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1. PURPOSE


1.1. This policy establishes the informed consent and assent process.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

- 3.1. Respect for persons requires that potential subjects, to the degree that they are capable, be given the opportunity to choose what shall happen to them. The informed consent process is the primary mechanism by which respect for persons is ensured. Unless otherwise approved or directed by the IRB, informed consent must be prospectively obtained.
- 3.2. Consent shall be sought only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- 3.3. Except as described at SOP IRB-210 no investigator may involve a human being as a research subject unless he or she has obtained legally effective authorization of the subject or the subject's legally effective representative.
- 3.4. Except as described at SOP IRB-210, the IRB requires documentation of informed consent by use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.
- 3.5. For purposes of HIPAA, authorization may be obtained by the use of a separate HIPAA Authorization Form, or combined with an IRB-approved informed consent document.
- 3.6. Except as described at SOP IRB-210, the consent form may be:
- 3.6.1. Written consent document that embodies the elements of informed consent and if necessary the required elements of HIPAA authorization. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. Each participant shall receive a copy of the signed consent document or signed combined consent authorization document.

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3.6.2. A "short form" written consent document stating that the elements of informed consent as required have been presented orally to the subject or the subject's legally authorized representative. The short form may be used when an investigator unexpectedly encounters a subject who does not speak English. When this method is used:

- The oral presentation and the short form written document should be in a language understandable to the subject; and
- There must be a witness to the oral presentation; and
- The IRB must approve a written summary of what is to be said to the subject (the approved full consent document may serve as this summary); and
- The short form document is signed by the subject;
- The witness must sign both the short form and a copy of the summary; and
- The person actually obtaining consent must sign a copy of the summary; and
- A copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

3.7. As part of the IRB's reviews to determine that the approval criteria found in the regulations at 45 CFR 46.111 and 21 CFR 56.111 have been met, the IRB reviews the consent form and determines that the form meets the applicable regulatory requirements as follows:


(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 any procedures which are experimental or investigational.

(2) A description of any reasonably foreseeable risks or discomforts to the subject, if any.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research, if any.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent to which, if any, the confidentiality of records identifying the subject will be maintained and that notes the possibility

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that the Food and Drug Administration and representatives of the IRB may inspect the records.

(6) For research involving more than minimal risk, or if the research proposes compensations for research related injury, 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. The informed consent document must not waive or appear to waive the rights of the participant or release or appear to release those conducting the study from liability for negligence.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject.


(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

3.7.1. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) 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.

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(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) 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

(6) The approximate number of subjects involved in the study.

3.7.2. When appropriate) (45 CFR46.116(c))

(1) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(2) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;

(3) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).


3.8. Other Requirements

3.8.1. The IRB consent template must be used, unless the IRB grants an exception.

3.8.2. The IRB has the authority to observe or have a third party observe the consent process and any other research procedures at any time.

3.8.3. Lay Language

- The information provided in the informed consent documents must be in language understandable to the subject. The informed consent document should not include complex language that would not be understandable to all participants. Technical and scientific terms should be adequately explained using common or lay terminology.

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3.8.4. Exculpatory Language

- Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights or releases or appears to release the investigator, the sponsor, the university from liability for negligence.

3.8.5. FDA-Regulated Test Articles

- For all research involving test articles regulated by the U.S. Food and Drug Administration (FDA), informed consent documents should include a statement that the purpose of the study includes evaluation of the safety or the safety and the effectiveness of the test article. The consent form must also include a statement that the FDA has access to the subject's medical records.

3.8.6. Translated Consent Documents


- When applicable: translations of consent documents will also be submitted for IRB approval and will be reviewed in an expedited manner. The investigator (or sponsor) may submit documentation to the IRB attesting to the consent document is a true and accurate translation.

3.9. Assent for Minors

3.9.1. In the State of Wisconsin, only individuals 18 years or older may legally consent to participate in research. Individuals who do not have this authority to consent must still provide assent. "Assent" is an active affirmation to participate in a research study. If the individual giving assent is able to read and write, then assent should be documented using the IRB Assent template; otherwise, assent should be obtained through dialogue with the subject. The assent discussion and form should be in language understandable to the subject and contain the same elements as those stated under "Informed Consent Process and Documentation." See IRB website for information regarding assent and parental permission templates.

3.10. IRB Review of Research Involving Informed Consent by a Legally Authorized Representative

3.10.1. When the proposed research involves individuals who may not be able to provide informed consent for themselves, the IRB reviews the research to ensure the rights, welfare, and autonomy of those individuals are respected.

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Wisconsin state law allows, under certain specific situations, designated persons to provide substituted judgments for others who may not be completely able to provide informed consent for themselves, specifically parents of minor children and legally appointed guardians. When reviewing research with vulnerable populations, including adults with diminished cognitive capacity and the potential need for other persons to provide consent for subjects, the IRB may seek legal counsel opinion or expert consultation from neuropsychologists or other professionals.