

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 Institutional Review Board (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 must be approved by the IRB. All versions of the consent documents in every language used must be approved by the IRB prior to use. 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 Human Subjects Protection Program (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 the required and additional elements of informed consent as appropriate.

IRB Approval Stamp

For projects approved under an expedited or full committee approval, always use the **stamped**, “Last Finalized” version of consent documents in eIRB to consent participants.

If utilizing REDCap for consenting, ensure the consent form is displayed correctly by using the [Inline PDF](#). Copying and pasting the consent form text into the Rich Text designer **does not** fulfill the IRB approval stamp requirement.

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 or Oral 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:

- Audio recording
- Video recording
- Photographs
- Drawings
- Witnesses
- Field notes

Electronic Informed Consent (eConsent)

eConsent is a method of obtaining consent from research participants using digital platforms.

Key Considerations for eConsent Implementation:

1. Use Authenticated Platforms

- If the study involves regulated data (e.g., Family Educational Rights and Privacy Act (FERPA) or Health Insurance Portability and Accountability Act (HIPAA)-protected data), eConsent must be obtained using a secure, authenticated platform such as **Qualtrics** or **REDCap**.



Informed Consent

- If the study is U.S. Food & Drug Administration (FDA)-regulated, eConsent must meet the requirements of [21 CFR Part 11](#), ensuring electronic records and signatures are legally valid.

2. Verify Participant Identity

- Researchers must implement authentication measures to verify the identity of participants before obtaining consent.
- Options include requiring institutional login credentials, multi-factor authentication, or personalized access links.

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.

*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. 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:

Informed Consent

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 and an interpreter are required to be present.

- 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.

After a short form has been used with a subject, a Reportable New Information (RNI) submission must be submitted in eIRB.

For studies regulated by the 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 Protected Health Information (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 that may be relevant to their safety and welfare through other mechanisms besides a complete consent process using a revised consent form document. Notification can take the form of verbal notification (in-person or by phone) or written notification, such as a participant letter/email or consent addendum. Regardless of the method used, the subject’s receipt of the new information must be documented and confirmed by the study team.

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.

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.

Informed Consent

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 Principal Investigator • 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 safety, the nature of their participation, or protection of their rights

When submitting a Modification in eIRB, investigators must indicate if current and/or former participants will be notified of the changes and provide a notification plan. The plan should be documented within the submission. If the study team feels that participants do not need to be notified of the changes, provide rationale as to why it is not necessary.

Note that if an RNI submission includes information that requires consent form updates, reconsent, or participant notification, a separate Modification submission is required to approve the revised consent form or notification material. Ideally, the Modification and RNI should be submitted together for concurrent IRB review.

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

Informed Consent

- 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.

Assessing Participant Understanding

Researchers should take reasonable steps to assess and support participant understanding throughout the informed consent process, particularly when studies involve complex procedures, higher risk levels, vulnerable populations, or participants with limited health literacy. Investigators should also encourage participants to ask questions before agreeing to participate.

One approach that may help assess participant understanding is the “teach-back” method. Using this technique, the researcher asks participants to describe key aspects of the study in their own words, such as the study purpose, procedures, risks, benefits, or voluntary nature of participation. A common approach includes:

1. **Explain:** Present study information clearly, using plain language and manageable sections.
2. **Assess:** Ask the participant to describe key information in their own words using open-ended questions.
3. **Clarify:** Re-explain misunderstood information without placing blame or causing embarrassment (e.g., “I want to make sure I explained this clearly. Can you tell me...”).
4. **Reassess:** Ask the participant to explain the information again to confirm understanding.

Examples of questions that may help assess understanding include:

- “We covered a lot of information. Can you tell me your understanding of the study risks (or visits, procedures, or medications)?”
- “To make sure I explained this clearly, can you tell me what it means to be randomized to the control versus placebo group?”
- “If a friend asked you what this study involves, what would you tell them?”

Teach-back should be used as a conversational tool to confirm understanding rather than as a test. Research staff should pause and use the technique frequently (after each section) when reviewing the informed consent form with participants.

If misunderstandings are identified, the researcher should provide clarification in simpler terms and reassess understanding as appropriate. If a potential participant is unable to correctly respond to teach-back questions after repeated attempts, the researcher should pause the consent process and consider the participant’s capacity to provide consent. Consent should not proceed until adequate understanding is demonstrated. If understanding cannot be achieved after reasonable attempts, the individual should not be enrolled unless consent from a legally authorized representative (LAR) is permitted by the IRB.

Researchers may consider documenting the use of teach-back or other comprehension assessments in the study records when relevant to the consent process.

Consent Resources

- Office of Human Research Protections [Tips on Informed Consent](#)
- National Science Foundation (NSF) [FAQ on Informed Consent](#) in Social and Behavioral Science
- FDA [Informed Consent Guidance](#) for IRBs, Clinical Investigators, and Sponsors
- University of Arizona [Qualtrics](#) Platform
- University of Arizona [REDCap](#) Platform
- FDA [Final Rule](#) on Waiver or Alteration of Informed Consent
- [21 CFR Part 11](#) Electronic Records; Electronic Signatures

Consent Templates

- National Cancer Institute: [Cancer Therapy Evaluation Program](#)
- National Institute on Aging (NIA) [Consent Form Template](#)
- University of Arizona [HSPB Informed Consent Form Templates](#)
- [World Health Organization Templates](#)

Simplification of Consent Forms

- Multi-Regional Clinical Trials Center (MRCT) [Consent](#) and [Interactive Techniques](#)
- National Human Genome Research Institute (NHGRI) [IRB Guide to writing consent forms](#)
- University of Tennessee Graduate School of Medicine [Glossary of Lay Terms](#)

Toolkits

- National Cancer Institute (NCI) [Research Resources](#)
- National Human Genome Research Institute (NHGRI) [IRB toolkit](#)
- National Institute on Aging (NIA) [Toolkit](#)