

INFORMED CONSENT PROCESS	SOP 5.1.02
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1. Purpose & Policy

The purpose of this SOP is to provide guidance to investigators on properly obtaining and documenting informed consent from research participants. See [IRB Policy Section 5.1](#).

2. General Information

Informed consent is an ongoing process of communication between the research team and study participants, not simply the signing of a consent form. Except when the IRB has approved a waiver or alteration of informed consent, investigators must obtain the legally effective informed consent of the participant or the participant's legally authorized representative (LAR) before involving the participant in research. A LAR is an individual, judicial body, or other organization authorized under applicable law to consent on behalf of another person who cannot make decisions for themselves.

The consent process must provide prospective participants with the information a reasonable person would want in order to make an informed decision about participation. Information must be presented in language and a manner that participants understand. Prospective participants must be given sufficient opportunity to consider participation and ask questions and the circumstances of consent must minimize the possibility of coercion or undue influence.

3. Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with the informed consent process; however, investigators should carefully read and follow this guidance.

4. Informed Consent Procedures

A. Preparing for Consent

Before conducting informed consent, the investigator obtaining consent must:

- Use the current IRB-approved Informed Consent Form (ICF) and consent process, including any IRB-approved electronic, remote, oral, or short-form consent procedures, as applicable;
- Confirm the investigator themselves is authorized to obtain consent;
- Be familiar with the study in order to answer participant questions; and
- Consider whether circumstances exist that could affect the participant's understanding or ability to make a voluntary decision.

B. Conducting the Consent Discussion

The person obtaining consent must review the study with the prospective participant using the IRB-approved consent materials. Providing a participant with a consent form to read does not, by itself, constitute an adequate informed consent process. The discussion should focus on the information most relevant to the participant's decision and should be organized and presented in a manner that facilitates understanding of why the individual might or might not want to participate. The discussion should include, as applicable:

- The purpose of the study,
- What the participant will be asked to do and the expected duration of participation,
- Reasonably foreseeable risks or discomforts,
- Potential benefits, if any,
- Alternatives to participation, when applicable,
- How participant information and/or specimens will be used and protected,
- Compensation and costs, when applicable,
- Whom to contact with questions about the research or participant rights, and
- The voluntary nature of participation, including the participant's right to decline participation or withdraw at any time without penalty or loss of benefits to which they are otherwise entitled.

C. Understanding and Voluntary Agreement

Participants must have sufficient opportunity to review the consent information and ask questions before deciding whether to participate. The person obtaining consent must take reasonable steps to determine that the participant understands the research. For complex or

higher risk studies, this may include asking the participant to describe important aspects of the study in their own words. If a participant does not demonstrate adequate understanding, additional explanation must be provided and consent should not be obtained until the investigator is reasonably satisfied that the participant understands the information necessary to make an informed decision.

Participation must be voluntary, and additional precautions may be necessary when recruiting individuals over whom investigators have academic, employment, supervisory, or other authority. See IRB SOP: [*Students and Lab Members as Research Study Participants*](#).

D. Documentation of Consent

When written documentation is required, the participant or LAR must sign and date the current IRB-approved consent document before research procedures begin, unless otherwise approved by the IRB. The investigator obtaining consent must also sign and date the document when required by the IRB-approved form. Consent may be conducted remotely and/or documented using an electronic signature when approved by the IRB. The methods must be described in the protocol and comply with applicable institutional and regulatory requirements.

Participants must be provided with a copy of the signed ICF. Signed ICFs, including electronically signed ICFs, must be retained with the study records in accordance with applicable campus records retention requirements. When appropriate, investigators should document relevant details of the consent process in the study records, including any unusual circumstances affecting consent.

E. Alternative Consent and Documentation Methods

The IRB may approve alternative methods of obtaining or documenting informed consent, including oral consent when documentation is waived or use of a short-form consent process. Investigators must follow the specific procedures and documentation requirements approved by the IRB. When a short-form consent process is used, the required consent information must be presented orally to the participant or LAR, a witness must be present, and applicable signature and document-copy requirements must be followed. See [*IRB Policy Section 5.2*](#).

F. Waiver or Alteration of Consent

Investigators may request that the IRB waive or alter informed consent when permitted by applicable regulations. Investigators may not implement a waiver or alteration unless it has been approved by the IRB.

G. Special Consent Circumstances

Additional requirements may apply when obtaining consent from or on behalf of children, adults who lack capacity to provide informed consent, individuals who are not sufficiently proficient in English, or other populations or circumstances requiring additional protections. Investigators must describe these circumstances in the protocol and follow the consent procedures approved by the IRB. Consent must be conducted in a language understandable to the participant or LAR. For research involving children, see IRB SOP: [Children as Study Participants in Research](#).

If a study includes activities, such as fasting, prior to participating in the study, and/or prior to providing formal informed consent, the investigator must receive general consent from the participant before the participant begins that activity. General consent can be obtained over the phone, such as during a screening interview, or by email and must be documented by the study team. Under these circumstances, the recruitment materials must clearly disclose the activity and indicate if the activity is an element of the screening process or a study related requirement that must be completed prior to participation in study procedures once enrolled. For research involving fasting, see IRB SOP: [Participant Fasting](#).

H. Ongoing Consent and Re-consent

Informed consent is an ongoing process. Investigators must inform participants of significant new information that may affect their willingness to continue participating. Changes to an approved informed consent document must be submitted to and approved by the IRB before use. The IRB will determine whether currently enrolled participants must be notified of the change or re-consented.

I. Consent Deviations / Errors

Any error or deviation in the informed consent process or documentation must be promptly reported to the PI and handled in accordance with applicable IRB reporting requirements.