

5. THE PROCESS OF CONSENT

5.1 A Process – Not a Form

Since subjects retain the right to withdraw from a study, consent is an ongoing process. It starts well before any forms are signed and continues until participation is complete.

The informed consent process is different from the consent form. The process involves meeting with a potential subject, determining whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation with that subject. The consent form formalizes the agreement to participate and should be designed to document the process. Obtaining informed consent is not just giving a prospective subject a consent form and getting it signed.

If consent is to be informed, the subjects must genuinely understand the study. Hence, researchers should strive to convey information to subjects, not merely disclose it to them. Subjects should be able to demonstrate their understanding of the procedures, risks, and benefits of the study in which they are agreeing to participate.

5.2 When to Discuss Participation with Research Subjects

To achieve understanding, potential subjects should not be presented information all at once or only at the last minute. People need time to think about whether or not they want to participate. They may wish to discuss the decision with family, close friends, or religious advisors. They should not feel rushed or coerced. They need time, especially if the information is disturbing or particularly complex, to digest the information and come to terms with it.

Information must be comprehensible. Even highly educated people must have technical information presented in simple terms. The best method of expression will vary with the proposed population. Researchers may explain a project involving optometry using discipline-specific technology when approaching students of optometry for example. Laypersons, however, should receive as simple and straightforward a presentation as possible. Some of the suggestions offered here for writing comprehensible consent forms are also useful for presenting information in discussions.

5.3 General Requirements of a Consent Form

Federal regulations for human research identify some information as “essential” to understanding any research project [45 CFR 46.116(a)&(b)]. At a minimum, investigators should:

- a. explain the purposes of the research;
- b. report the expected duration of the subject’s participation;
- c. describe the procedures to be followed;
- d. identify any procedures or products that are experimental;
- e. explain why the subject is eligible to participate;
- f. describe any foreseeable risks or discomforts that the subject might experience;
- g. describe any benefits to the subjects or to others that can reasonably be expected;
- h. disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- i. explain the confidentiality of any records that identify the subject;

- j. for research that involves physical contact or physical activity, explain whether compensation or medical treatment will be available if the subject is injured and provide referrals for further information;
- k. identify people who can answer questions about the research, including the principal investigator (and the faculty sponsor if the investigator is a student) and the institutional CPHS; and
- l. explain that participation is voluntary, that refusal to participate will involve no penalty or 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. (Note: If the potential subjects are students, it should be clearly explained that their class standing will not be affected by their decision as to whether or not to participate in the study.)

In addition to this essential information, circumstances may require that researchers:

- a. explain conditions under which the investigator can remove people from the study regardless of their consent.
- b. explain any additional costs of participation in the study.
- c. discuss the consequences of, and the procedures for, withdrawing from the study.
- d. declare that research findings that could affect participants' willingness to remain in the study will be disclosed to them.
- e. state the approximate number of people involved in the study.
- f. identify pilot or feasibility studies. Some subjects are willing to participate in a study that has a track record but are not willing to participate in a pilot phase of a study. Participants must be told if they are among the first people to receive the intervention or treatment.
- g. inform women of child-bearing age whenever a pregnancy test is part of the research protocol. They must also be told whether such tests will be repeated during the course of a research project and whether use of contraceptives is a requisite to participation. Men, too, must be told if contraception is recommended for them.
- h. explain that a treatment or procedure might involve currently unforeseeable risks (including risks to an embryo or fetus, if a participant is or become pregnant).
- i. make clear whether the procedures or drugs used in a study are standard, standard but used in a non-standard manner, or experimental.
- j. if the study involves experimental drugs or devices, inform the subject that the research and the medical records may be reviewed by the Food and Drug Administration (FDA) and by the company sponsoring the research.
- k. avoid stating that drugs or devices have been approved for human use by the FDA if any part of the study is outside the licensed and approved indications of those items. Patients interpret such a claim to mean that the FDA has licensed and approved this use of the item, not that the FDA has merely granted permission to investigate the use of the item.
- l. distinguish between consent to a study and consent to a treatment. In "treatment studies" (in which a patient who is undergoing a treatment is given a choice between undergoing that treatment as part of a study or undergoing it in a standard health care context), the study and the treatment involve different benefits, risks, and alternatives.

