



MCW Office of Research Standard Operating Procedure

INFORMED CONSENT DOCUMENT 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 prepare an informed consent document which incorporates the required elements and applicable additional elements as required by the Federal regulations, tribal law passed by the official governing body of an American Indian or Alaska Native tribe and institutional policies.

DEFINITIONS:

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.

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 a detailed description of the method for obtaining informed consent within the initial submission. As described in *IRB SOP: Informed Consent Process for Human Subject Research*, the eBridge SmartForm should include the following information:
 - a. Who (by title) will conduct the consent process;
 - b. Where and when the process will take place;
 - c. The process that will be followed;
 - d. Steps taken to minimize the possibility of coercion or undue influence;
 - e. How much time the potential subject (or the subject's legally authorized representative) will have to consider whether or not to participate;
 - f. How it will be determined that the potential subject (or the subject's legally authorized representative) understands the information presented;
 2. The informed consent document 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 research. This subsection must be organized and presented in a way that facilitates comprehension.
 - b. Utilize language to promote the subject’s understanding of the information;
 - i. The information provided in the informed consent documents must be in a language understandable to the subject (target population).
 - ii. Technical and scientific terms should be adequately explained using common or lay terminology.
 - iii. Generic names are preferable when describing pharmaceuticals unless the brand name is more commonly known and understood. Regardless of which name is preferred, it should be used consistently throughout the informed consent documents.
 - iv. Devices and procedures should also be described consistently throughout the documents and explained in simple language
 - c. 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 research and provide an opportunity to discuss that information
 - d. Not waive or appear to waive subjects’ rights; and
 - e. Include each of the required elements and applicable additional elements of informed consent describing the research and the nature of research participation as required by institutional policy
 - f. It is generally recommended that consent documents be written at a sixth to eighth-grade reading level
3. Investigators are responsible for incorporating the required, and if applicable additional elements, of informed consent and HIPAA standards into each informed consent document for their research studies.
4. Investigators are required to use the MCW IRB Consent Form Templates in their development of a consent form for use in research studies.
5. The consent document must include a provision for the research subject’s dated signature.
 - a. Additional signatures lines may be required per departmental policies or per a sponsor’s protocol.
 - b. If specific signature lines are required for the research but not identified in MCW Informed Consent Templates, Investigators must submit an *ICF Template Change Form* to the MCW HRPP Office prior to submitting for IRB review.
6. The required elements of informed consent may not be omitted unless specifically waived by the IRB.
7. In addition, there may not be discrepancies within the informed consent documents, the eBridge SmartForm, the Sponsor’s or Investigator’s Protocol, the Investigator’s Brochure, the grant and/or the contract regarding the purpose, foreseeable risks, and benefits of the research.
8. Investigators must include 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) in their application for review and must receive approval by the MCW IRB prior to use.
9. Investigator who wish to make any changes to the informed consent process or the documents after receiving initial IRB approval must submit an amendment to the MCW IRB for review and approval prior to implementing the change

Required Elements

The required elements of consent to be included in each informed consent document are:

- 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 research. This subsection must be organized and presented in a way that facilitates comprehension.
- A clear statement that the project involves “research”;
- Information that a “reasonable person” would want to have in order to make an informed decision and subjects must be provided an opportunity to discuss that information;
- Information organized and presented in sufficient detail to facilitate understanding of the reasons why one might or might not want to participate
- An explanation of the purposes of the research;
- The expected duration of the subject’s participation;
- A complete description of the procedures to be followed, and identification of procedures that are experimental and performed solely for the purposes of research;
- A description of the reasonably foreseeable risks and discomforts;
- A description of any benefits to the subject or others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject;
- When the research involves the collection of identifiable private information or identifiable biospecimens, the following statement must be included:
 - “The subject’s information or biospecimens will not be used or distributed for future research studies even if identifiers are removed unless additional consent is obtained or is waived by the IRB.”
- A description of the extent to which confidentiality of records identifying the subject and privacy will be maintained
- For research involving more than minimal risk, 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;
- An explanation of whom to contact for answers to pertinent questions about the research (e.g., Investigator), the research subjects' rights (e.g., HRPP Office), and whom to contact in the event of a research-related injury; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional Elements

The informed consent document should, where appropriate, include the following additional elements:

- A statement that 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;

- A statement indicating whether clinically relevant results, including individual research results, will be disclosed to subjects, and if disclosed under what conditions;
- A statement about whether the research project will or might include whole genome sequencing;
- For women of child bearing potential, a statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent;
- If there is the potential that costs of research procedures will not be paid by the sponsor or the subject's insurance, a description of any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 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;
- The approximate number of subjects involved in the project;
- The MCW IRB may require that information, in addition to that required by institutional policy, be given to research subjects when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
 - a. This may include if the research has a certificate of confidentiality and/or if data will be shared in accordance with NIH Data Sharing and Management policies.

ICH GCP additional elements

In addition to the required and if applicable additional elements consent forms for clinical investigations that follow ICH GCP guidelines must include these additional elements:

- Discussion of clinical trial treatments and probability of random assignment
- Subject responsibilities
- Anticipated prorated payment, if any, to the subject for participating in the clinical trial
- Information regarding the important potential benefits and risks of alternative procedures/courses of treatment
- Authorization to access medical records by regulatory authorities, the monitor, auditor and the IRB for verification of clinical trial procedures or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations.

