Informed Consent Process

The Consent Process

The central requirement for any human subjects research is that individuals participate *voluntarily*. *Informed* consent means ensuring that the subjects genuinely understand the purpose, risks, and benefits of participating in the research study. Thus, information must be comprehensible, expressed in terms and language appropriate for the study population. The consent *form* formalizes this agreement and should be designed to document the process. But because subjects always retain the right to withdraw from a study, the informed consent *process* continues until the subject's participation is complete.

Written consent forms are required for all research with two exceptions:

1. With mailed, e-mailed, or web-based questionnaires, one may assume that consent is given if the subject returns the questionnaire. However, an introductory statement must be included at the beginning that describes the nature of the study (as on a standard consent form) and explains that by submitting the questionnaire, the participant consents to participate in the study.
2. When obtaining signed consent is not feasible, the researcher must first explain the nature of the study (as on a standard consent form), and then a subject may give oral consent, provided that a witness signs to verify the consent. If audio or video data is to be collected, the oral consent should be recorded. (Examples: interviews with indigenous people who do not have a written language, or interviews with people who state that they do not wish to sign their names to preserve anonymity.)

Federal Requirements for the Consent Form

In accordance with Federal regulations **[45 CFR 46.116(a)&(b)]**, every consent form must include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any experimental procedures;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, stored, and used for future research.

6. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. Names and contact information of individuals able to answer pertinent questions about the research and research subjects' rights, and contact information of those to notify in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or no decrease in benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additionally, regulations require the following information to be provided, when applicable:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to an embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
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;
6. The approximate number of subjects involved in the study.

We encourage you to use the University of Central Arkansas Sample Informed Consent forms, but you may submit an alternate form or edit the template, according to the needs of your study.

Sample Informed Consent Agreement Form

Sample Informed Consent Coverletter

Additional University of Central Arkansas requirements:

1. Researchers must inform subjects of any **conflict of interest** they have in the research.
2. If subjects will be compensated for study participation, the consent form must describe the **terms of payment** and the conditions under which subjects would receive partial or no payment (e.g., withdrawing from the study before their participation is completed).
3. The statement "This study is being conducted by researchers from the University of Central Arkansas" should appear on the front of the consent form, with the name of the campus or clinic included. The department should also be identified.

4. The form should not say that the study is "sponsored" or "endorsed" by the University. The group conducting the study can be identified in the text of the document, but not at the very top of a consent form, and the identification should not advertise the group.
5. **If the project is conducted by faculty or staff**, the first page of the consent form must include the University of Central Arkansas name and logo and the Principal Investigator's name.
6. **For student projects**, the words "University of Central Arkansas" must appear at the top of the first page, and advisers' names and phone numbers should be given with the student's name and university contact information.

Children and Adolescents

Researchers must obtain parental *permission* for studies involving children under the age of majority (18 years old in Arkansas). If the research involves greater than minimal risk, signatures from both parents are required unless: only one parent has legal responsibility for the care and custody of the child, or if one parent is deceased, unknown, or incompetent. On some occasions, the IRB can grant a "waiver of parental permission" (see **Waiver or Alteration of Consent** below), if the research involves minimal risk, if it will yield significant benefits to the population being studied or a public program, and/or if obtaining parental consent would pose a considerable risk to the potential subjects. Additionally, for some research, the requirement for parental permission may be inappropriate. For example, research involving older adolescents who, under applicable law, may consent on their own behalf for selected treatments (*e.g.*, treatment for venereal disease, drug abuse, or emotional disorders). In other research (*e.g.*, research on child abuse or neglect), the parents' interests may not adequately reflect the child's interests. In these cases, primary investigators must ensure alternative procedures for protecting the rights and interests of the children asked to participate, including, perhaps, the court appointment of special guardians.

Parental permission is documented similarly to an adult subject consent form, in which "your child" is substituted for "you." Once the researcher has obtained written parental permission, the agreement of the child is required. (In therapeutic settings, parental permission overrules a child's decision not to participate.)

A child's agreement is documented with an "assent form," a child-friendly document that outlines the essential information about the research. Most children 8 years old and above have the cognitive and emotional maturity to understand a research project and should be given the opportunity to assent to participation. Some children under the age of 8 may also be capable of granting and withholding assent, and the IRB asks researchers to be sensitive to the needs of these children on an individual basis.

Language Barriers

For research involving non-English speaking subjects, a protocol submission must include both English-language and translated consent forms. An explanation of the translations and the expertise of the translator should be provided for IRB review. (The IRB may consult with language experts or require a "back-translation" into English.)

As an alternative to translated consent forms, an oral presentation of informed consent information together with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally can be approved by the IRB. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. When this procedure is used with subjects who do not speak English:

1. the oral presentation and the short-form written document should be in a language understandable to the subject;
2. the IRB-approved English language informed consent document may serve as the summary; and
3. the witness should be fluent in both English and the language of the subject.

At the time of consent, the following signatures should be obtained:

1. the short form document should be signed by the subject (or the subject's legally authorized representative);
2. the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and
3. the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB must receive all foreign language versions of the short form document as a condition of approval (**46.117(b)(2)**). Expedited review of these versions is acceptable when: the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

Sometimes a subject understands English but does not read or write English. An impartial witness should document that the subject understands the study and the consent process and consented to participate.

Deception

In some cases, a researcher may wish to employ deception (*deliberately withholding* information from subject participants) for the purpose of securing subject participation and/or to prevent potentially biased reporting of data or information by the subject. Before approving protocols involving deception, the IRB must verify that the following conditions will be met:

1. Deception is necessary due to the lack of any other alternative procedure for data collection.
2. Deceptive procedures will not place subjects at greater financial, physical, psychological, or social risk.
3. The data collection/experiment will be followed by careful debriefing sessions in which the subjects are fully informed of the nature and purpose of the deception.

The procedures for deception must meet the guidelines established by the discipline of the investigator through its professional code of ethics.

Waiver or Alteration of Consent

On some occasions, Federal regulations for human subjects research permit a waiver of the requirement for informed consent, or an alteration of consent, including waiving parental permission. For example, a study may investigate certain aspects of public benefit or service programs but may not be practicably carried out without waiver or alteration of the consent process (see **45 CFR 46.116[c]**). *Only* the IRB may approve waivers or modifications of the consent process, after having determined:

- the research involves no greater than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research would be impracticable without the waiver or alteration; and
- the subjects will be informed of the study when it is over (if at all possible).