

Informed Consent

Voluntary informed consent, a prerequisite for participation in research, is a process and a document. The informed consent process is about the protection and respect for research subjects. The consent process varies according to the level of review and nature of the research.

Informed consent process/document must

- Begin with a concise and focused presentation of key information about whether to participate
- Be presented in language easily understood by the subject
- Minimize the possibility of coercion or undue influence
- Allow subjects with sufficient time to consider participation
- Allow subjects to refuse or discontinue participation at any time
- Distinguish between research and standard medical care
- Be appropriately presented for the subject's physical, emotional and psychological capacity, and vulnerable status
- Assure that subject understands what participation entails

Required elements of informed consent

- A statement that the study involves research
- Expected duration of the subject's participation
- Purpose and procedures involved in the research
- Alternatives to participation
- All foreseeable risks and discomforts to the subject (e.g. physical injury, psychological, social, or economic damage).
- Benefits of the research to society and the individual subject
- Whether any compensation or medical treatment are available if injury occurs [required if the research is more than minimal-risk]
- Statement that participation is voluntary and refusal to participate with involve no penalty or loss of benefits
- Statement that identifiers might be removed from identifiable private information/ identifiable biospecimens and that the information/specimens could be used for future research without additional consent from the subject
- Person to contact for answers to questions or in the event of a research-related injury or emergency

- In the state of California subjects must be presented with a copy of the Experimental Subject's Bill of Rights

Waiver of one or more elements of informed consent may be permitted by the IRB for some research activities if appropriate.

Electronic Consent

Electronic consents (eConsent) and electronic signatures may be used if the procedures for obtaining them, and the vendor, are approved by the IRB, and the risk of breach of confidentiality is minimized. The IRB will consider vendor security confidentiality issues—such as how a copy of the consent document may be provided for review if requested by the subject.

The subject must agree to use the electronic format and must be provided a written copy of the informed consent in non-electronic form, and be provided description of any procedures that must be followed to withdraw their agreement to use an electronic record.

Consent may be obtained electronically using [DocuSign](#) or [REDCap](#). You may obtain HIPAA authorization electronically using DocuSign or REDCap for all studies, irrespective of risk level. In the event your participant population cannot access DocuSign or another secure and encrypted online platform (e.g., REDCap), you may consider having participants take photographs of their signed consents using their cell phones and emailing them to the study team. Make sure you document the consent process so that anyone examining your approach will be able to see how consent was obtained in good faith.

[eConsent Guidance](#)