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# Obtaining Meaningful Informed Consent from Newcomers

Meaningful informed consent entails more than a participant's signature on a consent form. The steps that we take for obtaining consent are crucial to safeguarding participants' dignity, autonomy, and wellbeing, especially when collecting data from vulnerable populations. This guide introduces the concepts of informed consent and informed assent and walks through five questions to ask yourself when developing plans and procedures for obtaining them.

## What is meaningful informed consent?

**Meaningful informed consent** to participate in a research project or evaluation occurs when an individual makes a voluntary decision to participate based on a genuine understanding of their ability to opt out; what data will be collected and how; how their data will be used, shared, and protected; and potential risks.

Voluntary informed consent is a legal requirement of human subjects research. But *meaningful*, voluntary informed consent is also a best practice in any program context. This is because we have an ethical obligation to ensure that program participants fully understand how their data is being used, for what reason, and by whom, including any potential risks, before deciding to participate. The process of obtaining informed consent also attempts to minimize the possibility of manipulation, coercion, or undue influence to ensure the decision to participate is **autonomous** (one's own).

Research projects, evaluations, and data collection efforts very often involve clients who are receiving services or benefits from an organization or program. In these cases, the consent process must ensure clients understand that services are not contingent on their decision to participate in the research project or on any information they provide during it. Clients must also understand that participation will not grant them special treatment.

Barriers to obtaining meaningful informed consent may include low literacy levels, language barriers, power dynamics within the community or between the participant and the person seeking consent, and inadequate time to fully consider the risks, benefits, and implications of participating.

Potential participants may also face financial pressures, family expectations, societal norms, or pressure to please a researcher or organization. In contexts where women's autonomy is restricted, this additional barrier may prevent female participants from giving autonomous informed consent.

**Switchboard has developed a Sample Informed Consent Form for research or evaluation projects that you can use as a starting point when developing your own meaningful informed consent forms.**

To help obtain meaningful, informed consent and overcome these barriers, take time during the planning process to consider the following questions:[1]

## Question 1: *What* information should be presented?

In general, prospective participants in data collection need to receive thorough information about what data will be collected from them and why, what it will be used for, with whom it will and will not be shared, and how it will be protected.

When seeking informed consent (both when developing the consent form and throughout the project period), ensure that you:

- Explain the purpose, procedures, and foreseeable risks of the data collection or research project;
- Clearly describe data-sharing protocols;
- Provide relevant contact information in case of questions or concerns;
- Emphasize the voluntary nature of participation and ability to withdraw from the program or study at any time;
- Accurately describe known benefits without exaggeration and note where benefits are uncertain.[2]

### Special Considerations for Research

**Research** can be defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (see 45 CFR 46.102d).

Where research involves **human subjects**, it is subject to federal regulations related to informed consent (see 45 CFR 46.116) and the research must be reviewed by an **institutional review board**, or IRB. Consult the most recent federal regulations to ensure your consent form contains all necessary components and ensure your project receives IRB approval.

## Question 2: *Who* should seek informed consent from the participant?

The potential participant should feel at ease expressing any questions or concerns they may have to the person seeking consent, so ensure those involved speak a common language or engage a qualified, trained interpreter.

When possible, give participants the option to speak with one of a few staff members. This allows them to indicate who they feel comfortable with. Train all data collection staff to ensure that they use consistent and appropriate greetings and help make participants feel comfortable during the initial consent phase and beyond.

## Question 3: *When* should you seek informed consent?

You must obtain informed consent from potential participants before they participate in any data collection activities or enroll in a research study.

Keep in mind that because participants can withdraw from a research study or opt out of a program at any time, the informed consent process should be an ongoing exchange of information. Going beyond the

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[1] Adapted from Jeffrey A. Cooper and Pamela Turner, "Improving Informed Consent," *Institutional Review Board: Management and Function*, ed. Elizabeth A. Bankert and Robert J. Amdur (Sudbury: Jones and Bartlett Publishers, 2006), 241.
[2] Adapted from HHS OHRP Guidance on Informed Consent.

initial consent form, this might include individual check-ins, community meetings, and Q&A sessions or presentations.

These opportunities give participants an outlet to express their questions and concerns and withdraw their consent if needed. These procedures extend the consent process throughout the full research or program period.

## Question 4: *Where* should you seek consent?

Keep in mind that the location where you choose to seek informed consent may affect the prospective participant's ability to make a truly autonomous, voluntary decision. 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.

In some cases, potential participants may not be comfortable with program staff entering their homes or speaking to them alone. If it is not possible to speak to participants alone, use discretion around sensitive topics when seeking consent and always prioritize participants' safety. For example, it would not be appropriate to ask questions about family violence while talking to the whole family at once, since this could risk aggravating a dangerous situation for survivors.

## Question 5: *How* should you present the information?

All information should be presented in a clear, non-threatening manner that encourages open communication between the person seeking consent and the participant. Give participants enough time to take in the information presented, to ask questions, to consider their options, and to make an informed decision regarding their participation.

