

Series 502 Informed Consent | Institutional Review Board

The Institutional Review Board from Series 502 of Informed Consent

I. Informed Consent

Informed Consent is a process that begins with the recruitment of a participant, and continues through (and sometimes beyond) that person's involvement with the research. It requires the research team to provide specific information about study participation in a way that is understandable to those prospective participants, to answer questions to ensure that participants understand the research and the role they are being asked to play, giving participants sufficient time to consider the information and their own decisions, and then finally obtaining the voluntary agreement of participants to enter into the study. This is, perhaps, the most important application of the Belmont Report principle of Respect for Persons.

Informed Consent is not the same thing as consent. Consent merely gives permission; informed consent gives permission after all of the relevant information has been disclosed and digested. Informed Consent is both the process of sharing all relevant information with participants, as well as the associated documentation utilized by the research team to provide a record that the process took place.

II. Informed Consent in Exempt Studies

Whenever a study involves prospective interaction with participants, researchers should seek informed consent prior to participation. In Limited IRB Review processes (resulting in an Exemption determination), this can be effectuated by including the following minimum information to participants with whom there is prospective interaction: that the activity involves research, a description of the research procedures, that participation is voluntary, risks and benefits of participation, the name and contact information for the researchers and the IRB, and a disclosure of the provisions made to maintain the privacy of participants and confidentiality of their information.

Participants should provide informed consent prior to participation; in cases where a participant cannot render legally effective informed consent, they should still be given a separate opportunity to assent to the research procedures. Coercion or undue influence must be minimized in a participant's decision-making process. All information should be made available in a manner easily understood to the participants.

III. Informed Consent Requirements in Non-Exempt Studies

In order to gain approval for a non-exempt human subjects research study, certain requirements must be found and documented by the Primary and Secondary reviewers. Waivers and Alterations are addressed in subsequent sections of this SOP.

1. The Informed Consent Process

The IRB must find and document that the process for obtaining informed consent meets each of these requirements:

- a. Each participant (or their legally authorized representative [LAR]) will render legally effective informed consent
- b. The circumstances of seeking informed consent permit the prospective participant and/or their LAR sufficient opportunity to discuss the research
- c. The circumstances of seeking informed consent permit the prospective participant and/or their LAR sufficient opportunity to consider whether or not to participate
- d. The circumstances of seeking informed consent minimize the possibility of coercion or undue influence
- e. The information given to the prospective participant and/or their LAR is easily understandable to the prospective participant and/or their LAR
- f. The information given to the prospective participant or their LAR is everything a reasonable person would want to have in order to make an informed decision about whether to participate
- g. The information given to the prospective participant or their LAR is everything a reasonable person would want to have in order to ask questions and discuss participation with people outside of the research team (i.e. family members, close friends, guardians, etc.)
- h. Both the process and the document are designed to facilitate understanding of the project, but especially why one might want to participate or why one might not want to participate
- i. The information described in the next section will be provided to the participant and/or the LAR, and they will have an opportunity to retain a copy of this information. In online settings, a download link is strongly recommended to meet this requirement
- j. When the research is a clinical trial supported by a federal agency, or when researchers choose to recruit using clinicaltrials.gov, the informed consent documentation used to enroll participants must be posted to clinicaltrials.gov within 30 days of the enrollment of the last participant.

2. The Informed Consent Documentation

Documentation for informed consent must meet certain minimum requirements. These considerations are in addition to the considerations regarding the informed consent process outlined in Section III.A, above. The information provided in the informed consent document must comply with each of the following requirements:

- a. If the document spans four or more pages for a sponsored project or clinical trial, it must begin with a concise presentation of key information explaining why someone might or might not want to participate in this research study
- b. No exculpatory language that waives or appears to waive any legal rights may appear in the informed consent document
- c. No exculpatory language that waives or appears to waive liability for negligence for the researchers, the sponsor, or the institution may appear in the informed consent document
- d. A statement that the study is research must appear
- e. The expected duration of participation must be disclosed
- f. A description of all procedures the participant will be asked to complete or participate in must be disclosed
- g. The document must identify any procedures that are experimental
- h. There must be a description of any foreseeable risks or discomforts to the participant
- i. There must be a description of any benefits to the subject that may reasonably be expected to result from the research
- j. A description of any benefits to others that may reasonably be expected to result from the research must be included, if applicable
- k. There must be a full disclosure of appropriate alternative procedures that might be advantageous to the participant
- l. There must be a full disclosure of any appropriate courses of treatment that might be advantageous to the participant
- m. A statement describing the extent to which confidentiality of records identifying the subject will be maintained must be included
- n. If the research is greater than minimal risk, the document must contain a disclosure regarding whether compensation is available if injury occurs (if so, the method of compensation and where to go to obtain more information about compensation)
- o. If the research is greater than minimal risk, the document must contain a disclosure regarding whether medical treatment is available if injury occurs (if so, what kind of medical treatment and where to go to obtain more information about the medical treatment)
- p. A contact person must be listed for answers to questions about the research
- q. A contact person must be listed for answers to questions about research participants' rights
- r. A contact person must be listed in the event of a research-related injury, regardless of level of risk
- s. A statement must be included that participation is voluntary
- t. A statement must be included that refusal to participate will involve no penalty, and no loss of benefits to which the participant is otherwise entitled
- u. The document must include a statement that the participant may discontinue participation at any time with no penalty, and no loss of benefits to which the participant is otherwise entitled
- v. A disclosure must be made regarding whether the research team intends to de-identify and share or use the data/information/biospecimens collected here for future research
- w. When appropriate, at the judgment of the Primary and Secondary Reviewers, the following information must also be disclosed:
 1. Whether a procedure involved carries risks to the subject or fetus (or fetus if likely to become pregnant) that are currently unforeseeable
 2. Circumstances under which participation may be terminated by the researchers without regard to a participant's consent to be withdrawn
 3. Any additional costs to the participants that may result from participation in this research
 4. Consequences of withdrawal
 5. A process for withdrawal

