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

a. Begin with a concise and focused presentation of the “key information” that is

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,

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 ae 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

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