Whenever possible, provide the information in both written and verbal form. You should make every effort to present the information in participant's native language. If this is not possible, engage a qualified sight translator. Bear in mind that when working with a group of newcomers who speak different languages, multiple translations/translators may be needed.

Written consent forms should use plain language, including active tense and the second person ("you"). A best practice is to use no higher than a Grade 6 (12-year-old) reading level. You can test the readability and grade level of text using MS Word or online tests such as SMOG, Flesch-Kincaid, and Gunning-Fog.

Also keep the form short and format it so it is easy to read. Use clear headings, bulleted lists instead of paragraphs, readable fonts, and adequate white space. For low literacy populations, providing supplemental visual aids like pictures and decision trees may help improve comprehension.[3]

While written, signed consent is always preferable, oral consent may be obtained in some cases. In this process, the person seeking consent reads the consent form aloud and discusses it with the participant, then indicates in writing whether the participant verbally consents. In this situation, it is especially important to provide adequate time and opportunity for participants to ask questions.

Refer to 45 CFR 46.117c for regulations on waiving the requirement for obtaining signed consent when conducting human subjects research.

### Put the Emphasis on Understanding

When seeking meaningful informed consent, it is a best practice to ask participants questions to help check comprehension, such as:

- In your own words, can you tell me why we are doing this project?
- Can you describe what will happen if you agree to participate?
- Can you describe what will happen if you decline?
- In your own words, what do the terms "voluntary", "withdraw", "risk", "benefit" mean?
- What do you expect to gain or lose by participating?
- What are your alternative choices if you do not participate?

*Adapted from Alan F. Isles, "Understood Consent Versus Informed Consent: A New Paradigm for Obtaining Consent for Pediatric Research Studies," Frontiers in Pediatrics 38 (2013).*

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[3] For a discussion of visual aids in consent forms, see William J. Heerman et al, "A Tool Kit to Enhance the Informed Consent Process for Community-Engaged Pediatric Research," *IRB: Ethics & Human Research*, 32:5 (October 2016). You can find examples of visual aids used in real studies in the Figures document for that article.

## Obtaining Informed Assent from Minors

**Assent** refers to a minor's affirmative agreement to participate in a data collection project. A minor's failure to object should not be construed as assent.

Obtaining informed assent is a best practice in all data collection with minors. When conducting research with minors, unless a waiver is granted by the IRB reviewing a study, researchers *must* obtain the assent of children as well as the consent of their parents or guardians. [4] It is important that even children under the umbrella of parental consent are informed of any risks involved in the study. Researchers and others collecting data from minors should work to obtain the assent of the child whenever possible.

Take special precautions when seeking 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 truly ensure the child understands what he or she is assenting to.

Reiterate that the minor has a choice and that it is acceptable to say no. Children may have a natural tendency to agree to tasks presented by adults, so they should be asked repeated questions to gauge their understanding of the choice they are making and the voluntary nature of participation. 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, as children may have a fear of disappointing adults by withdrawing their consent. Repeat that questioning or leaving a project or research study does not mean they have failed or are in trouble. Consistent follow-ups should remind children that they can leave without consequence if they no longer want to participate.

## Conclusion

Informed consent is a crucial component of ethical data collection and necessary for building trust with clients. Remember to clearly state the potential risks and benefits of participation and emphasize that clients have the right to withdraw their consent. Careful attention to the setting and tone of the conversation can further signal to your clients that you have their best interests in mind. Adherence to these best practices not only keeps you compliant with legal and regulatory requirements, it is also the right thing to do for clients.

## Resources

*Ethical Guidelines for Working with Displaced Populations through Programs, Research, and Media*: This extensive resource from the Women's Refugee Commission offers concrete guidance on collecting data with and from displaced populations, covering topics such as informed consent, psychological safety, and stakeholder engagement.

*Best Practices Guidance on Consent*: This resource from UNHCR provides additional considerations for ensuring informed consent, as well as tips for conducting data collection in a way that respects the comfort and safety of displaced individuals.

*Best Practices in Research with Newcomers: Safety, Sensitivity, and Ethical Standards*: If you are interested in conducting research projects with the newcomers you serve, this archived webinar from Switchboard can help you identify key approaches and strategies for ensuring adherence to ethical principles.

*Sample Informed Consent Form*: You can use this template as a starting point for your own informed consent form, adapting the language as needed to suit your clients or projects.

**To learn more about Switchboard, visit www.SwitchboardTA.org.**

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**Commented [MG3]:** Reference SB's consent form again?

**Commented [AB4]:** @Meg, this resource does mention sexual/gender minorities. It's quite a long resource and there's nothing in the title that should be flagged by EOs, but mentioning it for thoroughness regardless.

**Commented [MG5R4]:** Appreciate the attention to detail - I took a look and I think it is ok.

**Commented [MG1]:** True? Trying to hit both the research and program side

**Commented [AB2R1]:** Agreed, I think this is a fair statement!

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[4] 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.