Guidelines

Obtaining informed consent from participants fulfills the ethical requirement of “respect for persons” discussed in the Belmont Report. The prospective and voluntary consent of potential participants is required unless the IRB waiver or alters the requirements for consent. Remember, consent is a process, not a signature on a form. Once the consent form is signed, consent continues through ongoing communication with the subject throughout the study. Unless waived by the IRB, consent from subjects must be obtained freely without coercion and/or undue influence.

Participants should be presented with a consent document in a language understandable to them and with ‘information that a reasonable person would want to have in order to make an informed decision about whether to participate.’ Informed consent must begin with a ‘concise and focused presentation of key information’ and not merely provide lists of isolated facts. No informed consent may include any exculpatory language that the subject is made to waive or appear to waive any legal rights or release the institution, investigator, or sponsor from liability for negligence.

Researchers must be aware of any real or perceived power differential between researchers and potential subjects (such as doctor/patient, employer/employee, or teacher/student relationships), in which case(s) the recruitment and consent process must be modified accordingly (such as relying on a trained independent third-party on the research staff to recruit and consent subjects). If subjects are being targeted for recruitment and they may not speak or read English, then documents must be translated into a language they understand or an alternative process is approved by the IRB. Investigators are strongly encouraged to recruit and include all segments of the community in research. This complies with the Belmont Report principle of ‘justice.’

Parental permission is required for all Human Research involving minors (in Arizona this is any person under the age of 18) unless waived by the IRB. In addition, minor assent must be obtained from subjects unless waived by the IRB. When the minor reaches the age of majority (age 18) they should be consent as an adult to continue participation in the Human Research project. See HSPP Guidance, Children, for more information.

Creating a consent document

Informed consent documents should:

- Written at a sixth (6th) to eighth (8th) grade level and in a language the subject will understand. The HSPP maintains multiple Informed Consent templates to use when writing a consent document on the website.
- Informed consent documents must contain all of the required and additional elements of informed consent as appropriate.
Always date the revisions of consent documents to ensure that the most recent version approved by the IRB is used. All versions of the consent documents in every language used must be approved by the IRB prior to use.

**Documenting consent**
Consent must be documented in writing unless waived by the IRB. Regardless of the consent template used, all the required and additional elements of informed consent (if applicable) must be included in all written consent materials unless waived by the IRB. If consent documentation (e.g. signature) is waived, each participant will be asked whether they want documentation linking the participant with the research and the participant’s wishes will govern.

The following are requirements for written consent documents:
- The subject or representative signs and dates the consent document;
- The individual obtaining consent signs and dates the consent document (this is best practice) but not required by the regulations;
- Whenever required by the IRB, the subject’s or a representative’s signature is to be witnessed by an individual who signs and dates the consent document;
- For subjects who cannot read, and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document; and
- A copy of the signed and dated consent document is provided to the subject.

**Documenting unwritten, oral, or electronic informed consent**
Unwritten, oral consent also requires documentation. Be thinking of how to verify human subject oral consent if required to produce verification. This can be accomplished in a variety of ways, including these:

- Audio recording
- Video recording
- Photographs
- Drawings
- Witnesses
- Thorough field notes

**Waiver of Informed Consent Guidelines**
The IRB must review the description of information provided to participants when the IRB considers waiving consent or waiving the requirement to obtain documentation of consent.
To obtain a waiver of consent or documentation of consent the project may not be FDA-regulated, including for research where parental permission or child assent is required.

**What is the short form informed consent?**
The regulations allow, in certain circumstances, the use of a short form consent process (45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2)). The IRB must determine that the short form process is appropriate before it may be used to consent potential subjects.

**Examples of appropriate requests for use of the Short Form Informed Consent Process**
- A study population is seeking Hispanic males, then Spanish translated documents must be submitted to the IRB for review and approval. A short form process will not be approved in this instance.
- If the study seeks to enroll a single individual* who happens to meet the eligibility criteria, but the subject does not read or speak English, then a short-form process may be approved. A request must be submitted to the HSPP before the subject is enrolled in the study.

