	UNIVERSITY RESEARCH POLICY: Informed Consent and Waiver of Informed Consent			
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Policy Statement

This policy describes the policy and procedures for Institutional Review Board (IRB) review of research involving informed consent. Research involving informed consent requires compliance with the federal regulations at 45 CFR 46.116 and 21 CFR 50.25.

Initial Screening


Upon acceptance of a complete package, the Research Integrity office staff makes a preliminary determination as to whether the proposed informed consent procedure is consistent with this policy. If the informed consent process does not meet the criteria for review per this policy, the Research Integrity office staff returns the application to the researcher for further clarification.

Required Elements of Informed Consent (45 CFR §46.116b)

The following elements must be provided to each subject or their legally authorized representative:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that 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 subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. 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;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. 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; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - a. 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 subject or the legally authorized representative, if this might be a possibility; or
 - b. A statement that the subject'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.

The IRB may also require that additional elements or information be given to the prospective subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of the research subject.

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For research subject to FDA regulations (21 CFR §50.25) the following element must also be included:

1. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

For clinical trials research, the following elements must also be included:

1. The approval of the IRB.
2. The probability for random assignment into 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, a statement to this effect.
7. The monitors, auditors, IRB, and 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 applicable laws and regulations and that, by signing the consent document, the participant or their LAR is authorizing such access.

Additional Elements of Informed Consent (45 CFR §46.116c)


One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

1. A 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) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's 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;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. 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).

Waiver or Alteration of Informed Consent (45 CFR §46.116f)

The IRB may approve a consent procedure that omits some, or alters some or all, of the required or additional elements of informed consent, or the IRB may waive the requirement to obtain informed consent, provided that the IRB determines:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;

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3. 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;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
6. The research is not FDA-regulated.

Exception of Requirement to Obtain Informed Consent for Screening, Recruitment, or Determination of Eligibility (45 CFR §46.116g)

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

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Review

All required elements of informed consent are included in the [informed consent templates](#) provided by the IRB. The templates should be modified as appropriate for the study. The informed consent form submitted with the study package should be the final version of the form.

The assigned reviewers are expected to evaluate informed consent documents from the perspective of addressing the required and additional elements of informed consent addressed under 45 CFR 46.116, 21 CFR 50.20 (if applicable), and any other relevant ethical or compliance considerations.

The IRB reviewers make the final determination as to whether the informed consent documents meet the criteria for review and approval under this policy.

Post-approval monitoring requirements

If any revisions are made to the informed consent form after approval, the IRB must approve the consent form prior to implementation. A copy of the amended/modified form must be submitted as an Amendment/Modification for review and approval.

Additional Information

For additional information on the informed consent process, see the [informed consent guidance](#) offered by the Office of Human Research Protections (OHRP).

For information on requirements for documentation of informed consent and waivers of documentation, refer to the policy: [Documentation of Informed Consent / Waiver of Documentation of Informed Consent](#)

Policy Updates

Date	Update
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Updated to reflect the implementation of the Revised Common Rule regulations