INFORMED CONSENT PROCESS FOR HUMAN SUBJECT RESEARCH

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
It is the Investigator responsibility to obtain legally effective and prospective informed consent from research subjects as required by federal regulation, tribal law passed by the official governing body of an American Indian or Alaska Native tribe and institutional policies.

DEFINITIONS:
Assent: an affirmative agreement to participate in research project. The failure to object should not, without an affirmative agreement, be construed as assent.

Consent: refers to an explicit agreement to participate in a certain action, particularly and especially after thoughtful consideration.

Coercion: the use of force or intimidation to persuade someone to do something which they are unwilling to do.

Exculpatory language: language that waives or appears to waive any of the subject's legal rights or attempts to prospectively remove responsibility from the Sponsor or project team.

Impartial witness: Per International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP): A person, who is independent of the project, who cannot be unfairly influenced by people involved with the project, who attends the informed consent process if the subject or subject's legally acceptable representative cannot read, and who reads the consent form and any other written information supplied to the subject.

Legally Authorized Representative (LAR):

PROCEDURE:

Investigator Responsibilities

1. Investigators must provide the information regarding the consenting process to the IRB for review.
    a. A detailed description of the intended method for obtaining initial informed consent
    b. All informed consent documents (full written documents, oral scripts, a list of talking points, videos, comprehension materials, any type of comprehension or assessment aids, and short forms)
    c. Assurance that the informed consent process is an ongoing exchange of information between the project team and the project participants throughout the course of a project. Informed consent is a continuous process of communication and acknowledgement over time, not just a signed document.
2. The consenting process may begin after the Investigator has provided the necessary information and documents to the MCW IRB and received approval by the MCW IRB. *See IRB SOP: Informed Consent Document for Human Subject Research.*
3. Any changes in the informed consent documents or process must be must submitted via an amendment to the MCW IRB for review and approval prior to implementing the change
4. The informed consent process must:
    a. Begin with a concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the project. This subsection must be organized and presented in a way that facilitates comprehension.
    b. Be obtained in circumstances that minimize the possibility of coercion and undue influence;
    c. Utilize language to promote the subject's understanding of the information;
    d. Provide the essential information a reasonable person would want to have in sufficient detail and organized to facilitate the prospective subject's understanding of the reasons one might consider in order to make an informed decision about whether to participate in project and provide an opportunity to discuss that information
    e. Allow sufficient time for consideration of the information and decision regarding participation
    f. Not waive or appear to waive subjects' rights; and
    g. Include each of the required elements and applicable additional elements of informed consent describing the project and the nature of research participation as required by federal regulations, tribal laws, institutional policies and approved by the IRB.
    h. Include a discussion regarding the use and retention of data, if they choose to withdraw from a project. *See IRB SOP Withdrawal of Informed Consent for Human Subject Research.*
5. The consent form may be read to the subject, but it is not a requirement.
6. In accordance with institutional policy research subjects must sign & date the informed consent document. A potential research subject's agreement to participate in a research project is documented by the subject indicating their approval by signing and dating the consent document which includes, where appropriate, the HIPAA authorization information unless the project has received approval for waiver of consent, a waiver of documentation of consent or a waiver of HIPAA authorization from the IRB.
    a. If the subject is capable of written assent but not consent, the legally authorized representative (LAR) must provide written consent. A signature line for the

subject must also be included. *See IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability.*

7. In the event the consent process includes remote consent process (an platform such as Zoom) and/or an electronic consent, electronic signatures are allowed for consent documentation. A written copy must be given to the person signing the electronic consent form.
    a. Investigators must describe in their IRB application the remote consent process along with identifying any platforms and tools which will be used to faciliate the consent process.
8. If a waiver of documentation or waiver of informed consent is requested and approved by the MCW IRB, this section does not apply, and will be discussed further in this document.

ADDITIONAL CONSIDERATIONS WHEN OBTAINING INFORMED CONSENT:
Research involves Adult Subjects with Decreased Decisional Ability
Depending on the proposed research, Investigators must identify when the research will include individuals with decreased decisional ability in their eBridge SmartForm.

Investigators should will provide a description of the project population and the consenting/assenting process in their application and address the requirements outlined in *IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional ability.*

Research includes the treatment of mental illness, developmental disability, alcoholism, or drug dependency
If the focus of the project includes the treatment of mental illness, developmental disability, alcoholism, or drug dependency, Investigators must include a plan to reconsent subjects every 15 months per Wisconsin state law.

Research includes ICH GCP guidelines
When following ICH GCP e6 the consenting process includes additional activities.

