the corresponding revised materials [Research Description (“Form B”) or other documents as applicable].

Evaluating the accuracy of contact information in the consent document serves to help protect human subjects in research, and helps UK maintain a quality human research protections program.

Investigator Signature on informed consent forms

As outlined in the Principal Investigator’s (PI) Guide to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research, investigators are responsible for ensuring that appropriate signatures on the consent document(s) are obtained.

In this regard:

Only an investigator should sign on the line provided for “Investigator.” The investigators signature on the informed consent document verifies that the person who explained the study and obtained informed consent is qualified and that the IRB has approved him/her to do so (may not be applicable nonmedical protocols in which IRB may approve use of an alternate signature procedure).

Only individuals approved by the IRB to obtain informed consent should participate in the consent process and/or sign on the line provided for “Name of [authorized] person obtaining informed consent.”