5.4 What Must Be Said About the Conduct of the Research?

Confidentiality/Anonymity

The researcher must describe the level of confidentiality or anonymity of the research data and the measures that will be taken to ensure that protection is maintained. It is important to understand that confidentiality and anonymity are different forms of protection of research data. Confidentiality means that a link exists between the subject's name and the subject's individual participation in the study. Adequate explanation should be provided to the subject regarding the protection of this link, access to the information, and any limits to the protection.

Anonymity allows a subject to participate without recording any identifiable information. No one, including the investigator, will have the means to match an individual's responses with their identity.

The phrase "only aggregate data will be presented" is appropriate only when it is true. This phrase implies that the researcher will not describe individual subjects or the subject as an individual, even if the subject has a unique event. What is more common, however, and what the subject should be told, is that the subject's identity will not be disclosed.

Conflict of Interest

The University of Houston's CPHS' require that researchers inform their subjects of any conflicts of interest in the research. For example, researchers should disclose any personal stake in companies that might be affected by the research might affect.

Finder's Fees

Companies sometimes offer researchers incentives for recruiting subjects or conducting research on an investigational drug or device manufactured by the company. The incentive may be either a monetary fee or a donation of equipment or materials. Researchers must report these incentives to the CPHS, which may require that this information be disclosed to prospective subjects.

Payments to Research Subjects

If researchers plan to compensate subjects for participating in a study, the consent form must describe the terms of payment and the conditions under which subjects would receive partial compensation or no compensation (for example, if they withdraw from the study before their participation is completed). See section 3.14 Payment to Subjects

5.5 Assessing the Subject's Understanding

The responsibility of ensuring that potential participant genuinely understands the research, including the risks and benefits involved, falls upon the researcher, not upon the prospective subject. Hence it is critical to the consent process that the researcher not only field questions, but also asks questions.

Asking questions can further the discussion, elicit questions from the prospective subject, prompt the prospective subject to think more carefully about the project, and help the researcher decide whether the person has adequately understood the project. These questions must be prepared in advance.

Useful questions are open-ended and non-directive. Such questions do not imply a correct answer and invite greater discussion than a simple “yes” or “no.” Open-ended questions often begin with “what,” “where,” “how often,” “when,” and “please describe.” Examples of open-ended questions are:

- “So that I can be sure you understand what is expected of you here, would you please explain to me what you think we’re going to ask you to do?”
- “Describe the purpose of the study in your own words.”
- “What more would you like to know?”

In contrast, examples of closed-ended and far less useful questions are:

- “Do you understand?”
- “Do you have any questions?”

Closed-ended questions tend to stop discussion and therefore should be avoided.

5.6 Documenting the Subject’s Consent with a Consent Form

Once a subject understands a study and expresses a willingness to participate, researchers must document the subject’s consent with a consent form. A signature certifies the subject’s willingness to participate, though a signed form is not equivalent to assuring that the subject has understood the research. Including a date with the signature avoids confusion about whether the subject began to participate before giving consent.

A researcher may need to prepare several consent forms, depending on who the subjects are likely to be. For example, a single project may require a consent form for the guardian or parent of a child, a consent form for a competent adult subject, a simplified assent form for the 8- to 17- year-old or for the adult who is not competent to give consent alone, and a script for obtaining assent from children younger than 8. [See following sections for discussion of assent forms.] Foreign-language versions of the consent forms are necessary for enrollment of people who do not speak and/or comprehend English. [See section 4.11 for discussion of translated consent forms. This section also discusses unexpected enrollment of non-English speaking subjects.]

The person who prepares the documents should:

- Print all documents in font no smaller than 12 points to make sure they are readable. If the subjects will have difficulty with 12-point font, a larger font is necessary.
- Place the title of the study on the first page, exactly as it appears in the CPHS files absent a compelling reason to shorten or change the title. “Informed Consent” is not an acceptable title because it obscures the fact that informed consent is a process, not the document itself, and implies a completeness that the form may not have.
- Number each page after the title page so that pages appear in a logical order and to insure that missing pages will be readily noted (example: “page 2 of 4”).
- Include a consent form version date. This date should be updated each time a new version of the consent form is approved by the CPHS.

Format and Specific Requirements

The consent form must:

- **Identify the researcher(s) by name along with their University and departmental affiliation on the first page of the consent form.**

If the project is conducted by faculty or staff, the first page of the consent form should be printed on departmental letterhead. For student projects, the words “University of Houston” should appear in the header on the first page, and the faculty sponsor’s name and phone number should be given with the student’s name and contact information.

- **Invite participation.**

Consent forms should “invite” participation. They should not say that a friend or a school’s principal recommends participation, nor should they “offer the opportunity” to participate.

