



Obtaining Meaningful Informed Consent

IRC Research Toolkit

Purpose

This document provides guidance for those conducting human subjects research on obtaining meaningful informed consent in order to safeguard the dignity, autonomy and wellbeing of research participants.

Voluntary informed consent is a legal requirement of human subjects research, but meaningful informed consent entails more than the participant's signature on a consent form. The [Belmont Report](#), which provides an ethical foundation for human subjects research, requires that "subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them," and this occurs during the consent process.¹ The manner in which we obtain this consent is crucial to ensure the protection of research participants, especially among the vulnerable populations with whom we work.

The Consent Form

For guidance on what to include in a consent form, please refer to the [Informed Consent Checklist](#). This document provides a full list of necessary elements required by [federal regulations](#) on research involving human subjects.² Special requirements may apply when working with vulnerable populations including women, children, refugees, and persons with mentally impairments.

Obtaining Meaningful Informed Consent

Federal regulations require that researchers only seek consent under conditions which allow the potential subject the opportunity to fully consider whether they would like to participate in the study. In order to do so, investigators must attempt to minimize the possibility of coercion or undue influence to the best of their ability and ensure that information is presented in language comprehensible to the subject.³ Participants should fully understand *what* they are consenting to and have the ability to make the informed decision *autonomously*.

In order to design appropriate conditions under which to obtain voluntary and autonomous consent, investigators must consider and account for particular challenges that may arise within the context of their research.

Common barriers to obtaining truly informed consent include, but are not limited to:

- Low literacy levels and language barriers, which impede the subject's understanding
- Power dynamics within the community or between the subject and researchers seeking consent, which coerce the subject to make a decision they wouldn't have made otherwise
- Inadequate allowance of time for the subject to fully consider the risks, benefits and implications of participating

¹ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research](#) (1979).

² See [45 CFR 46.116](#) for complete regulations on informed consent.

³ Adapted from [45 CFR 46.116](#).

Methods for Obtaining Informed *Understanding*

When seeking consent, the following steps can be taken to facilitate improved understanding of the research:

- Provide the information in both written and verbal form. Ask the subject questions about the research procedures, time commitment, potential risks, and difficult or technical vocabulary to check for comprehension. Example questions include the following:⁴
 - In your own words, what does optional/withdraw/compensation/voluntary mean?
 - Tell me in your words what this study is about and why we are doing it.
 - Tell me what you think could happen to you in this study, both good and bad.
 - What do you expect to gain or lose by participating in this research?
 - What are your alternative choices if you do not participate in this research?
 - Tell me in your own words about your options if you decide to exit the study.
- Whenever possible, present the information in the native tongue of the subject. If this is not possible, utilize the services of a trusted, vetted translator. Confirm that the participant feels comfortable speaking through the specific translator and encourage him/her to ask questions throughout the process.
- Consent documents should use plain language no higher than a Grade 6 (12-year-old) reading level.⁵ Though a lower grade level is often necessary, given the populations with whom we work. Readability and grade level statistics are available on Microsoft Word documents and through numerous online tools including SMOG, Flesch-Kincaid, and Gunning-Fog.
- For low literacy populations, providing supplemental pictures or images of research procedures, activities, risks, or other components of the consent form can aid comprehension.
- Repeat important information multiple times when seeking consent. Topics including the voluntary nature of the research and the ability of the subject to withdraw at any time without penalty should be mentioned throughout the process. Subjects should be able to repeat the concept back in their own words to ensure full understanding.
- Format the consent document in a way that is visually easy to read and do not let the form exceed 2 pages (note, the IRC IRB prefers shorter consent documents). Strategies for encouraging understanding include adding headings, formatting in lists or bullet points instead of paragraphs when applicable, using short sentences (under 20 words), opting for a larger font size (12 pt. or larger), using second person (“you”), writing in active tense, allowing for adequate white space, and using numerals in place of words (10 instead of ten).⁶

Methods for Minimizing Coercion and Undue Influence

Extra precautions should be taken during the consenting process when working with vulnerable populations who may face higher risks of manipulation, coercion, and undue influence. Outside forces including

⁴ Alan F. Isles, “[Understood Consent Versus Informed Consent: A New Paradigm for Obtaining Consent for Pediatric Research Studies](http://dx.doi.org/10.3389/fped.2013.00038),” *Frontiers in Pediatrics* 38 (2013), <http://dx.doi.org/10.3389/fped.2013.00038>.

