SOP: Observation of Consent Process

1 PURPOSE

1.1 This procedure establishes the process to observe the consent process.

1.2 The process begins when the IRB determines that the consent process should be observed.

1.3 The process ends when the consent observation is complete.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes: Updated SOP to add additional details regarding the observation process and ensure observation findings are reported back to the IRB.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The IRB may consider requiring observation of the consent process when:

3.1.1 The IRB wants verification from sources other than the investigator that consent processes adhere to the current version of the IRB-approved study protocol and applicable regulatory requirements.

3.1.2 There are Allegations or Findings of Non-Compliance.

3.1.3 The nature of the research or reportable new information indicates that the consent process can be improved through observation.

3.2 The IRB, Institutional Official/ Organizational Official (IO/OO), or designee determines who conducts the observation. The individual conducting the observation should have sufficient experience to appropriately evaluate the consent process. This may include, but is not limited to:

3.2.1 IRB staff.

3.2.2 IRB members.

3.2.3 A person recommended by the investigator.

3.2.4 An independent person hired by the IRB but paid for by the investigator's funds.

4 RESPONSIBILITIES

4.1 The person designated to conduct the observation of the consent process carries out these procedures.

5 PROCEDURE

5.1 Notify the subject or the subject's Legally Authorized Representative (LAR) of the intent to observe the consent process, including the purpose of the observation, and obtain their agreement to observe the process.

5.1.1 If the subject objects to the observation, document that the observation could not take place and work with the study team to re-schedule the observation.

5.2 Observe the consent process and determine whether consent was obtained in a manner consistent with:

5.2.1 Section 1 ("Consent Process") of HRP-314a - WORKSHEET - Criteria for Consent; and

5.2.2 The current version of the IRB-approved study protocol.

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5.2.3 If these requirements are not met, indicate that consent is not legally effective and the prospective subject may not be entered into the research.

5.3 If these requirements are met, when applicable, verify consent was documented in a manner consistent with Section 2 (“Long Form of Consent Documentation”), of HRP-314a - WORKSHEET - Criteria for Consent and the current version of the IRB-approved study protocol.

5.3.1 Document in writing that the consent process was observed, including whether informed consent was freely given by the subject or LAR and the requirements identified above were met. Report this information back to the IRB, submitting the information as Reportable New Information (RNI), when necessary.

6 MATERIALS

6.1 HRP-314a - WORKSHEET - Criteria for Consent

7 REFERENCES

7.1 45 CFR §46.109
21 CFR §56.109

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