Valparaiso University
Institutional Review Board (IRB)
Office of Sponsored and Student Research

INSTITUTIONAL REVIEW BOARD (IRB)
CONSENT AND ASSENT

1. Purpose

Obtaining informed consent – and assent from minors and others unable to provide consent – is a cornerstone of human subjects research. The ethical treatment of human subjects involves many aspects of respect and autonomy along with a lack of coercion (Belmont Report). Investigators must assure that research participants are treated in accordance with ethical standards and applicable laws and regulations.

2. Informed Consent

Informed consent is the process of telling potential research participants about the key elements of a research study and what their participation will involve. The consent process typically includes providing a written consent document containing the required information (i.e., elements of informed consent) and the presentation of that information to prospective participants.

The Principal Investigator (PI) must obtain the legally effective informed consent (i.e., signature) of the participant or the participant's legally authorized representative unless the IRB waives this requirement (see #3 below).

The prospective participant or the representative must be given sufficient opportunity to consider whether to participate. The PI and the investigative team should take measures to minimize the possibility of coercion or undue influence.

The information that is given to the participant or the representative should be in language and at a literacy level understandable to the participant or the representative.

No informed consent, whether oral or written, may include language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the PI, the sponsor, the institution or its agents from liability for negligence.

The following information must be conveyed to each participant:

- A statement that the study involves research and an explanation of the purposes of the research;

- The expected duration of the participant's involvement;
- A description of the procedures used and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participant or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent to which confidentiality of records identifying the participant will be maintained;
- Instructions on whom to contact in the event of a research-related injury or other harmful event;
- An explanation as to whether any compensation and medical treatments are available if an injury or other harmful event occurs; specifically explaining what the compensations are and if/when further information may be obtained;
- Instructions on whom to contact for answers to pertinent research questions and research participants' rights; and
- Statements that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Signed consent forms must be retained as part of the research project's files.

The process for obtaining consent and the informed consent documents must be included in the application for IRB review. The Valparaiso University standard consent form template approved by the IRB can be found here.

In the event that a participant or representative has questions, concerns or complaints regarding their experience in the research project, they should be directed to the contact information on the consent form. The responsible parties should respond to the participant/representative in a timely manner, providing information and resources that

address the concerns presented. If significant, the concerns should be reported to the IRB Chair for consideration by the IRB regarding possible hazards or breach of protocol.

3. Waiver of Informed Consent

In most cases, investigators are expected to obtain a signature from the participant on a written informed consent document unless the IRB issues a waiver. The IRB may:

- Waive the requirement to obtain informed consent, or
- Alter some or all of the elements of informed consent, or
- Waive the requirement to document informed consent (i.e., to obtain a signature).

For research that is no more than minimal risk, the IRB may waive some or all of the required elements of informed consent under specific circumstances. Waivers of informed consent are primarily requested for projects involving the secondary analysis of existing data or in projects involving deception. To waive in total or to alter informed consent elements, the IRB must determine that:

- The research involves no more than minimal risk to subjects;
- The research could not be carried out practicably without the waiver or alteration;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**,
- Where appropriate, the subjects will be provided with additional information about their participation.

4. Waiver of *Documentation* of Informed Consent

For some research projects, the IRB may approve a request to waive the *documentation* of informed consent. The investigator must provide subjects with the required consent information, but is not required to obtain the subject's signature on the informed consent document. Subjects should be offered a copy of the consent information for their records even when a signed document is not required for the project.

A waiver of documentation is permissible when:

- The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of

confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities;

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online, or
- Where the participants are members of a cultural group in which signing forms is not a normal/acceptable practice.

It is not appropriate to request a waiver of documentation of informed consent for human subject projects that collect biospecimens.

5. Assent

When a research project involves children/teens under the age of consent (age 18 in Indiana) or adults lacking the capacity to give informed consent, the participant's assent is sought. The assent process assures that participants understand the research and what it means to participate. The process for obtaining assent and any related documents must be included in the application for IRB review.

Upon reviewing the proposed research protocol and the characteristics of the research subjects, the IRB will decide whether child assent is required. Generally, the IRB will require child assent unless it can be appropriately waived, or if the child is not capable of providing assent.

The regulations at 45 CFR 46.408(a) identify three types of circumstances where the IRB may determine that waiver of children's assent is appropriate:

1. if the capability of some or all of the children is so limited that they cannot reasonably be consulted;
2. if the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.
3. if the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(c) or 45 CFR 46.116(d).

The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, the IRB should decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent's assent. If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not warranted.

6. **Parental/Guardian Permission**

Parental/guardian permission is generally required for children to participate in a research study. The term "parent" means a "child's biological or adoptive parent." The term "guardian" means "an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care." The IRB may approve a waiver of parental permission in certain circumstances (see 45 CFR 46.116(c) or (d)).

Parental permission should be documented in a manner similar to that used to document informed consent. The process for obtaining parental permission and the way it will be documented must be included in the IRB application for review.

In general, permission should be obtained from both parents before a child is enrolled in research. However, the Institutional Review Board (IRB) may find that the permission of one parent is sufficient for research to be conducted under 46.404 or 46.405. When research is to be conducted under 46.406 and 46.407 permission must be obtained from both parents, 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.