⁵ Isles, “[Understood Consent Versus Informed Consent](http://dx.doi.org/10.3389/fped.2013.00038).”

⁶ Adapted from Elizabeth H. Winslow and Paula Hagan, “[Making Research Consent Forms More Readable](http://dx.doi.org/10.3389/fped.2013.00038)” (2003).

monetary incentives, family members, societal norms and expectations, and a pressure to please the researcher or NGO can weigh heavily on a participant's decision. Therefore, preliminary research is necessary to understand the context in which investigators are working. From this information researchers can best adapt the consent process to limit outside influence, and enable the potential subject to make an autonomous, voluntary decision. Best efforts should be made to ensure that participants feel comfortable with the “who, what, where, when, why, and how” of the consent process, which requires careful consideration of the following questions.⁷

Who should seek informed consent from the subject?

The participant should feel at ease expressing any questions or concerns they may have to the researcher seeking consent, but perceived power dynamics can at times hinder this process. To diminish the perception of an uneven relationship between investigator and subject as much as possible, researchers must first ensure that participants are able to understand and communicate with the investigator or translator seeking consent.

Furthermore, participants may not feel comfortable speaking to a person of the opposite gender, so whenever possible it is helpful to pair a male participant with a male investigator or a female participant with a female investigator.

Cultural sensitivities should also be taken into account during the consent process. Participants may feel more comfortable interacting with a local investigator or someone that shares their cultural background. If this is not possible, it is important that those seeking consent are provided training on the context and culture within which they are working.

What information should be presented?

Consult the [Informed Consent Checklist](#) to ensure the consent form contains all necessary components. The purpose, procedures and all foreseeable risks of the research should be properly explained, local contact information for someone on the research team should be provided in case of questions or concerns, and the voluntary nature and ability to withdraw from the study at any time should be emphasized, both on the consent form and verbally throughout the process. Investigators should accurately describe known benefits without exaggeration and note where benefits are uncertain.⁸ It may be helpful to utilize visual aids like pictures and decision trees to supplement the consent form when working with lower literacy populations.

When should consent be sought?

Investigators must obtain informed consent from subjects before enrollment in the study or participation in any research activities. The process does not end here, however, as participants can withdraw from the study or opt out of a procedure at any time. As designed under federal regulations, the informed consent process is an ongoing exchange of information which could take multiple forms, including individual check-ins, community meetings, Q&A sessions or presentations. No matter the method, participants must have an outlet to express their questions and concerns and withdraw their consent if needed. These procedures extend the consent process throughout the full period of participation.⁹

⁷ Jeffrey A. Cooper and Pamela Turner, “Improving Informed Consent,” in *Institutional Review Board: Management and Function*, ed. Elizabeth A. Bankert and Robert J. Amdur (Sudbury: Jones and Bartlett Publishers, 2006), 241.

⁸ Adapted from [HHS OHRP Guidance on Informed Consent](#).

⁹ Adapted from [HHS OHRP Guidance on Informed Consent](#).

Where should consent be sought?

Investigators must bear in mind how the location in which they choose to seek informed consent may affect the participant's ability to make a truly autonomous, voluntary decision. Researchers should select neutral, private spaces where the participant can confidentially express any concerns or hesitations they may have without fear that others will overhear or interrupt.

How should the information be presented?

All information should be presented in a clear, non-threatening manner that encourages open communication between the investigator and subject. The investigator should encourage questions and comments from the participant and continually repeat key concepts including the voluntary nature of the study. Additionally, the process should not be rushed. The subject should be allowed enough time to take in the information presented, ask questions, consider their options, and make an informed decision regarding their participation.