- **Summarize cautiously.**

Information described earlier in the consent form should be summarized only in order to clarify. Summaries that suggest a warning or limitation of liability or opportunity for redress are not acceptable. Examples that are unacceptable are:

- “You understand that ...”
- “The possible risks associated with this study have been presented.”
- “The method and purpose of administration of this study have been explained to you.”
- “You have been made aware of certain risks and consequences.”

Readability and Technical Language

In writing consent forms, researchers must:

- Use the recommended format (see Sample Consent Forms)
- Use declarative sentences suited for an eighth-grade reading level.
- Write in the second person (“you”) rather than the first person (“I”), and avoid shifting from one to the other.
- Avoid strike-out formats (such as “You/Your spouse/Your child”), since they depersonalize the form and often make it difficult to read.
- Keep the description of the study as brief as possible, even if the study is complex. The details can be placed in an appendix.
- Use paragraph headings and illustrations. Use flow charts or calendar-like tables to explain studies that involve multiple visits, that ask subjects to go from one place to another, or that involve different protocols depending on research benchmarks.
- Describe quantities in lay terms (teaspoons, for example). Communicate size with an illustration or a reference common household object of the same size.
- Ask someone who is unfamiliar with the field to read the final draft of a consent form. Software packages that evaluate a text’s “readability” may be helpful.
- Replace technical language with lay terms.

5.7 When to Submit the Form to the CPHS

Researchers must submit consent forms when they first apply for CPHS review and approval, and when they apply for continuing review. Since the standards for consent forms change over time, in part due to changes in regulatory mandates and community styles and expectations, the CPHS reviews the form at renewal to ensure that it is up to date.

In addition, the CPHS may ask researchers to modify consent forms at other times, when circumstances warrant. Any revisions made to a previously approved consent form must be submitted to the CPHS for approval *before* use.

5.8 When the Consent Requirement can be Waived

On rare occasions, the federal regulations for human subjects research allow a waiver of the requirement for informed consent. For example, a waiver is possible if a study investigates certain aspects of public benefit or service programs (see 45 CFR 46.116[c]). Also, either a waiver or a consent process that omits or modifies the essential elements of informed consent is possible if the CPHS finds that:

- 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).

Only the CPHS can waive or modify the consent process. Researchers are not authorized to make this decision.

5.9 Confidentiality

The use of confidential information is an essential element in many research studies, especially in the social and behavioral sciences. The CPHS reviews research applications with regard to the necessity of obtaining private and confidential information and the safeguards used to protect breaches of confidentiality that could lead to a loss of privacy and potential harm to participants. Potential harms include the risks of criminal or civil liability or damage to financial standing, employability, insurability, or reputation, stigmatization, and damage to social or family relationships.

The more sensitive the data collected about participants, the greater the protections of confidentiality the CPHS will require. Protections and safeguards may include the use of identifying numbers for participants, the storage of data in a secure location (e.g., locked office or file cabinet, with limited access), and computerized security systems (e.g., password protected or encrypted). Investigators should be aware and take appropriate precautions against unauthorized access to computerized data. Violations of confidentiality can occur even when university researchers only have access to participant identification numbers and not their names. For example, if investigators receive data containing identification numbers from another source, which can link the numbers with names, a breach of security at that source can compromise the confidentiality of participants.

Whenever possible, surveys and questionnaires should be anonymous, with no information about participants' names and identifying information recorded.

Although the CPHS generally requires investigators to protect the confidentiality of participants, it may waive this requirement when participants explicitly and with knowledge of possible consequences agree to have their names, pictures or other identifying information disclosed in publications or presentations or serve as co-authors of reports or published materials.

5.10 Certificates of Confidentiality

The Public Health Service Act provides protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research. Protection is given in the form of a certificate of confidentiality issued upon application for a particular project (note: federal funding is not a prerequisite).

A “Certificate of Confidentiality” protects subjects’ anonymity by protecting research records from compelled disclosure. Protection is available only to “research” (defined as a systematic investigation designed to develop or contribute to generalizable knowledge) under two conditions: (1) the research is on sensitive topics and (2) the additional protection is necessary to achieve the research objectives.

Research would be considered sensitive if it involves the collection of:

- information about sexual attitudes, preferences, or practices;
- information about the use of alcohol, drugs or other addictive products;
- information about illegal conduct;
- information that, if released could be damaging to an individual’s financial standing, employability, or reputation within the community;
- information in a person’s medical record that could lead to social stigmatization or discrimination;
- information about an individual’s psychological well being or mental health; or
- genetic information.

