



Informed Consent

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 waives 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 consented as an adult to continue participation in the Human Research project. See HSPP Guidance, *Research Involving Children*, for more information.

Creating a Consent Document

Informed consent documents should:

- Be 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. The HSPP has published an ‘Elements of Informed Consent’ checklist on the website.
- Contain all of the required and additional elements of informed consent as appropriate.

Always use the stamped, ‘Last Finalized’ version of consent documents in eIRB to consent participants. All versions of the consent documents in every language used must be approved by the IRB prior to use.



Informed Consent

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 consent materials unless waived by the IRB.

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;
- 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. Consider ways in which to verify human subject participants' 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 for FDA-regulated projects, the research must involve no more than minimal risk to subjects. This includes 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.

Example of an appropriate request for use of the Short Form Informed Consent Process:

- 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, a fully translated consent form is not available in the subject's language, and it is in the subject's best interest to participate before a translated document is available, then a short-form process may be approved. A request must be submitted to the HSPP before the subject is enrolled in the study.



Informed Consent

*If a short form is used more than five times for one language, the IRB will require that the project be amended to provide fully translated consent forms to be used with this population. Please note, it is at the discretion of the IRB Chair to request fully translated documents at any time.

Example of an inappropriate request for use of the Short Form Informed Consent Process:

- If the study population is seeking Hispanic speaking individuals, 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.

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 a Modification if a subject presents that meets the requirements for use of the short form. Include the following documents when requesting Short Form use:

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

*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.



Informed Consent

After a short form has been used with a subject, a Reportable New Information (RNI) submission will be needed in eIRB. This information is also reportable on the Continuing Review Smart Form in eIRB, if applicable.

For studies regulated by the U.S Food & Drug Administration (FDA), the investigator must promptly obtain a translated copy of the IRB-approved English version of the consent form and submit it to the IRB for review and approval via a Modification in eIRB. Once the translated consent form is approved by the IRB, the investigator must provide it to the subject as soon as possible. Please review the [FDA Guidance on Informed Consent](#) for more information.

PHI Authorization and the Short Form Informed Consent Process

There is no short form process for obtaining PHI authorization. If the IRB finds it appropriate, they may grant an alteration of the required PHI authorization 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.

Reconsenting of Subjects

Informed consent is an ongoing process requiring researchers to provide subjects with continual information and clarification, which will enable them to decide whether to continue participating in research studies. Often, this ongoing process involves providing subjects with written documents that contain new information. Although in some instances this information may appear within a memo or letter, most often researchers must formally amend the consent document and submit it to the IRB for review. After receiving notification of approval, researchers must explain to subjects all changes in the consent document and ask them once again to sign it if they choose to continue participating given the new information. The IRB refers to this process as 'reconsent.'

'Notification' is the process of providing new information to subjects after their active participation has ended but may be relevant to their safety and welfare. This can be a verbal notification or a written notification, such as in the form of a subject letter. The subject's receipt of the new information must be documented and confirmed.

Reconsenting and notification requirements are handled on a case-by-case basis.

Reconsent requirements are often contingent on the status of the study subjects. Examples include:

Subjects currently enrolled:

- Reconsent all subjects who are affected by the new information.
- Reconsent at an in-person visit with a revised consent document or a new consent addendum is the default requirement. A consent addendum is used when there is a new portion of a research project that requires a participant's signature.
- Alternatives may be approved by the IRB.



Informed Consent

Subjects currently in long-term follow-up only:

- Reconsent all subjects who are affected by the new information.
- A letter or consent addendum describing the new information is likely the most effective approach since research procedures are complete, and most of the revised consent document would no longer be relevant.
- Alternatives may be approved by the IRB.

Subjects currently off-study:

- Notification to all subjects only if the new information impacts ongoing safety or subject rights.
- Use a letter format, phone call, and/or documentation of receipt as described above.
- Alternatives may be approved by the IRB.

Example Scenarios Related to Reconsenting and Notification

Reconsent/Notification Generally Required	Reconsent/Notification Generally Not Required
<ul style="list-style-type: none"> • New procedures for affected subjects only • New risks • Change in frequency of risks • Change in costs or payments • Change in FDA status of the test article • Change in PI • Change in sponsor • New contact information for the study team • Change in the HIPAA section • New information about conflicts of interest • New treatment options or alternatives to participation • New use of identifiable data and/or specimens • Minor subject turns age of majority (18 years of age in Arizona) • Subject enrolled by a surrogate regains ability to consent for themselves • Subject has a new surrogate decision-maker 	<ul style="list-style-type: none"> • Minor administrative changes such as change to the version date, typographic corrections, or formatting changes • Change in the dates of approval on the consent form • Increases in the number of subjects • Other changes, depending on the subject’s status, that do not impact their safety, the nature of their participation, or protection of their rights



Informed Consent

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.

Consent Resources

- OHRP Tips on Informed Consent: <http://www.hhs.gov/ohrp/policy/ictips.html>
- National Science Foundation (NSF) FAQ on Informed Consent in Social and Behavioral Science: <http://www.nsf.gov/bfa/dias/policy/hsfags.jsp#informed>
- U.S Food & Drug Administration (FDA) Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors: <https://www.fda.gov/media/88915/download>
- University of Arizona Qualtrics Platform: <https://it.arizona.edu/service/qualtrics-surveys>
- University of Arizona REDCap Platform: <https://cb2.uahs.arizona.edu/services-tools/surveys-clinical-databases-redcap>
- FDA Final Rule on Waiver or Alteration of Informed Consent: <https://www.federalregister.gov/documents/2023/12/21/2023-27935/institutional-review-board-waiver-or-alteration-of-informed-consent-for-minimal-risk-clinical>

Consent Templates

- National Cancer Institute; Cancer Therapy Evaluation Program: <http://ctep.cancer.gov/forms/>
- National Institute on Aging (NIA) Consent Form Template: <http://www.nia.nih.gov/research/dgcb/clinical-research-study-investigators-toolbox/informed-consent>
- University of Arizona HSPP Informed Consent Form Templates: <https://rgw.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates>
- World Health Organization Templates: https://www.who.int/ethics/review-committee/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/ic toolkit2.htm>
- National Cancer Institute; Simplification of Consent Forms for Cancer Clinical Trials: <http://www.cancer.gov/clinicaltrials/education/simplification-of-informed-consent-docs/page3>



Informed Consent

- National Human Genome Research Institute (NHGRI) IRB Guide to writing consent forms:
<http://www.genome.gov/27026588>
- University of Tennessee Graduate School of Medicine Glossary of Lay Terms:
http://gsm.utmck.edu/irb/Forms/irb_glossay_body.pdf

Toolkits

- National Cancer Institute (NCI) Research Resources:
<https://resresources.nci.nih.gov/resources/>
- National Human Genome Research Institute (NHGRI) IRB toolkit:
<http://www.genome.gov/27528182>
- National Institute on Aging (NIA) Toolkit:
<http://www.nia.nih.gov/ResearchInformation/CTtoolbox/>