

N	SOP: Observation of the Consent Process		
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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 IRB determines that the consent process no longer should be observed.

2 PREVIOUS VERSION

- 2.1 Revised from previous version 10/15/2020.

3 POLICY

- 3.1 The IRB has the authority to observe, or have a third party observe, the consent process.
- 3.2 The IRB also may require that one or more informed consent process visits be observed for selected study.
- 3.3 The IRB may consider the observation of the consent process when:
 - 3.3.1 The IRB wants verification from sources other than the investigator that no material changes have taken place prior to IRB review.
 - 3.3.2 There are Allegations or Findings of Non-Compliance.
 - 3.3.3 The nature of the research indicates that the consent process can be improved through observation.
 - 3.3.4 The consent process is being observed as part of the institution's post-approval monitoring assessment.
 - 3.3.5 Any other situation the IRB deems appropriate to provide additional protections to the research participants.
- 3.4 The IRB, Institutional Official / Organizational Official, or designee designates who conducts the observation. The IRB may have the observation conducted by:
 - 3.4.1 IRB Office Compliance staff.
 - 3.4.2 IRB members.
 - 3.4.3 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 The compliance analyst or designee will notify the Principal Investigator (PI) and the primary contact about the need to observe the process of consenting study participants and coordinate mutually agreeable dates and times for the analyst to observe the consenting procedures.
- 5.2 The person performing the observation will contact the PI and primary study contact to schedule the consent observation using the Directed Review Notification – Consent Process Observation template or the Routine Post Approval Monitoring Consent Process Observation Notification template.
- 5.3 The person performing the observation will review the protocol and consent documents for the study that will be reviewed.
- 5.4 Just before observing consenting, the observer will:
 - 5.4.1 Introduce themselves to the potential study subject,
 - 5.4.2 Explain the reason for the observer's presence, and
 - 5.4.3 Obtain the participant's verbal permission for observing consent.



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- 5.5 The person who observes the consent process will determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally authorized representative, and that informed consent was freely given by the participant or the legally authorized representative.
- 5.6 The observer will document their findings using the [Observation of the Consent Process](#) Checklist (HRP-443). During consenting, should any issues or questions arise that the consentor cannot address and that the observer is qualified to discuss or answer, the observer may offer appropriate explanations or information.
 - 5.6.1 If the consent process was inadequate, indicate that consent is not legally effective. The prospective participant may not be entered into the research.
 - 5.6.2 If the consent process was adequate, document in writing that the consent process was observed and that informed consent was freely given by the participant or legally authorized representative.
- 5.7 The observer will schedule a time to discuss their initial observations with the person who administered the consent.
- 5.8 The observer will then coordinate a subsequent visit, or visits, to determine if the person obtaining consent corrected the observed "deficiencies" identified during the initial consent process.
- 5.9 The observer will prepare a written report based on the information recorded in the Observation of Consent Checklist (HRP-443) and convey it to the consentor.
- 5.10 If the person obtaining consent or the PI wish to discuss the findings further, the observer will schedule a follow-up meeting.

6 MATERIALS

- 6.1 AUDIT CHECKLIST: Observation of the Consent Process (HRP-443)
- 6.2 WORKSHEET: Reportable New Information Items (HRP-321)

7 REFERENCES

- 7.1 45 CFR §46.109(e)
- 7.2 21 CFR §56.109(f)