A Certificate of Confidentiality does not prohibit voluntary disclosure of identifying information about research subjects. Researchers, therefore, may voluntarily disclose matters such as child abuse or a subject’s threatened harm to self or others. However, if a researcher intends to make such voluntary disclosures, the consent form should clearly indicate the circumstances of disclosure.

In some instances, the CPHS may require an investigator to obtain a Certificate of Confidentiality. Additional information is available through the National Institutes of Health (<http://grants1.nih.gov/grants/policy/coc/index.htm>) web site.

5.11 Children and Adolescents

Written parent (or legal guardian) permission is required for studies involving children under the age of 18. If the research involves greater than minimal risk, signatures from both parents are required unless the second signature is not reasonably available. A single signature is sufficient if only one parent has legal responsibility for the care and custody of the child or if one parent is deceased, unknown, or incompetent. Parental permission is documented in a form similar to a consent form for an adult subject, but tailored to invite “your child” to participate rather than “you.”

The CPHS can grant a “waiver of parental consent,” but does so only on rare occasions and only if (1) the research will yield great benefit to the population being studied and (2) the procurement of parental consent would pose a considerable risk to potential subjects.

Once parental permission has been obtained, the agreement of the child is required. Parental permission may overrule a child’s decision not to participate in therapeutic settings.

The child's agreement is documented with an "assent form," a child-friendly document that outlines the essential information about the research. All children between 8 and 17 years old should receive an opportunity to assent; most children 8 years old or older have the cognitive and emotional maturity to understand a research project and to decide whether they want to participate in it.

Some children under the age of 8 may also be capable of granting and withholding assent, and the CPHS' ask researchers to be sensitive to the needs of these children on an individual basis. Researchers should draft a form (or a verbal script) that is age-appropriate and study-specific, considers the typical child's experience and level of understanding, and treats the child respectfully while conveying the essential information about the study. The form (or script) should:

- state why the study is being conducted;
- describe what will happen and for how long or how often;
- state that the decision to participate belongs to the child, and that refusal or withdrawal is "okay;"
- explain if participation will hurt and, if so, for how long and how often;
- describe the child's other choices, if any;
- describe any good things that might happen;
- mention any compensation for participating; and
- ask for questions.

The document should be no longer than one page if possible. Illustrations can be helpful, and larger type is easier for young children to read. Studies involving children who are unable to read should provide appropriate procedures for a verbal assent process. Studies involving older children or adolescents should include more information and may use more complex language.

Subpart D of 45 CFR 46.401-409, "Additional Protections for Children Involved as Subjects in Research," outlines the conditions of participation for minor subjects [<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd>].

5.12 Consent and Language Barriers

When planning research that will include non-English speaking subjects, researchers should prepare consent forms in English and in the other relevant language(s). The CPHS may consult with language experts or require a "back-translation" into English.

As an alternative to translated consent forms, the CPHS may approve a process consisting of an oral presentation of informed consent information in conjunction with a short form document stating that the elements of consent have been presented orally and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must receive copies of the short form document and the summary.

When this procedure is used with subjects who do not speak English:

- the oral presentation and the short form written document (see sample attached) must be in a language understandable to the subject;
- the CPHS-approved English language informed consent document may serve as the summary; and
- 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 should be signed by the subject (or by the subject's legally authorized representative);
2. the summary (i.e., the English language informed consent document) should be signed by the person authorized under the protocol to obtain consent; and
3. the short form and the summary should be signed by the witness. When a translator assists the person responsible for obtaining consent, the translator may serve as the witness.

All foreign language versions of the short form document are a condition of CPHS approval (see 46.117(b)(2)). Expedited review of these versions is acceptable if 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 CPHS.

If 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 consents to participate.

5.13 Cross-Cultural Consent Issues

The requirements for documenting informed consent vary among cultures. The CPHS does not exempt from the consent requirement projects conducted in foreign countries or with other cultural groups here, but can waive the requirement for written documentation of consent. In some settings, the process of signing the form is very intimidating and is thought to be riskier than the research itself.

Researchers planning to conduct cross-cultural research must justify the proposed method of documenting consent. The justification must include a description of any customs that constrain the typical informed consent process.

Subjects in foreign sites should receive referrals to local contacts for answers to any questions they may have about the research or about their rights.