Except under certain conditions where the IRB can waive the requirements for informed consent or its documentation, informed consent must be documented by the use of a written consent form approved by the IRB and signed and dated by the participant or the legally authorized representative.

Informed consent is one of the primary ethical considerations underlying research with human subjects. UA investigators are expected to realize that informed consent is an ongoing educational process that takes place between the investigator and the prospective participant. The consent process should allow for an exchange of information between the investigator and the prospect and afford ample opportunity for the prospect to ask questions and consider whether or not to participate in the study. (See POLICY: Informed Consent Process and Documentation.) In most cases federal regulations require that informed consent be documented; however, signing of the consent document does not substitute for discussion.

The following instructions are provided to help you develop a satisfactory consent document for your study. See also the IRB Application Guide, policies on consent and vulnerable populations, the informed consent template, and the sample consent form.

The IRB requires that only consent and assent documents with a valid “IRB APPROVAL” stamp can be used when enrolling participants, unless waiver of this requirement is approved by the IRB.

Guidance on ASSENT is found elsewhere on the IRB website.

Instructions

1. Use the informed consent template and guidance documents on assent and telephone consent. The informed consent template is intended to cover both medical and non-medical studies, so not every element will be relevant to every study. It is only a guide, and investigator judgment about what to include or in what order to include them is always required. Deviations from recommended practice can always be requested from the IRB by presenting the rationale in the application.
2. Prepare your document so that it is written at an eighth grade reading level or less. Use white space, indentation, and bullets to enhance the readability of the document. Piloting the document on people from the intended population may be very helpful in assessing the comprehensibility of the document.

3. If you are using a short form of the consent document, justify the need for its use and its adequacy under the research circumstances and prepare a written information sheet for prospects as part of your application. Then, describe how you will present the study orally to prospects or their legally authorized representatives and ask them to sign and date the short form if they consent. Note that oral presentations of studies must be witnessed by a third party who signs and dates both the short form and a copy of the information sheet. If the prospect or LAR does not speak English, the witness must speak both English and the language of the participant. The person obtaining consent shall sign and date the short form to the prospect, parent, or LAR.

4. Please number the pages of the consent form. The IRB thanks you!

5. If you are recruiting non-English speaking persons, the consent document should be in their native language. If you do not speak that language, the services of a speaker of that language should be obtained for recruitment purposes and consultation. (Your application should include documentation that the translated documents are equivalent to the English version and contact information for your cultural/linguistic consultant (FORM: Translator’s Declaration). You may also be required to develop a plan for evaluating the level of prospects’ comprehension of English.)

6. Avoid exculpatory language through which the prospect or the representative is made to waive or appear to waive any of his legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence.

7. The consent form for research involving prisoners must always contain words to the effect that the prisoner’s participation or non-participation in the research will have no effect on the length of his sentence.

8. For research involving children (under 19 years of age under Alabama law), please read the federal regulation about research with children (45 CFR 46, Subpart D, especially 46.408), the UA IRB policy on research with children available online, and the guidance document on assent. Parental permission is always required for research with children. The UA IRB does not allow passive
consent, in which the failure of a parent/guardian to actively refuse is taken as evidence of permission to participate. The regulations also state that the permission of both parents is necessary for child participation but IRBs are allowed to approve the use of only one parent with appropriate justification. The informed consent template can be used as a guide for the parental permission form by rewriting it from the perspective of the parent (e.g., Your child is being asked to be in a research study; I give my permission for my child to participate).

9. For research directed at pregnant women, both mother and father must give consent after having been fully informed about the impact of the research on the fetus. (NOTE: The federal regulations do identify certain conditions under which the father's consent is not necessary.)

10. If the research could jeopardize (1) an unborn child, (2) a man’s or woman’s ability to procreate or (3) a woman’s ability to conceive or carry a child, the following statement or a study-specific adaptation should be included in the consent form:

   If you are pregnant, you cannot participate in this study. If you are a woman who could have children, you will have to have a urine or blood (which) test to see if you are pregnant before you start this study. If you are sexually active, you must agree to take precautions (certain methods may be specified) to avoid conceiving a child because it is not known how this drug/treatment/device will affect an unborn child. If you are a woman and become pregnant during this study, you must tell the principal investigator about this fact as soon as possible.

11. If the research involves people deemed incompetent or cognitively/decisionally/impaired or to have diminished capacity to consent, additional elements are needed in the consent process and on the consent form. These may include initial and ongoing medical or professional assessments of competence, details of referral procedures, terminating study participation if impairment increases, and working through a legally authorized representative. (See POLICY: Investigator Assessment of Participant Comprehension and GUIDANCE: Investigators and Legally Authorized Representatives.) VA hospitals also have additional requirements for their impaired patients that the investigator should be familiar with and meet.
12. If the research involves deception, complete a request for waiver of full disclosure of the study purpose. (Use FORM: Request for Waiver/Alteration of Informed Consent.)

13. If the researcher believes that any fluids, tissues, or other substances obtained from a research participant could lead to the development of a commercial product (such as development of a cell line for commercial use) please address what rights the research participant will have pertaining to monetary gain from the sale of such materials.

14. If the research is part of a National Institutes of Health (NIH)-sponsored multicenter clinical trial, copies of the NIH-approved sample informed consent document must also be included in the application packet.

15. As of March 7, 2012 the Food and Drug Administration requires the following language in all consent forms for drug or device clinical trials that are initiated on or after that date: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. Law. This website will not include information that can identify you. At most, the website will include a summary of results. You can search this website at any time.”

16. If the research involves investigational drugs, devices, or biologics, inform prospects in the purpose statement that the study includes evaluation of both the safety and the effectiveness of the test article. Clearly state in the consent form that the test article is investigational/experimental/not approved by the Food and Drug Administration and that the research may involve unknown risks.

17. Dose escalation in drug studies should be clearly described so that the prospect understands that the dose will get larger or the dose for each new subject will get larger.

18. The consent form for research involving HIV screening and/or AIDS research should state that an HIV screening test will be performed, describe how participants will be informed of the result of the screening test, and state that qualified counseling will be provided at the time the test result is given (the procedures for meeting this requirement must be described in the IRB application). As HIV/AIDS is often a stigmatizing condition, procedures for protecting physical privacy and the confidentiality of data must be described in both the application and the consent form. The consent should also state that
HIV positive test results including the prospect’s name must be reported to health authorities in accordance with Alabama state law. (See GUIDANCE: HIV/AIDS.)

19. No lists should be retained identifying those who choose not to participate.

20. For research involving DNA banking, genetics, illegal behavior, and similar sensitive or stigmatizing issues, consider whether you should request a federal Certificate of Confidentiality to exempt your study from subpoena of data by third parties such as insurance companies and employers.

21. If a Certificate of Confidentiality is obtained, prospects must be told about the protections afforded by the certificate and any exceptions to that protection in the consent form. The NIH Office of Extramural Research provides an example of appropriate language (scroll to Informed Consent section at the bottom of the web page). This language can be adapted to specific protocols but must cover the basic points.

22. A copy of the consent form signed by the participant and the investigator should be given to each participant or the legally authorized representative.

23. Additional separate consent forms are needed for use of photographs, videos, or other identifiable images for viewing by other than the research team; for permission to have data entered into a database; or to be contacted about future research studies.

24. If conflict of interest is actual or apparent, please follow UA and IRB policies on conflict of interest. It may be necessary to inform participants of the conflict and provide assurances that their welfare will not be affected.