



MCW Office of Research Standard Operating Procedure

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): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. [45 CFR 46.102 (c) 21 CFR 50.3 (1)]

Reasonable Person: A phrase in law to denote a hypothetical person in society who exercises average care, skill, and judgment in conduct and who serves as a comparative standard by which to make a determination.

Undue Influence: (as a term in jurisprudence) is an equitable doctrine that involves one person taking advantage of a position of power over another person.

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 submitted via an amendment to the MCW IRB for review and approval prior to implementing the change. Please see *IRB SOP: Amendments* for exceptions to this requirement.
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 facilitate 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.

Consent for Subjects Who Demonstrate Limited Literacy

If the Investigator unexpectedly determines that a prospective subject demonstrates limited or a lack of literacy when discussing the project, the Investigator should:

1. Identify a literate adult person to work with the prospective subject and to serve as a witness to the consenting process
 - a. The Individual may not be a part of the project team
 - b. The individual may be a family member
2. Read and explain the entire consent to the subject or their LAR, and
 - a. Obtain the subject or their LAR's informed consent
 - b. After the subject or the subject's LAR have provided written informed consent (dated signature), obtain the witness's dated signature
 - c. Provide a copy of the signed ICF to the subject for future reference
 - d. Highlight the name and contact information in the consent form of a project team member who can be contacted at any time for information or help.
 - e. Document the process in their project records.

Investigators who anticipate to recruit and enroll more than 1-2 subjects who may have limited or a lack of literacy, Investigator must develop and describe in the eBridge submission their consent process for this subject population.

Consent for Subjects with Limited or No English Proficiency

- The investigator must include additional safeguards when consenting individuals with no or limited English proficiency in accordance with the *IRB SOP: Recruitment and Enrollment of Non-English or Limited English Proficient Subjects*.
- Guidance regarding the use of the Short Form or Translated Consent Documents is included in the *IRB SOP: Recruitment and Enrollment of Non-English or Limited English Proficient Subjects*.

Participants who cannot give consent or those with decreased decisional capacity.

Additional safeguards must be in place when obtaining consent for research involving children, fetuses, neonates, prisoners, adults with diminished decisional ability and those who are economically or educationally disadvantaged. Please review the IRB SOPs addressing these populations.

IRB SOP: Research Involving Children

IRB SOP: Research with Pregnant Women, Fetuses and Neonates

IRB SOP: Research Involving Prisoners

IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability

IRB SOP: Research Involving Economically or Educationally Disadvantaged Persons

Prohibited Elements

Initial and ongoing consent discussions must not include:

- Unproven claims of effectiveness or certainty of benefit, either implicit or explicit,

- Any exculpatory language through which the subject 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, or its agents from liability for negligence.

Waiver of Consent

1. The IRB may waive or alter the requirement for the investigator to obtain a potential subject's consent for participation. To approve such a waiver or alteration, the IRB must find:
 - The project involves no more than minimal risk to the subjects;
 - The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - The project could not practicably be carried out without the waiver or alteration; and
 - The project could not be carried out using deidentified data or specimens,
 - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
2. When considering a waiver of the consent process for Public Demonstration Projects, the IRB must find:
 - The research is conducted by or subject to the approval of state or local government officials
 - The research or demonstration project is designed to project, evaluate, or otherwise examine:
 - Public benefit or service programs
 - Procedures for obtaining benefits or services under those programs
 - Possible changes in or alternatives to those programs or procedures
 - Possible changes in methods or levels of payment for benefits or services under those programs
 - The research cannot be practicably carried out without the waiver of alteration
3. Greater than minimal risk research subject to FDA regulation may occur without prior consent of the subject in these circumstances:
 - When the research involves planned research in life-threatening emergent situations where obtaining prospective informed consent has been waived for some or all of the potential subjects, as provided by 21 CFR 50.24. The research plan must be approved in advance by FDA and the IRB, and publicly disclosed to the community in which the research will be conducted. For more information refer to *IRB SOP: Planned Emergency Research*
 - When the research involves an unplanned emergency use of an FDA regulated product for a single subject. The investigator is required to obtain informed consent of the subject or the subject's LAR as described in the *IRB SOP: Emergency Use of an Investigational Drug, or Biologic* or *IRB SOP: Emergency Use of an Investigational Device*.
4. The IRB may not waive the consent process for any research to be conducted under DoD regulations where the research is classified or if subject meets the DoD definition of an experimental subject. Research involving an experimental subject is defined as: An activity, for research purposes, where there is an intervention or interaction with a human subject for the primary purpose of obtaining the effect of the intervention or interaction.
 - A waiver of the consent process for such DoD regulated research requires permission of the Secretary of Defense.
 - If a waiver of consent is granted, the PI must identify their process to solicit and obtain consent from an experimental subject's legally

- 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?
 - Does the project involve no more than minimal risk, and would written consent be required for the project procedures if they were not part of a research project?

Consent Monitoring

1. The MCW IRB has the authority under institutional policy to observe or have a third party observe the consent process and the research.
2. In order to ensure that the consent process is appropriate and the IRB-approved process is being followed, the IRB may determine that additional monitoring of the process must occur. Such monitoring may be particularly needed for the IRB to meet its responsibilities to ensure human subject protections for research project that:
 - Involves a vulnerable population
 - Involves use of a high risk and/or innovative procedure or test article
 - Is conducted by an inexperienced investigator and/or project team
 - Is project about which the IRB has concerns that the consent process is not being conducted properly

REFERENCES:

21 CFR 50.24
21 CFR 56.109(c)(1)
45 CFR 46.117(c)

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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