6. Significant new findings that may develop over the course of the research that may relate to a participant's willingness to continue, and how those will be provided to the participant
7. The approximate number of participants who will participate in the study
8. A statement regarding whether biospecimens (identifiable or not) used in this research may be used for commercial profit. If so, whether the participant will or will not share in the commercial profit.
9. Whether clinically relevant research results will result from this research, and if so, whether they will be disclosed, and if so, under what conditions
10. Whether whole genome sequencing is used

IV. Waivers of Documentation

When certain circumstances are present, a waiver of documentation for the informed consent process may be available. A waiver of documentation of informed consent means that all of the required processes listed in Section III.A are met, and documentation will be given to the participants (or their LARs) including all of the information in Section III.B. The only difference is that a signed and dated document will not be collected from the participant or their LAR. The subsections below outlined the different circumstances where a waiver of documentation of informed consent is appropriate, along with the criteria a project must meet for the waiver to be granted. IRB member reviewers are required to find and document that these criteria are met, using the Reviewer's Checklist, before a waiver can be granted.

1. **The Only Record of Participation is Informed Consent Documentation**

The IRB may waive the requirement for the investigator to obtain a signed informed consent document from some or all participants if it finds that the only record linking the subject and the research would be the informed consent document, and:

- a. The principal risk in the research is from a breach of confidentiality; and
- b. All participants will be given an opportunity to sign an informed consent document if they want to, and their preference will govern.

This requires that investigators develop a process that permits participants to sign and date a document, if they choose to. Participants that choose not to should be given all of the information outlined in Section III.B, above, without a requirement sign their name and provide a date.

2. **Written Consent would Not Be Required Outside of Research Context**

When the research presents no more than minimal risk of harm, the IRB may waive the requirement for the investigator to obtain a signed informed consent document from some or all participants if it finds that the research involves no procedures for which written consent would normally be required outside of the research context. Investigators should provide examples of the procedures that would not normally require written consent in their protocol submission form when selecting this waiver category.

3. **Distinct Cultural Setting**

When the research takes place in a distinct cultural setting where signing an informed consent document would not be the norm, the IRB may waive the requirement to obtain written, signed, and dated informed consent. The IRB member reviewer must find and document that signing forms is not the norm in that distinct cultural context, that the research presents no more than minimal risk of harm to participants, and that there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Waivers or Alteration of the Requirement to Obtain Informed Consent

When certain circumstances are present, a waiver of all requirements related to informed consent may be appropriate. From time to time, a full waiver would not be appropriate, but an alteration of the requirements to obtain informed consent might be. The circumstances and their accompanying requirements are detailed in the subsections below.

1. a. Public Benefit or Service Program Research Conducted by State or Local Officials

The USU IRB may waive or alter the requirement to obtain informed consent for research for demonstration projects that are conducted by or subject to the approval of state or local government officials if the research is designed to study, evaluate, or otherwise examine:

1. Public benefit or service programs;
2. Procedures for obtaining benefits or services under these programs;
3. Possible changes in or alternatives to those programs or procedures; or
4. Possible changes in methods or levels of payment for benefits or services under those programs.

In addition, the research must not be able to be practicably completed without the waiver or alteration.

b. General Waivers & Alterations

The USU IRB may waive or alter the requirement to obtain informed consent for research if the IRB member reviewer (or Convened IRB) finds and documents that:

1. The research involves no more than minimal risk to participants;
2. The research could not practicably be carried out without the waiver or alteration being requested;
3. (If the research involves using identifiable private information or identifiable biospecimens) the research could not practicably be carried out without using such information or biospecimens in that format;
4. The waiver or alteration will not adversely impact the rights and welfare of the participants; and
5. Whenever appropriate, the participants or their LARs will be provided with additional pertinent information after participation.

c. Screening & Eligibility

No waiver is required for investigators to obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants (subject to other laws and regulations regarding privacy) if one of the two following situations describe those activities. Otherwise, either informed consent or a waiver/alteration of informed consent should be requested:

1. The investigator will obtain information through oral or written communication with the prospective participant; or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The screening or recruitment activities must be limited to only the information or biospecimens that are necessary to determine eligibility or conduct recruitment activities. Otherwise, either a waiver of informed consent is needed, or informed consent must take place before the screening and recruitment activities.

d. Deception, Misinformation, or Incomplete Information

If the IRB member reviewer finds and documents that the use of deception, misinformation, or incomplete information provision (commonly referred to with the umbrella term “deception”) to participants is necessary to achieve the scientific aims outlined in the protocol submission, investigators may be permitted to use these tactics to design their informed consent processes and documents. This is generally accomplished using an alteration of the informed consent process. The alteration permits researchers to provide full information about the study at a later time; generally, following study participation. If the research team does not wish to provide full information to participants at a later time, a waiver (rather than an alteration) should be requested. The general requirement for using deception, misinformation, or incomplete information with participants is that participants will be debriefed regarding the deceptive practice. They will also be given an opportunity to withdraw their data after receiving full information about the study. The debrief materials should be provided in the protocol submission alongside the informed consent documentation that will be utilized. This requirement can be waived when appropriate, at the discretion of the IRB member reviewer and HRP staff.