1. The individual conducting the informed consent process must sign and date the consent form.
2. An impartial witness should be present during the entire informed consent discussion if a subject or the LAR is unable to read due to decreased vision, literacy level, or language barrier. The witness must witness the consenting process not just the documentation of informed consent.
3. The witness should sign and personally date the consent document after:
    a. the written consent document and any other written information to be provided to the subject has been read and explained to the subject or their LAR, and
    b. after the subject or the subject's LAR has orally consented to the subject's participation in the research project, and
    c. if capable of doing so, the subject or LAR has signed and personally dated the consent document.
4. By signing the consent document, the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject's LAR, and that consent was freely given by the subject or the subject's LAR.
5. The subject or their LAR must receive a copy of the signed and dates consent form and any other written information provided to the subject and/or LAR.

6. Unless specifically waived by the MCW IRB, informed consent is documented in writing through the use of the currently IRB-approved informed consent document signed and dated by the subject or by the subject's LAR prior to enrollment or participation in the project.

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authorized representative, and the PI must include a description regarding how the research will benefit the individual subject.
The convened IRB will make a final determination if research is intended to be beneficial to the individual experimental subject.

- The Assistant Secretary of Defense for Research & Engineering may waive the requirement of consent when all of the following elements have been met:
  The research is necessarily to advance the development of a medical product for the Military Services.
  The research might directly benefit the individual experimental subject.
  The research is conducted in compliance with all other applicable laws and regulations

For additional information see *IRB SOP: Research Involving Department of Defense Funding and/or Military Participants.*

5. For research subject to Department of Education regulations, the IRB will follow the requirements of the Family Educational Rights and Privacy Act (FERPA) when considering whether it may grant exceptions to parental/student consent to release of records for research
   - In addition, the Investigator must ensure the project complies with and follows the requirements set forth the Protection of Pupil Rights Amendment, for research seeking a waiver of consent involving students.

Waiver of Documentation of Consent

1. For certain types of projects, the investigator may request IRB approval for a waiver of documentation of consent (45 CFR 46.117(c) and 21 CFR 56.109(c)(1)). Whenever the IRB approves a consent process involving waiver of documentation of consent, the IRB will need to approve a written description of the project that also contains all of the elements of consent. This written description may be in the form of a script for verbal use, such as during a telephone conversation. However, the IRB may approve an alteration of consent if some elements are omitted. The IRB must always approve a waiver of documentation of consent and, where appropriate, a waiver of HIPAA authorization if the investigator will not obtain a consent document signed and dated by the subject or their LAR.
2. An IRB may waive the requirement for the investigator to obtain a signed and dated consent document for some or all subjects, if it finds:
   - That the subjects are members of a distinct cultural group or community in which signing forms is not the norm. This is limited to minimal risk research projects and requires an appropriate alternative method for recording that informed consent was obtained; or
   - That the only record linking the subject and the project would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the project, and the subject's wishes will govern; or
   - That the project presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the project context.
3. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the project. When the research involves an FDA-regulated product, the IRB may waive written consent only for research that meets federal regulations and guidance.

4. The MCW IRB considers the following points when assessing whether to approve waiver of documentation of consent:
    - Does the written description or script for presentation to the potential subject include the required elements of consent, and additional elements, if applicable?
    - Does the written description or script for presentation to the potential subject include the required elements of HIPAA authorization?
    - Does the written description or script include the requirement for the signature of the subject or their legally authorized representative?
    - If the written description or script is to be signed and dated by the subject or their legally authorized representative, and the consent process occurs by telephone, does the written description or scripts include the requirement for signature by a witness to confirm the identity of the subject?
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SUPPORTING DOCUMENTS:
IRB SOP Withdrawal of Informed Consent for Human Subject Research.
IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional ability
IRB SOP: Informed Consent Document for Human Subject Research
IRB SOP: Legally Authorized Representatives (LAR's): Who Can Consent on Behalf of an Adult Subject with Decreased Decisional Ability
IRB SOP: Emergency Use of Investigational Drugs, Devices and/or Biologics
IRB SOP: Planned Emergency Research
IRB SOP: Recruitment and Enrollment of non-English or Limited English Proficient Subjects
IRB SOP: Research Involving Children
IRB SOP: Research Involving Economically and Educationally Disadvantaged Persons
IRB SOP: Research with Pregnant Women, Fetuses and Neonates
IRB SOP: Research Involving Prisoners
IRB SOP: Research Involving Department of Defense Funding and/or Military Participants
MCW Informed Consent Templates

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