*If the IRB receives continued requests for use of the short-form process, for the same language as previously approved by the IRB, then the IRB will require that the project be amended to provide fully translated consent forms to be used with this population.

**Documents required to obtain IRB approval for short form informed consent process**
The use of the short form is reviewed on an individual IRB protocol basis. Investigators can include the request in the initial submission, or may submit an amendment if a subject presents that meets the requirements for use of the short form.

1. Justification for use of the short form.
2. Summary of what will be presented to the subject (this can be the English version of the informed consent document).
3. Text of the short form - This document highlights that the basic elements of consent will be obtained from subjects.

**Documenting the short form informed consent process**
The short form process provides the elements of informed consent to the potential subject in a language they understand, a witness is required to be present, and a translator is used.

- If the Person Obtaining Consent (POC) is not fluent in the participant’s language, an interpreter must be present to assist in the consent process.
Requirements for Obtaining Informed Consent

- The interpreter must be fluent in English and the language of the participant. A family member may be the interpreter only if the participant has declined use of a hospital interpreter.

- Required signatures:
  - Short Form (translated): Participant or the participant's legally authorized representative [LAR] and Witness*
  - Summary Form (English): Person Obtaining Consent (POC) and Witness*
  
  * A member of the study staff acting as interpreter and POC cannot also act as witness. The witness may be the interpreter (including the hospital interpreter), study staff, a family member, or other person conversant in both English and the participant’s language.

- The participant should be given a copy of both the translated Short Form and the Summary Form.

PHI Authorization and the short form informed consent process
If the IRB finds it appropriate, they may grant an alteration of the required PHI elements (e.g. the signature). The IRB expects that all elements of the authorization will be presented to the subject, but in the short form process, the alteration of PHI can be used to document that PHI authorization was obtained orally, but a signature will not be obtained on an actual PHI authorization form.

Public Demonstration Projects
A public demonstration project is research conducted by or subject to the approval of state or local government officials. The research or demonstration protocol is designed to study, evaluate, or otherwise examine:
- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs.
- Possible changes in or alternatives to those programs or procedures.
- Possible changes in methods or levels of payment for benefits or services under those programs

A waiver of consent may be granted for these projects so long as the criteria above are met and the research is not FDA regulated.

Consent Resources
Requirements for Obtaining Informed Consent

- National Science Foundation (NSF) FAQ on Informed Consent in Social and Behavioral Science: http://www.nsf.gov/bfa/dias/policy/hsfqs.jsp#informed

Consent Templates

- National Cancer Institute; Cancer Therapy Evaluation Program: http://ctep.cancer.gov/forms/
- University of Arizona Informed Consent Form Template: http://orcr.arizona.edu/hspp/forms
- World Health Organization Templates: http://www.who.int/rpc/research_ethics/informed_consent/en

Simplification of Consent Forms

- Agency for Healthcare Research and Quality (AHRQ); How to Improve Informed Consent and Authorization: http://www.ahrq.gov/fund/informedconsent/ictoolkit2.htm
- National Cancer Institute; Simplification of Consent Forms for Cancer Clinical Trials: http://www.cancer.gov/clinicaltrials/education/simplification-of-informed-consent-docs/page3
- University of Tennessee Graduate School of Medicine Glossary of Lay Terms: http://gsm.utmck.edu/irb/Forms/irb_glossay_body.pdf
- University of Washington’s Institute for Translational Health Sciences (ITHS) and Group Health Research Institute Plain Language Toolkit:
Requirements for Obtaining Informed Consent

http://www.grouphealthresearch.org/capabilities/readability/readability_home.html

**Toolkits**

- National Cancer Institute (NCI) Research Resources: [https://resresources.nci.nih.gov/resources/](https://resresources.nci.nih.gov/resources/)

