Office of Human Research Ethics Training Tips

June 2016 IRB Member Training--Re-consenting of Research Participants

21 CFR 50.25 b. (5):

A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

When it is anticipated that significant new findings that would be pertinent to the subject's continued participation are likely to occur during the subject's participation in the study, the IRB should determine that a system, or a reasonable plan, exists to make such notification to subjects.

Examples of "new findings" include:

- changes to the research plan (procedures have been added, modified or removed
- identification of new risks or an increase in the magnitude of known or suspected risks
- new findings that change the risk/benefit profile
- a decrease in expected benefit
- results of related research
- new alternative treatments become available
- new conflict of interest declaration by a newly named Principal Investigator

Consent Form Addendum v. Revised Consent Form

- The UNC IRB *requires* the use of an Consent Form Addendum
- New information is the focus of the Consent Form addendum
- Some sponsors may require that the full consent document be revised and re-signed by enrolled participants. Although this may be easier for the investigator, it may be less informative for the participants. If this method is utilized, the new information should be highlighted in some fashion.

Consent Form Addendum

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Addendum to provide additional information to subject after original consent

Consent Form Version Date: _____
IRB Study # [IRBNO WILL BE INSERTED]
Title of Study: [TITLE]
Principal Investigator: [PINAME]
Principal Investigator Department: [PIDEPT]
Principal Investigator Phone number: [PINUMBER]
Principal Investigator Email Address:
[PIEMAIL][COINVESTIGATORS][FACULTY_ADVISOR][FUNDING_SOURCE][STUDY_CONTAC

The following information should be read as an addition to the original Consent form that you read and signed at the beginning of the study. Unless specifically stated otherwise in the following paragraphs, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate, or may withdraw your consent to participate at an time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study doctor.

New or additional information

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to continue to participate in this research study.

IRB Regulatory Findings

When reviewing a modification/amendment, it is the responsibility of the reviewing IRB member to identify:

1. When the consent form should be revised to include changes or new information (to be signed by future subjects.)
2. When a consent form addendum should be created (to be signed by current subjects.)
3. When a letter or information sheet should be created (to be provided to subjects who participated but have withdrawn or completed the study.)

The IRB has determined that this modification includes changes to the protocol or new information that may affect the subjects' willingness to participate, rights, welfare or safety.
--All future subjects must be consented using the revised consent form AND/OR,
--Current subjects must be re-consented using a consent form addendum AND/OR,
--All previously enrolled subjects must be provided with study information sheet.

The consent process (Application Section D.1)

An **effective informed consent process** involves these elements:

- Conducting the process in a manner and location that ensures participant privacy,
- Giving adequate information about the study in language understandable to the participant,
- Providing sufficient time for the participant to consider all options, "Sufficient time" can range from minutes to days, depending on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and alternative treatments.
- Responding to the participant's questions,
- Ensuring that the participant has comprehended the information provided,
- Obtaining the participant's voluntary agreement to participate and,
- **Continuing to provide information as the participant or research requires.**

In addition to reading and signing the informed consent document:

- subject recruitment materials
- verbal instructions
- question/answer sessions and measures of subject understanding

The IRB, clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, **the consent document should be the basis for a meaningful exchange between the investigator and the subject.**

DHHS Regulations and Guidance

• General Requirements for Informed Consent; Elements of Informed Consent; Waiver or Alteration of Consent: 45 CFR 46.116
• Documentation of Informed Consent; Waiver of Documentation of Informed Consent (Oral Consent): 45 CFR 46.117
• OHRP Informed Consent FAQs

FDA Regulations and Guidance

• General Requirements for Informed Consent: 21 CFR 50.20
• Elements of Informed Consent: 21 CFR 50.25
• Documentation of Informed Consent: 21 CFR 50.27
• Waiver of Documentation of Informed Consent (Oral Consent): 21 CFR 56.109(c)
• FDA Guide to Informed Consent Information Sheet (revised January 2016)