

Improving the Informed Consent and Authorization Process

AHRQ recommends the following process for all study personnel who will be obtaining written informed consent and authorization. The objective is to teach potential subjects about research protocols and confirm their comprehension.

Create a Research Culture To Promote the Process

Many of the safeguards that have been put in place to protect subjects' rights can be easily subverted if research personnel are not motivated to perform their duties with integrity. Professionalism needs to be modeled. In addition, some of the activities needed to promote the consent process require preparation and training. If the activities described below are presented in a fashion that exhibits the ethical and regulatory importance of the consent process, investigators will be able to communicate these values to their staff.

Staff Training

- **Create a teaching version of your Informed Consent and Authorization documents.** These are educational materials. Researchers can create a companion teaching version with embedded prompts (e.g., "stop here and ask for questions") to serve as a teacher's guide. Give a copy of this teaching version to personnel in contact with subjects and potential subjects. Use the teaching version in a supervised simulation of the consent process and give feedback about what worked well and what did not work well.
- **Review the Informed Consent and Authorization Certification document** prior to beginning the discussion with a potential research subject. It serves as a reminder of the topics to discuss with the potential subject. When supervising a simulated or actual consent process, use the certification document as a checklist to keep track of what was or was not done.
- **Take steps to differentiate between clinical care and research.** Research personnel need to approach the informed consent and authorization process in a fashion that helps potential subjects understand that they can freely refuse to participate. Research personnel should avoid activities that falsely impart the impression of a therapeutic relationship, such as wearing a white coat. Investigators who are clinicians need to be especially careful to separate their clinical and research roles and, whenever possible, should not be directly involved with the consent and authorization process.

Physical Environment

- **Conduct the discussion in a private and quiet place.** The informed consent discussion should be held in a private setting, unless the potential research subject would like to include other people (e.g., family, friend). An exception may be made when providing information to a group of potential subjects at the same time, as is frequently the case when focus groups are conducted.

- **Be prepared to accommodate potential subjects with disabilities.** For example, people with visual impairment often can benefit from materials with large font, high contrast, adequate illumination, and reduced glare. People with hearing impairment benefit from interactions in private quiet environments and may need sign language interpreters. The physical route people take to interact with research staff should be accessible. Research staff should be taught about accommodating disabilities and should prepare in advance for these possibilities.

Communication To Promote Comprehension

- **Plan for potential subjects with limited English proficiency.** If the researcher anticipates that a portion of potential subjects will not be fluent in English, translated forms and bilingual staff are needed. In such circumstances, care should be taken that informed consent not only meets appropriate standards, but also ensures that all survey instruments will provide valid data for such subjects.
 - In some settings, if no study personnel are fluent in the appropriate language, a qualified interpreter can be used.
 - For any subject who does not understand English, the consent form to be signed by the subject must be translated into a language understandable to the subject. Under the Office for Human Research Protections' guidance titled "Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English," this can be a short-form written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative.
 - Translation does not ensure that the materials are readable by the potential subject. Care needs to be taken to ensure that translated materials are not overly complex.
 - Study personnel who are fluent in the appropriate language or an interpreter should be used for any potential research subjects who request one, even if they appear to speak and understand English well.
 - If you cannot communicate with potential subjects, they may not be enrolled.
- **Offer to read the document with all research subjects.** There is no need to make any reference to reading ability. For example, the researcher could say, "Let's read this document together," or "It's my job to explain things clearly. If you like, I can read the document along with you to make sure all the information is clear." Do not rely on the document to provide the subject with the necessary information. **It is the explanation of what the document says that is important. The purpose of the consent form is to document what information has been disclosed to the subject and that the subject's consent was obtained.**
- **Give the potential research subject time** to review the document. There should be no time pressure. When possible, potential research subjects can be encouraged to take the document

home and discuss their participation with family members, friends, and their primary care physician.

- **Verify and document that the potential research subject has understood** the document through use of the teach-back method. The teach-back method is an interactive educational approach that can be used to confirm comprehension and is described in detail below. Study personnel should practice the teach-back method in simulated sessions prior to approaching potential subjects. If interpreters will be used, simulated teach-back sessions with the interpreters should be conducted. Other methods to evaluate comprehension, such as a written test, may be beneficial, but may be difficult for patients with limited literacy. People need to be excluded if they fail to understand key elements of the protocol despite multiple attempts to teach the material.

Teach-Back: Part 1

Start with phrases such as:

- "I want to make sure we have the same understanding about this research. Can you tell me what this project is about in your own words?"
- "It's my job to explain things clearly. To make sure I did this I would like to hear your understanding of the research project."

Teach-Back: Part 2

Make sure that the potential research subject has understood all the important elements of the study. Allow the potential research subject to consult the document when answering the questions. **The purpose is to check comprehension, not memory.** Listen for simple parroting; probe further if a potential research subject uses technical terms. Ask open-ended questions such as the following:

- **Goal of the Research and Protocol**
 - "Tell me in your own words about the goal of this research and what will happen to you if you agree to be in this study."
- **Benefit and Compensation**
 - "What do you expect to gain by taking part in this research?"
- **Risks**
 - "What risks would you be taking if you joined this study?"
- **Voluntariness**
 - "Will anything happen to you if you refuse to be in this study?"

- **Discontinuing Participation**
 - "What should you do if you agree to be in the study but later change your mind?"
 - "What will happen to information already gathered if you change your mind?"
- **Privacy**
 - "Who will be able to see the information you give us?"
- **Contact Information**
 - "What should you do if you have any questions or concerns about this study?"

Teach-Back: Part 3

Correct any misinformation until potential research subjects indicate that they have understood by correctly answering all the questions. Make clear that the need to repeat is due to the complexity of the material rather than the "fault" of the potential research subject.

For example, you could say, "Let's talk about the purpose of the study again because I think I may have not explained it clearly."

- Potential research subjects **should not be enrolled** if they cannot comprehend the study protocol, despite repeated attempts to explain the details.
- Document completion of the teach-back process on the Researcher's Certification of Consent and Authorization.
- Ask the potential research subjects what questions they still have.
 - Avoid yes or no questions such as, "Do you have any questions?" and "Do you understand?"
 - Ask instead, "What questions do you still have?" and "What would you like to hear more about?"
- If the potential research subject signs the document (unless written consent and authorization have been waived), make a copy for him or her. Alternatively, have two copies and give one to the subject.
 - Emphasize that subjects should keep the document since it has important phone numbers in case they have any questions or concerns later.
- Complete and sign the Researcher's Certification of Consent and Authorization.