SOP 402: Informed Consent

Terms and Abbreviations

CFR: Code of Federal Regulations
IRB: Institutional Review Board
IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually
OHRP: Office of Human Research Protections; a division of HHS that oversees human subjects research
Subject: For the purposes of this SOP, "Subject" refers to the subject and/or the subject's legally authorized representative. "Subject" may also be used interchangeably with "Participant".
UWM: University of Wisconsin – Milwaukee

Overview

The Belmont principle of 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. Before involving a human subject in research, an investigator must obtain the subject's informed consent.

The IRB reviews the informed consent process and documents that Principal Investigators will use to ensure that research subjects are adequately informed about the research before agreeing to participate.

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

Under certain circumstances, the IRB may waive the requirement to obtain or document informed consent or may approve an alteration of informed consent. In cases in which the signed consent requirement is waived, the IRB may still require the Principal Investigator to provide subjects with a written statement regarding the research.

Details and Procedures

Informed Consent Process

Informed consent is a process that begins with recruitment and continues throughout the study until all activities are complete. The participant should receive sufficient information to provide consent, and must be told if any new developments occur that might affect their willingness to participate. Participants must retain the ability to withdraw from the research at any point, with no negative consequences.

Researchers should avoid any appearance of coercion or pressure to participate in the consent process. For studies where there is a power differential, such as an instructor recruiting their own students, it may be appropriate to have someone else on the research team conduct the consent discussion.

After the study is complete, the consent process may still continue. In some studies, it's appropriate to allow a participant to review the research results before publication and choose to remove their data at that point. This is particularly important when an individual or community may be identifiable based on details in the final publication or presentation, to prevent harms to the participant's or community's reputation.

Informed Consent Requirements

UWM generally follows the consent requirements outlined at 45 CFR 46 for all research, unless another agency's requirements apply (e.g. FDA requirements of 21 CFR 50).

1. An investigator shall seek informed consent only under circumstances that provide the prospective subject sufficient opportunity to discuss and consider whether or not to participate. The consent discussion must occur in such a way that minimizes the possibility of coercion or undue influence.
2. The information must be in language understandable to the subject.
3. The prospective subject must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate. They must also be given an opportunity to discuss that information.
4. Informed consent must present information in sufficient detail and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's understanding of the reasons why one might or might not want to participate.
5. No informed consent may include any exculpatory language. Exculpatory language is that through which the subject is made to waive, or appears to waive, any legal rights. This also includes language that releases, or appears to release, the investigator, sponsor, institution, or its agents from liability for negligence.

All informed consent documents must contain the following elements of informed consent, except when the IRB has approved an alteration to these requirements:

- Statement that the study involves research and an explanation of the purposes of the research
- The expected duration of the subject's participation
- Description of the procedures to be followed and identification of any procedures which are experimental
- Description of any reasonably foreseeable risks or discomforts to the subject
- Description of any benefits to the subject or to others which may reasonably be expected
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

- Statement describing the extent to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained
- Research, Rights or Injury: An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury
- 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
- Informed consent must begin with a concise and focused presentation of the key information most important for helping a potential subject decide whether to participate.
    - The UWM IRB interprets this requirement to apply only to longer consent documents, and defines “longer” as more than 4 pages. Informed consent documents that are 4 pages or less do not need to contain this summary at the beginning.
- One of the following:
    - Statement that identifiers might be removed from the data or biospecimens, and, after this de-identification, the data or biospecimens could be used for future research studies or distributed to another investigator without additional informed consent; OR
    - Statement that the subject’s data or biospecimens will not be used or distributed for any future research, not even if de-identified.

The following additional elements must be included when the IRB deems them appropriate:

- 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
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- 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
- 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 study

- Statement that the subject's biospecimens may be used for commercial profit, and whether the subject will or will not share in this profit
- Statement regarding whether clinically relevant research results will be disclosed to subjects, and if so, under what circumstances
- For research involving biospecimens, whether the research will or might include whole genome sequencing

Waiver to Obtain Informed Consent and Alterations of Informed Consent

The IRB may waive or alter the requirement to obtain informed consent, if the IRB finds and documents that one of the sets of criteria below are met.

A. Public benefit or service programs:

A1. The research or demonstration project is to be conducted by or is subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

A2. The research could not practicably be carried out without the waiver or alteration.

OR

B. All other research:

B1. The research involves no more than minimal risk to the subjects;

B2. The research could not practicably be carried out without the waiver or alteration;

B3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

B4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

B5. Whenever appropriate, the subjects are provided with additional pertinent information after participation.

OR

C. Screening, recruiting, or determining eligibility

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens without informed consent for the purpose of screening, recruiting, or determining the eligibility of prospective subjects if either of the following conditions are met:

C1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; or

C2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Waiver to Document Informed Consent

An IRB may waive the requirement for the Principal Investigator to obtain a signed consent form for some or all subjects, if one or more of the following conditions exist:

1. The only record linking the subject and the research 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 research, and the subject's wishes will govern.

OR

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

3. The subjects are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Parental Consent and Waivers of Parental Consent

For the purposes of this section, "parent" refers to parents or legal guardians of minors.

As a general rule, parents are in the best position to protect their children's best interests, and should be given the opportunity to decide whether or not their child should participate in research.

Waivers of parental permission are granted only if:

- The research is educational in nature, AND qualifies for Exempt category 1, AND the participation of all students is necessary to the aims of the research;

OR

- The criteria for waiver of consent as outlined above are met;

OR

- All of the following criteria from 45 CFR 46.408 are met:
    - The IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).
    - An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. The choice of an appropriate mechanism

would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
- The waiver is not inconsistent with Federal, state or local law.

References

45 CFR §§ 46.116, 46.117, 46.408

21 CFR 50

OHRP Guidance: Informed Consent Tips (1993)

Revision History

Version	Date	Summary of Changes
1	2 Jul 2020	Initial version