Research involving test articles regulated by the U.S. Food and Drug Administration (FDA)

In addition to the required and if applicable additional elements, consent forms for clinical investigations that involve a test article (drug, device or biologic) regulated by the FDA must include these additional elements:

- A statement noting the possibility that the FDA may inspect the records that will be provided to each subject.
- A statement that a description of the clinical trial will be available on <http://www.clinicaltrials.gov> as required by US law.

- In studies that evaluate the safety of the test article, include the statement:
 - “A purpose of the project includes an evaluation of the safety of the test article.”
 - Statements that test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the project includes determination of safety.
- In studies that evaluate the effectiveness of the test article, include the statement:
 - “A purpose of the project includes an evaluation of the effectiveness of the test article.”
 - The consent document should not contain claims of effectiveness.
- Phase I Studies. Phase I studies are typically designed to determine safety, but not effectiveness. Phase I consent documents will include the approved Phase I template language that can be found within the “Clinical Interventions” ICF template.
- Phase II and Phase III Studies. Potential subjects should be told, and a statement included in the purpose of the informed consent document, that Phase II and III studies are designed to determine both safety and effectiveness.
- Phase II & III consent documents will include the approved template language that can be found within the “Clinical Interventions” ICF template

Other Federal Agency Requirements

Bureau of Prisons: In addition to the required elements and any applicable additional elements, research conducted within the Bureau of Prisons the consent form must include:

- Identification of the researchers.
- Anticipated uses of the results of the research.
- A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
- A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.

Department of Defense (DoD): In addition to the required elements and any applicable additional elements, consent forms for research funded or supported by the Department of Defense must include:

- A statement that the DoD or a DoD organization is funding the research project.
- A statement that representatives of the DoD are authorized to review research records.
- A statement as to whether any compensation, and/or whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.

Department of Justice (DOJ): In addition to the required elements and any applicable additional elements, consent forms for research supported by the Department of Justice must include the following statements:

- The name of the funding agency
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- Confidentiality may only be broken if the subject reports immediate harm to participants or others. The participant must be informed about any disclosure and the risk of harms from the disclosure.
- Investigators do not have to report child abuse unless the participant signs another consent form allowing the child abuse reporting
- In studies supported by the NIJ, the subjects must be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If the identity of the individual cannot be maintained the participants must be explicitly notified.

Department of Energy (DOE): In addition to the required elements and any applicable additional elements, consent forms for research supported by the Department of Justice must include the following statements:

- The identify of the sponsoring agency, unless the sponsor requests that it not be done, because
 - doing so could compromise intelligence sources or methods;
 - the research involves no more than minimal risk to the participants;
 - the IRB determines that by not disclosing the identity, the investigators will not adversely affect the participants.
- A statement that the project is classified and what it means for the purposes of the research.

Prohibited Elements

1. The informed consent documents may not contain 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.
2. In addition, informed consent documents may not contain any unproven claims of effectiveness or certainty of benefit, either implicit or explicit.
3. **Examples of Unacceptable Exculpatory Language:**
 - By agreeing to this use, you should understand that you would give up all claims to personal benefit from commercial or other use of these substances.
 - I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all rights, title, and interest to said items.
 - By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
 - I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Consent Documents for Subjects with Limited or No English Proficiency

IRB approved short form consents or translated consent forms must be used when consenting individuals with no or limited English proficiency. Please review the IRB SOP: *Recruitment and Enrollment of Non-English or Limited English Proficient Subjects*.

Requests to waive the requirement to obtain written documentation of informed consent

When requesting a waiver of the requirement to obtain written documentation of informed consent for FDA regulated research the investigator must provide:

- A written description of the information that will be provided to the participants, and
- Provide participants with a written statement regarding the research

Posting of Clinical Trial Consent Form

1. With the implementation of the revised common rule, federal regulations (45 CFR 46.116 (h) requires the posting of clinical consent forms on a publicly available federal website.
 - a. Posting of consent forms is required for two categories of clinical trials
 - i. Category 1 – Nonexempt clinical trials conducted or supported by HHS initially approved by an IRB on or after January 21, 2019
 - ii. Category 2 - Nonexempt clinical trials conducted or supported by HHS initially approved by an IRB before January 21, 2019 that continue on or after January 21, 2019 and both of the following are true:
 1. An institution transitions a clinical trial to comply with the 2018 Requirements in compliance with the transition provision (45 CFR 46.101(l))
 2. The transition determination was documented and dated by the IRB or institution before the timeframe specified in 45 CFR 46.116(h)(3) has passed (i.e., the clinical trial is closed to recruitment and 60 or fewer days before the last protocol-required study visit by any subject enrolled in the protocol)
2. Two federal websites have been identified as locations where consent forms can be posted to satisfy the federal regulations:
 - a. ClinicalTrials.gov
 - b. A designated docket folder on Regulations.gov

Each website has instructions on how to upload a clinical consent form.

3. Investigators must post one IRB approved unsigned consent form for each clinical trial on one of the federal website after the clinical trial is closed to recruitment and no later than 60 days after the last research visit by any subject.

REFERENCES:

OHRP Informed Consent Posting Instructions (2022)- General Instructions on the Informed Consent Posting Requirement (45 CFR 46.116(h))

SUPPORTING DOCUMENTS:

IRB SOP: *Recruitment and Enrollment of Non-English or Limited English Proficient Subjects*

MCW Informed Consent Templates

ICF Template Change Form

Effective Date: 07/01/2023
Version number: 2.0
Previous Version/date: 1.0, 06/15/2018
Responsible Office: HRPP Office
Approval Date: 05/29/2023

Approved By

HRPP Authorized Official: Ryan Spellecy, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin