

Human Research Protection Program Policies & Procedures



Consent Forms: Assurance of the Required Elements of Informed Consent

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Background:

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. The Common Rule (45 CFR 46) establishes standards for informed consent. The FDA also has informed consent requirements for FDA-regulated research activities.

Informed consent involves an interactive discussion between the subject or representative and the investigators, not just a document. However, the informed consent document is essential in memorializing the consent process and must contain evidence that all relevant information has been provided to the subject or representative in a manner consistent with regulatory and ethical requirements.

Scope:

This policy provides a description of the required elements of informed consent and explains IRB review of the informed consent process. Additional issues regarding Informed consent for research involving special or vulnerable populations are discussed in a separate policy.

I. Policy

- A. Legally effective informed consent must be obtained before a subject undergoes any research interventions. Legally effective informed consent requires that the basic elements of informed consent at 45 CFR 46.116, and additional elements when appropriate, are included in the consent form, unless a waiver or alteration is approved by the IRB (see Appendix A). Additional elements of informed consent are not required for minimal risk studies. There are two times when consent may not be required to be obtained:
 1. Under an IRB-approved waiver of consent and authorization
 2. In emergency research that allow exception to informed consent.
- B. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
- C. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.
- D. The consent form should have language that minimizes the possibility of coercion or undue influence.

- E. The consent form should have appropriate signature spaces to document the legally effective informed consent of the subject or the subject's legally authorized representative as required by the IRB and the law.

II. Procedure

A. The PI Submits the Consent form(s) to IRB for Review

1. The eIRB submission should include all proposed consent and assent forms.
2. The documents should be developed using the consent form creation guidelines, the appropriate template forms and appropriate liability language. Templates for various types of studies are available on the IRB Forms website and contain all required standard language.
3. The consent form(s) should include all of the required elements of informed consent and any relevant additional elements, unless a waiver or an alteration is requested. Requests for waiver or alteration of the informed consent process should be made in accordance with the OHSU IRB policy on this topic.
 - a. Additional elements of informed consent are not required for minimal risk studies.
 - b. For greater than minimal risk studies, the PI should provide justification for excluding any of the additional elements of informed consent and the IRB will consider it.

B. ORIO Analyst review

During the initial evaluation/administrative review process, an IRB Analyst will review the proposed informed consent process or proposed modifications to the process. The Analyst will:

1. Validate that the informed consent process is described in IRB applications.
2. Validate that the required elements of informed consent are included in the consent documents submitted and that all required template language is present.
3. Review the document for understandability, readability and consistency.

C. IRB review

1. The full board or the expedited reviewer reviews each consent form and request for waiver or alteration of consent or waiver of the requirement to document consent.
2. The IRB reviews to ensure that the consent form is understandable by verifying that:
 - a. Technical and scientific terms are adequately explained or that common terms are substituted.
 - b. The informed consent document properly translates complex scientific concepts into simple concepts that the typical subject can read and comprehend.
 - c. The purpose statement is clear and simply stated.
 - d. The Procedures are accurate and clearly explained. Visual guides may be requested for complex processes.

- e. The stated risks accurately represent those of the study and any drugs, devices or procedures involved.
- 3. The IRB removes statements of unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects. Overly optimistic representations are misleading and violate FDA regulations concerning the promotion of investigational drugs [21 CFR 312.7] or investigational devices [21 CFR 812.7(d)] as well as the requirement to minimize the possibility of coercion or undue influence [21 CFR 50.20].
- 4. The IRB removes all exculpatory language from the consent form(s).
- 5. The reviewer(s) confirm that all of the required elements of consent are satisfied.
- 6. The reviewer(s) confirm that, when necessary, the additional elements of informed consent are satisfied.
- 7. The IRB requires changes as necessary to approve the consent form(s).

D. Post review

- 1. The research team responds to the IRB requests and makes changes to the consent document(s) in order to secure approval.
- 2. The IRB approves the finalized forms and provides a stamp which indicates the approval and expiration date of the form(s). Consent forms may not be used without an IRB-approval stamp or past the indicated expiration date.
- 3. Approved consent forms must be used as indicated in an IRB-approved protocol to obtain informed consent for volunteers to participate in research.

Definitions

- A. **Coercion** - occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.
- B. **Informed Consent:** An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.
- C. **Informed Consent Templates:** Provide specific guidance on how consent documents should be worded and the order in which the information should be presented, as well as required language. The OHSU IRB posts current templates for various types of studies on the [IRB Forms website](#).
- D. **Legally Effective Informed Consent** – for research purposes, is consent obtained in compliance with all of the legal requirements for informed consent, including content of the consent process and forms and signatures.
- E. **Undue Influence** - occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable. (Belmont Report)

- F. **Exculpatory Language** - language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Authority

45 CFR 46.116(a) & 21 CFR 50.25(a): Requirements for consent

45 CFR 46.116(b) & 21 CFR 50.25(b): Additional requirements for consent

Additional Resources

Consent Templates – IRB Forms Website

OHSU HRPP Policies & Procedures:

- Waiver or Alteration of Informed Consent, Documentation of Informed Consent, or Authorization
- Informed Consent for Special and Vulnerable Populations
- Obtaining and Documenting Informed Consent from Subjects with Limited English Proficiency
- Re-Consent and Notification
- Inclusion of Children in Research
- Inclusion of Adults who Lack Decision-Making Capacity in Research

[OHRP Examples of Exculpatory Language in Informed Consent \(1996\)](#)

[OHRP Informed Consent FAQs](#)

[OHRP Informed Consent Tips](#)

APPENDIX A - §46.116 & 21 CFR 50.25

GENERAL REQUIREMENTS FOR INFORMED CONSENT.

- 1.)** A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of an procedures which are experimental;
 - a.)** A description of any reasonably foreseeable risks or discomforts to the subject;
 - b.)** A description of any benefits to the subject or to others which may reasonably be expected from the research;
 - c.)** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - d.)** A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - e.)** For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
 - f.)** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 - g.)** A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- 2.)** Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
 - a.)** A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 - b.)** Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - c.)** Any additional costs to the subject that may result from participation in the research;
 - d.)** The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 - e.)** A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
 - f.)** The approximate number of subjects involved in the study.