Chapter 8

Informed Consent, Interview Feasibility, and Contact Information

BACKGROUND AND RATIONALE

Completing the 'informed consent' process is the first and most important requirement for conducting a research project. All staff should be trained and certified according to regulations mandated by their local Institutional Review Board (IRB) for conducting research with human subjects, including procedures for administering informed consent.

Before any assessments or interviews can be conducted on a human being as a subject in research, the investigator or his/her staff must first obtain the legally effective informed consent of the subject or the subject's legally authorized representative. This procedural requirement is known as "obtaining informed consent" and is met after the potential participant carefully reviews all study related information summarized on a consent form and then signs her name on the document to indicate she has read and understands the details outlined in the consent form, and agrees to participate. Such consent shall be sought only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

This study plans to obtain consent through a written consent document that embodies the elements of informed consent required by each field center's local IRB. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator/study staff shall give either the subject or the representative adequate opportunity to read it before it is signed. Please address any concerns the participant may have in clear, concise language without coercion. If the subject agrees to participate after any questions have been address, s/he or his/her legally authorized representative must sign the consent form on the line provided along with the witness. A copy of the consent form shall be given to the subject or the representative while the original consent form must remain in the participant's charts as a source document

In addition to the participant informed consent, field centers should investigate the regulations within their institution for consents to contact proxies when participants are unable to complete the information, and for telephone consent to obtain study information when an in-person visit cannot be completed.

INFORMED CONSENT

Under the page header, mark the appropriate box to indicate whether the consent form was administered in person or by phone.

Once informed consent is obtained, check the appropriate box under Q1 to indicate that informed consent was obtained by the participant. If the participant is unable to provide informed consent, s/he is not eligible to participate. Simply check the box for "No" under Q1 and end interview.

For **Q2a**, document the date the participant signed the consent form. Please be sure to use the convention for dates (i.e. June 5, 2006 is 05/JUN/2005).

Q2b requests the Version Number and Date of the consent form that the participant signed. Complete **one** of these fields by **either** jotting down the Version Number or Version Date listed on the consent form. Use the date convention mentioned above.

For **Q2c** and **Q2d**, place an X in the box to indicate whether the participant provided permission to share data/samples, allow samples to be stored, etc. Please note: The number/type of questions in this section may vary by site depending on the required checkboxes inserted onto each FC's consent form as required by the local IRB.

For **Q3**, record the date the participant signed the HIPAA Authorization Form. This is not applicable for the Pittsburgh Field Center.

INTERVIEW FEASIBILITY

From the informed consent process alone, please use your judgment based on that interaction to complete **Q4a-d**. Then, follow the instructions on this panel by using your best judgment to determine whether any visual, auditory or cognitive impairments will make it impossible for the individual to participate in this study. Please check the appropriate box provided if this person is too impaired to participate and then jot down the specifics of the impairment on the line provided.

Respond to **Q6** by placing an X in the correct box to indicate whether the participant is confined to a bed. For purposes of this study, "confined to a bed" includes someone who rises from the bed when going to the toilet and taking a bath.

PARTICIPANT CONTACT INFORMATION

The Participant Contact Information Sheet provides an opportunity to collect complete and accurate contact information, thus helping to minimize missing data and losses to follow-up. An attempt will be made to collect full contact information on the participant, one other person who knows the participant well, and the participant's health care provider. Please use the appropriate fields on this Sheet to document the contact information first for the participant and then for his/her informant. As directed, indicate whether the informant is also enrolled in this study and select the appropriate category to indicate the relationship between the participant and the informant.

Q7a-7c provides several fields to document whether or not the participant has a primary care physician (PCP), the location they have chosen to obtain healthcare and the primary care physician's contact information. After checking the appropriate box for **Q7a** to indicate whether the participant has a PCP, then check **only one** box for **Q7b** to document where the participant goes to obtain actual health care or advice regarding his/her health. Then use the lines provided in **Q7c** to collect contact information details on the participant's PCP if one exists. Please try to collect as much information as possible and carefully document all details on the lines provided so that the participant's PCP can be easily contacted if necessary (i.e. medical alerts arising during data collection).

Study Documents Referred to in this Chapter

- Informed Consent
- Consent Tracking and Interview Feasibility Form
- Participant Contact Information