Wayne State University
Institutional Review Board (IRB)

WSU IRB Administration Office
87 East Canfield, Second Floor
Detroit, MI, 48201
313-577-1628
irb.wayne.edu

Required Elements of Informed Consent

The Information that MUST be provided to potential participants of Research

The informed consent process is one of the primary ethical requirements when conducting research with human participants; it reflects the basic principle of respect for persons. Obtaining informed consent seeks to ensure that potential participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The elements of informed consent are mandated in the regulations at 45 CFR 46.116, 38 CFR 16.116, and 21 CFR 50.25.

The consent templates on the WSU IRB website include these required elements. The researcher must adequately address each per the research study design. If the required elements are not adequately stated in the consent document, the IRB will be unable to grant approval for the research. Once approved, only the versions that have an IRB stamp should be used. Any changes to approved consent documents require IRB approval and a new IRB stamp prior to use.

Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's understanding of the reasons why one might or might not want to participate.

The prospective participant or Legally Authorized Representative (LAR) 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 and an opportunity to discuss that information.

Key Information:

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Required Elements:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the participant;

3. A description of any benefits to the participant or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any medical treatments or compensation are available if injury occurs and, if so, what they consist of or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and

8. A statement that participation is voluntary and refusal to participate will not involve a penalty or loss of benefits to which the participant is otherwise entitled, that the participant may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled and that the participant will receive a copy of the signed informed consent.

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the LAR, if this might be a possibility; or
    ii. A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements:

One or more of the following elements of information, when appropriate shall also be provided to each prospective participant or LAR in the body of the consent form.

1. A statement that the particular treatment or procedure may involve risks to the participant (or the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;

2. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's or LAR's consent.

3. Any additional costs to the participant that may result from participation in the research;

4. The amount and schedule of all payments provided to participants

5. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant

6. A statement that the significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant

7. The approximate number of participants involved in the study

8. A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;

9. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and

10. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Additional Elements for FDA-Regulated Research:

One or more of the following elements of information, when appropriate shall also be provided to each prospective or LAR in the body of the consent form when the study is FDA regulated.

1. A statement that the results of the research will be posted on clinicaltrials.gov
2. A statement that notes the possibility that the Food and Drug Administration may inspect the records.

Additional Requirements when Following the ICH-GCP (E6) Guideline

One or more of the following elements of information, when appropriate shall also be provided to each prospective or LAR in the body of the consent form when following the ICH-GCP (E6) Guideline.

1. The approval or favorable opinion by the IRB
2. The probability for random assignment to each treatment
3. The participant's responsibilities
4. When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant
5. The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the participant
6. When there is no intended clinical benefit to the participant, the participant should be made aware of this
7. A statement that the monitors, the auditors, the IRB and the regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally authorized representative is authorizing such access.
8. If the results of the trial are published, the participant's identity will remain confidential

Additional Requirements for Department of Defense (DoD) research

1. A statement that the DoD or a DoD organization is funding the study
2. A statement that representatives of the DoD are authorized to review research records

Additional Requirements for Department of Energy (DoE) Research

1. The identity 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 participants; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the participants.
2. When research is classified, consent documents must state the project is classified, and what it means for the purposes of the research project.

Additional Requirements for Department of Justice Research

When research is funded by the National Institutes of Justice, the consent document must disclose:

1. He name(s) of the funding agency(ies)
2. The extent to which confidentiality of records identifying the participant will be maintained. For studies sponsored by NIJ the participant should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the participants need to explicitly informed what information would be disclosed, under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.

When research is sponsored by the Bureau of Prisoners, consent documents must disclose:

1. The identity of the researchers
2. Anticipated uses of the results of the research
3. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation on the project any time without penalty or prejudice (The inmate will be returned to regular assignment or activity by staff as soon as practicable).
4. 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 participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization
5. A statement that participation in the research project will have no effect on the inmate participant’s release date or parole eligibility.

Additional Requirements for VA Research

1. A statement that in the event of a research-related injury the VA has to provide necessary medical treatment to a participant injured by participation.
2. Any payments the participant is to receive for participating in the study
3. Any real or apparent conflict of interest by the researchers where the research will be performed
4. A statement that VA will provide treatment for research related injury in accordance with applicable federal regulations.
5. A statement that informs VA research participants that they or their insurance will not be charged for any costs related to the research
6. A statement that a veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with Federal law and that certain veterans were required to pay co-payments for mental care and services provided by VA.

7. Consent for research must describe any photographs, video, or audio recordings obtained for research purposes; how they will be used, and whether they will be disclosed outside the VA.

Note: The Wayne State IRB has opted out of the Broad Consent option in the revised Common Rule. Therefore, additional requirements for broad consent are not listed.