

INFORMED CONSENT SELF-ASSESSMENT TOOL

Use this tool to perform a review of the informed consent process, consent documents, and required record-keeping for your research. For more information on informed consent, see the OSU Human Research Protection Program policies, [Informed Consent Process and the Elements of Informed Consent](#) and [Documentation of the Informed Consent Process](#).

CONSENT PROCESS

Informed consent is an essential part of ethical human subjects research. Investigators are responsible for ensuring that potential participants provide informed consent prior to participating in research, unless the requirement for informed consent is waived or altered (in non-exempt research) by the IRB.

Informed consent is an ongoing process. Even in the absence of new information or changes to research procedures, periodic review or confirmation of a participant's consent is often desirable. The consent process must be culturally and linguistically appropriate for the population under study. In addition to the language and content of the consent process, the nature and circumstances of the process are also important aspects of informed consent. All are critical to facilitating the potential participant's understanding of what has been disclosed and promoting the voluntariness of the participant's decision about whether or not to participate in the research.

When assessing the consent process, consider the following:

- Who conducts the consent interview? Have all who obtain consent been named on the IRB-approved protocol?
- What is the timing of obtaining informed consent? What is the process to assure that consent is obtained before research begins?
- How much time is devoted to the consent discussion? Does the process provide sufficient opportunity for participants to consider whether or not to participate? Is there a waiting

period between informing participants and obtaining consent?

- Does the consent process minimize the possibility of coercion or undue influence? Is the process free from excessive motivating factors?
- Is the process culturally and linguistically appropriate for the research population? Is the consent discussion in language that is understandable to participants? If potential participants speak languages that prevent direct communication with someone on the research team, are appropriate translation arrangements available?
- Is the discussion free of exculpatory language? Is information provided to participants in a way that does not waive (or appear to waive) any of the participants' legal rights or release (or appear to release) the investigator, sponsor, or institution from liability for negligence?
- For research involving protected health information, is HIPAA research authorization obtained?
- If a legally authorized representative will provide consent, is it clear who can serve as a legally authorized representative for research participants?

If the consent process involves participants who are likely to be vulnerable to coercion or undue influence (e.g., pregnant women, prisoners, children, or adults unable to consent), also consider the following:

- Have additional safeguards been included to protect these participants?
- For research involving pregnant women, are women (and/or fathers if providing consent) fully informed regarding the reasonably foreseeable influence of the research on the fetus? Is it clear which risks (if any) apply only to the woman?
- For research involving prisoners, are procedures for obtaining consent immune from arbitrary intervention by prison authorities or other prisoners? Are prisoners clearly informed in advance that participation in research will have no effect on possible parole?
- For research involving children, if assent is obtained, does the assent process provide children sufficient opportunity to make voluntary decisions about participation, considering their ages, maturity, condition, and psychological/emotional states? Is assent language appropriate, based on the nature of the study and the expected capacity of child participants to understand the purpose and procedures involved in the research?
- For research involving adults unable to consent, if assent is obtained, does the assent process provide potential participants sufficient opportunity to make voluntary decisions about participation, considering their condition and psychological/emotional states? Is assent language appropriate, based on the nature of the study and the expected capacity of participants to understand the purpose and procedures involved in the research? Are additional measures to further enhance comprehension needed?

CONSENT DOCUMENT

In most circumstances, informed consent is documented by use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative. Consent forms must include the required (and any applicable additional) elements of informed consent, unless the IRB approves either an alteration of consent, use of a short form stating that the elements of consent have been presented (in limited circumstances), or a waiver of the requirement for written documentation of the consent process.

When assessing the use of consent documents, consider the following:

- Does the consent document include the basic and appropriate additional elements of consent? Is the consent document written in language that is understandable to the participant?
- Who will sign (and date) the consent document? How will the person signing receive a copy?
- How much time is allotted for signing the consent document? Is adequate opportunity provided for participants to read consent forms before they are signed?
- Is the consent form free of exculpatory language? Is the document free of language that waives (or appears to waive) any of the participants' legal rights or releases (or appears to release) the investigator, sponsor, or institution from liability for negligence?
- Is all contact information (e.g., names, phone numbers) on the consent form current and accurate?

- Has the appropriate version of the consent form (i.e., including all IRB-approved revisions) been used? For non-English speaking participants, have appropriately translated consent forms been used?
- For research involving protected health information, has a HIPAA research authorization form been used?
- Are the study population and number of participants who signed consent forms consistent with the study population and number of participants approved by the IRB?

WAIVER OF WRITTEN DOCUMENTATION

When the requirement for written documentation of consent is waived, a written description of the information that will be provided to participants (i.e., a “script”) is required. This information must include the basic elements of informed consent and any applicable additional elements, unless an alteration of consent has also been approved by the IRB.

When research involves waiver of consent documentation, consider the following:

- Does the consent script include the basic and appropriate additional elements of consent?
- If a written statement regarding the research is given to participants, is all contact information (e.g., names, phone numbers) or other information current and accurate?

RECORD-KEEPING AND RETENTION

Original, signed consent forms and other records related to the research should be stored confidentially and in a secure location for at least three years after completion (or cancellation) of the research, unless a longer retention period is required by other applicable University policy or contractual agreement.

Review your research-related records for the following, *as applicable to the research*:

- ☐ Original, signed (and dated) consent forms
- ☐ Original, signed (and dated) parental permission forms
- ☐ Original, signed (and dated) translated consent forms for non-English speaking participants
- ☐ Original, signed (and dated) assent forms for child participants
- ☐ Original, signed (and dated) assent forms for adults unable to consent
- ☐ Original, signed (and dated) HIPAA research authorization forms
- ☐ All versions (current and previous, if any) of IRB-approved consent forms
- ☐ All versions (current and previous, if any) of IRB-approved consent scripts
- ☐ All versions (current and previous, if any) of IRB-approved parental permission forms
- ☐ All versions (current and previous, if any) of IRB-approved translated consent forms
- ☐ All versions (current and previous, if any) of IRB-approved assent forms
- ☐ Information sheets, contact cards, etc. provided to participants (for waivers of documentation)
- ☐ Information sheets or other tools used to enhance comprehension
- ☐ IRB approval letters corresponding with each approved consent form, script, or other document used in the consent process