

SOP number SOP CW AHC 242	SOP Name Observation of the Informed Consent/Assent Process in Research
Location Company-wide	Responsible Department Research Services
SOP Owner/Executive Owner Executive Director of Research Services	Original Creation Date (If applicable) 3-16-2022
Effective Date	Review Date

- I. **SCOPE:** This standard operating procedure (SOP) applies to the AdventHealth Institutional Review Board (IRB) staff members or third-party personnel who will observe the informed consent/assent process.
- II. **PURPOSE:** The purpose of this SOP is to establish the process to observe the informed consent/assent process.
- III. **QUALIFIED PERSONNEL:** IRB staff members or a third party selected by the IRB carry out this process.
- IV. **TRAINING:** Not applicable
- V. **SUPPLIES & EQUIPMENT:** Not applicable
- VI. **PROCESS/PROCEDURE:** This process begins when the IRB determines that the consent/assent process should be observed. This process ends when the IRB determines that the consent/assent process should no longer be observed. Consent Observation includes both the IRB or third party attending a consent/assent visit, and/or the IRB requesting copies of one or more completed consent/assent documents and/or documentation of consent/assent process for review.
 - A. The IRB may consider observation of the consent/assent process or collection and review of any number of completed consent/assent documents and/or the documentation of the consent/assent process when any of the following occurs:
 1. The IRB determines that the risk level or complexity of the study is such that the consent/assent process should be monitored;
 2. The nature of the research indicates that the consent/assent process can be improved through observation;
 3. The consent/assent process is being observed as part of the institution's post approval monitoring assessment plan;
 4. There are Allegations of Noncompliance or findings of Noncompliance related to the consent/assent process or documentation;
 5. The Principal Investigator is new to research, or new to research at AdventHealth
 6. A study is randomly selected for observation of the informed consent/assent process per IRB processes; or

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7. Any other situation the IRB deems appropriate in order to provide additional protections to the research participants.

B. Procedures to observe the informed consent/assent process:

1. Select protocol for observation of the informed consent/assent process.
2. Contact Principal Investigator or coordinator to schedule a time to meet and observe the consent/assent process.
3. Consent Observation may take place in person or remotely.
4. Engage in the observation by:
 - a) Introducing themselves to the participant or Legally Authorized Representative (LAR)
 - b) Explaining why they are there; and
 - c) Obtaining verbal permission from the participant to observe the informed consent/assent process.
5. Observe the informed consent process and complete the HRP-209 FORM: Informed Consent Observation to determine whether the following occurred:
 - a) The informed consent/assent process has been appropriately performed and documented;
 - b) The participant has had sufficient time to consider study participation;
 - c) No coercion or undue influence has been used by the researcher; and
 - d) The information presented to the participant reflects the content of the consent document and is conveyed in an understandable language and manner.
6. Provide immediate recommendations to the study team, if necessary, to aid in the informed consent/assent process.
7. Assist in determining if additional education or corrective action is required or if a second observation should be scheduled or planned.
8. Make completed observation form and notes available to the IRB Executive Chair and IRB Manager.
9. The IRB will provide a report summarizing any findings or required actions following the observation period.

VII. DEFINITION(S): For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research.

VIII. EXCEPTION(S): See CW AHC 101 Research Oversight

IX. REFERENCE(S):
45 CFR 46.109(g)
21 CFR 56.109(f)

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X. RELATED DOCUMENT(S) / ATTACHMENT(S):

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- CW AHC 110 Legally Authorized Representatives, Children, and Guardians in Research
- Supporting Documentation
 - SOP CW AHC 242 – Exhibit A - HRP-209 FORM – Informed Consent Observation
 - SOP CW AHC 242 – Exhibit B – HRP-210 FORM – Informed Consent Documentation Observation

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