Standard Operating Procedure (SOP)

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 process should be observed. This process ends when the IRB determines that the consent process should no longer be observed.

A. The IRB may consider observation of the consent process when:

1. The IRB determines that the risk level or complexity of the study is such that the consent process should be monitored;
2. The nature of the research indicates that the consent process can be improved through observation;
3. The consent process is being observed as part of the institutions post approval monitoring assessment plan;
4. There are Allegations of Noncompliance or findings of Noncompliance related to the consent process or documentation;
5. A study is randomly selected for observation of the informed consent process; or
6. Any other situation the IRB deems appropriate in order to provide additional protections to the research participants.

B. Procedures to observe the informed consent process:

1. Select protocol for observation of the informed consent process.
2. Contact Principal Investigator or coordinator to schedule a time to meet and observe the consent process.

3. 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 process.
4. Observe the informed consent process and complete the HRP-209 FORM: Informed Consent Observation to determine whether the following occurred:
    a) The informed consent 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.
5. Provide immediate recommendations to the study team, if necessary, to aid in the informed consent process.
6. Assist in determining if additional education or corrective action is required or if a second observation should be scheduled or planned.
7. Make completed observation form and notes available to the IRB Executive Chair and IRB Manager.
8. 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)

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