

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-012 SOP: Observation of the Consent Process				
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1 PURPOSE

- 1.1 This procedure establishes the process for IRB-designated personnel to observe authorized study team member's conduct of the informed consent process with a human subject.
- 1.2 The process begins when the IRB determines that the consent process should be observed.
- 1.3 The process ends when the IRB determines that further observations of the consent process are no longer required, or some other pre-determined endpoint set by the IRB is reached.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 GUIDANCE

- 3.1 The IRB may consider observation of the consent process when:
 - 3.1.1 There are allegations or findings of non-compliance.
 - 3.1.2 The nature of the research indicates that the consent process can be improved through observation.
 - 3.1.3 The IRB determines that observation of the consent process is necessary to protect human subjects.
 - 3.1.4 The IRB determines that verification from sources other than the investigator is indicated to confirm that no material changes in the informed consent documents or processes have taken place since prior IRB review.
 - 3.1.5 The IRB wishes to conduct consent process observation for routine or for-cause quality assurance/quality improvement activities.
- 3.2 The IRB, institutional official, Office of IRB Administration (OIA) director, or designee determines who may conduct the observation. The IRB may delegate the observation to:
 - 3.2.1 OIA staff.
 - 3.2.2 IRB members.
 - 3.2.3 Representative(s) from other institutional compliance office(s).
 - 3.2.4 A person recommended by the investigator.
 - 3.2.5 An independent person selected and hired by the IRB, but paid from the investigator's funds.

4 RESPONSIBILITIES

- 4.1 The person observing the consent carries out these procedures.

5 PROCEDURE

- 5.1 Contact the investigator to arrange a mutually agreeable time for the consent process observation.
- 5.2 Observe the consent process between the human subject and the investigator or IRB-approved investigator designee.
- 5.3 Determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the human subject or the human subject's legally authorized representative (LAR); that IRB-approved informed consent process was followed; and that informed consent was freely given by the human subject or the LAR.
 - 5.3.1 If one or more of these conditions are not adequately met, the person observing consent documents this in writing, indicating that the consent does not meet the informed consent requirements and the prospective human subject may not be entered into the research.
 - 5.3.2 If these conditions are met, the person observing consent documents in writing that the consent process was observed and that informed consent adequately met the conditions required by IRB for informed consent from the human subject or LAR.
- 5.4 Once the observation is complete, the person observing consent provides the written report of the observation to the IRB for convened review, if appropriate, and the IRB will provide follow-up communication to the investigator, including the observer's report, if indicated, along with any further comments or actions required. Send outcome of IRB review using *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*.

6 MATERIALS

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6.1 *OIA-001 SOP: Definitions*

6.2 *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*

7 REFERENCES

7.1 [21 CFR 56.109](#)

7.2 [45 CFR 46.109](#)