Working with Vulnerable Populations

Children

Unless a waiver of consent or assent is granted by the IRB reviewing a study, researchers must obtain the assent of children¹⁰ as well as the consent of their parents or guardians.¹¹ While the age of consent varies by country, it is important that even children under the umbrella of parental consent are informed of any risks involved in the study. Researchers should obtain the assent of the child whenever possible, in addition to parental consent, as the latter may be influenced by outside pressures or coercion. Beyond the general methods for improving understanding listed above, researchers must take special precautions when working with children. The following list, while not exhaustive, provides guidance on obtaining assent from children.

- If possible, have a parent or guardian present to assist the child. If the parent or guardian is not present, take additional steps to ensure the child understands what he or she is consenting to (see *Methods for Obtaining Informed Understanding* above).
- Reiterate to the child that they have a choice, and that it is acceptable to say no. Children have a natural tendency to blindly agree to tasks presented by elders, so they should be asked repeatedly if they understand their choice and the voluntary nature of the study. A visual aid or decision tree may be helpful to illustrate the choice the child is making.
- The concept of voluntary withdrawal should also be emphasized with children, as they often have a fear of disappointing elders. Repeat to the child that questioning or leaving the study does not mean they have failed or are in trouble. Consistent follow-ups during the study should remind children that they can leave the study without consequence if they no longer want to participate.

Women

In many contexts where we work, outside factors including patriarchal or religious customs and laws limit a woman's autonomy. When conducting research in such environments, investigators must take additional

¹⁰ Assent refers to the child's affirmative agreement to participate in the research. Failure to object should not be construed as assent.

¹¹ Consent of one parent is needed for research that does not involve greater than minimal risk or involves greater than minimal risk, but presents the prospect of direct benefit to the subject. Consent of both parents is needed in all other cases unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

steps to ensure that female participants are able to give their individual, autonomous informed consent, such as:

- Speaking with local leaders ahead of time to learn about specific rules and customs regarding women in the community.
- Ensuring female researchers are available to work with female participants. In certain contexts, women may be restricted from speaking with male investigators, and beyond this, women may feel more comfortable speaking with someone of the same gender.
- In contexts where women must have a male escort, making sure that all consent information is actively explained to the woman, not just her escort. The decision of whether or not to participate is ultimately her choice to make.
- Discussing sensitive topics such as family violence or gender inequality in front of both the female participant and her escort can put the participant in an uncomfortable position, and possibly even danger. If possible, have a female researcher present the information to the woman alone so that the presence of her escort cannot influence, scare or coerce her into a decision. If not possible to separate the participant from her escort, use discretion around sensitive topics and consult with the overseeing IRB when uncertain.
- Due to decreased access to education in some contexts, women may have a lower literacy level than the population as a whole. Take this into account when drafting the consent form and simplify further.
- Women who are pregnant, nursing, or caring for young children may be in greater need of financial or nutritional support for themselves and their children, making them increasingly vulnerable to coercion. Investigators must consider this risk of coercion when deciding whether or how much to offer participants in terms of compensation, as it should not sway their decision to participate in the research.

Refugees

Refugee camps are often comprised of people from varying national, cultural, religious and linguistic backgrounds. Investigators should account for this variance by ensuring the consent process is culturally sensitive of everyone participating and that adequate translation of forms and translator services are available. Initial meetings with camp leaders can help investigators understand how best to adapt their consent process to the particular context.

Additionally, refugees are often aware that outside donors are providing them aid to survive in extremely desperate situations. They may at times view the researchers as analogous with these donors, and therefore feel pressure to participate in the study. During the consent process, investigators must ensure that subjects clearly understand that the aid they receive is in no way related to or contingent upon their participation in the study, nor will voluntary participation grant them special favors or advancements in terms of general treatment by the NGO.