| UC San Diego<br>Senior Associate Vice Chancellor for Health Sciences<br>Office of Clinical Research | SOP Number | OCR:002<br>Page 1 of 3 |
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| | Date: | 04/02/2025 |
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| | Approved by: | Susan Little |
| SOP TITLE: INFORMED CONSENT PROCESS | | |

## 1 PURPOSE

1.1 This procedure establishes the process to obtain and document informed consent from subjects, the legally authorized representatives (LAR) of adults unable to consent, or the parents or guardians of children or adolescents.

1.2 The process begins when a potential candidate for a research study requiring informed consent is identified.

1.3 The process ends when a subject completes the study, or declines to participate. For adolescents or children, this process may require permission of the parent(s) or guardian(s) and assent of the adolescent or child to participate.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 None

## 3 REQUIREMENTS

3.1 The Office of IRB Administration (OIA) has published the following SOPs for consenting and assenting research participants: OIA-013 SOP: Legally Authorized Representatives, Children, and Guardians; OIA-090 SOP: Informed Consent Process for Research; OIA-091 SOP: Written Documentation of Consent; OIA-092 SOP: Assent Process for Research; and OIA-093: Written Documentation of Assent. Any protocol reviewed and approved by the OIA is subject to the procedures and requirements described in these SOPs and the federal regulations.

3.2 If the informed consent process is to be conducted with a study participant by any means other than in-person, or if the investigator proposes to modify the IRB-approved consent procedures, the IRB electronic submission must include a description of the method and means by which the consent will be obtained and maintained, and any other proposed modifications, and the submission must be approved before implementing the modifications.

## 4 RESPONSIBILITIES

4.1 In accordance with OCR-001-SOP: Study Team Roles and Responsibilities, the Principal Investigator (PI) is responsible for obtaining informed consent from participants by ensuring all participants are fully informed about the study and their consent is obtained following ethical and regulatory requirements and practices. Study team members may perform consent tasks as delegated by the PI.

4.2 If the informed consent process is to be conducted with a study participant by any means other than in-person, the investigator is responsible for ensuring that the technology platform employed meets security and privacy standards, that there are measures in place to confirm the identity of the participant being consented (e.g., confirming identity by reviewing a photo ID), and that other consent considerations are followed during the consent process, e.g., providing an opportunity for the participant to ask questions, ensuring a means to provide a copy of the consent to the participant, and taking appropriate steps to safeguard participant privacy and confidentiality.

4.2.1 Electronic signatures that are compliant with 21 CFR Part 11 may be approved by an IRB or designated reviewer for FDA-regulated studies. Electronic signatures which are compliant with institutional policies, and the applicable regulations from which these policies are drawn, may be approved by an IRB or designated reviewer for all other studies. It is Office of IRB Administration (OIA) practice to accept the use of a secure system for electronic or digital signature, provided the system generates an encrypted identifiable "signature." OIA can assist researchers in determining whether their proposed system meets the requirements of this SOP.

## 5 PROCEDURE

5.1 Develop the informed consent document and process to be used for the study with consideration to the following:

5.1.1 Ensure the required elements of informed consent that are applicable to the type of study are included in the consent document.

5.1.2 If appropriate, interactive features and/or multimedia elements are included in the consent process to enhance participant comprehension.

5.1.3 If the informed consent process is to be conducted with a study participant by any means other than in-person:

5.1.3.1 The technology platform to be used for conducting virtual informed consent will comply with UC San Diego security and privacy standards.

5.1.3.2 The following aspects of the remote consent process will be documented in the study records:

5.1.3.2.1 Description of method(s) used to verify the identity of the participant who not consented in person

5.1.3.2.2 Description of means of providing the informed consent document to the participant in advance of the consent discussion, and the provisions to give the participant a copy of the consent form

5.1.3.2.3 Description of means of overcoming literacy and/or language barriers during the consent process

5.1.3.2.4 Training provided to research team members who are involved in remote consent procedures

5.2 Utilize the current version of the IRB-approved informed consent document from the electronic submission system, as applicable.

5.3 To obtain informed consent and assent from research participants, consult and follow the procedures described in: OIA-013 SOP: Legally Authorized Representatives, Children, and Guardians; OIA-090 SOP: Informed Consent Process for Research; OIA-091 SOP: Written Documentation of Consent; OIA-092 SOP: Assent Process for Research; and OIA-093: Written Documentation of Assent.

5.4 Once all signatures are obtained on informed consent and, if applicable, assent documents, record relevant details of the consent process in the participant's study record, using OCR-101 Checklist: NIH Sample Informed Consent Process Checklist, or equivalent.

## 6 MATERIALS

6.1 OCR-101 Checklist: Sample Informed Consent Process Checklist

## 7 REFERENCES

7.1 OIA-013 SOP: Legally Authorized Representatives, Children, and Guardians
7.2 OIA-090 SOP: Informed Consent Process for Research
7.3 OIA-091 SOP: Written Documentation of Consent
7.4 OIA-092 SOP: Assent Process for Research
7.5 OIA-093: Written Documentation of Assent
7.6 21 CFR Part 50 Subpart B: Informed Consent of Human Subjects
7.7 21 CFR Part 56: Institutional Review Boards
7.8 45 CFR Part 46: Protection of Human Subjects