Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 219	**SOP Name:** IRB Records
Location: *Company-Wide Policies	**Responsible Department:** Research Services
Executive Owner: Executive Director of Research Services	**Original Creation Date:** 01/18/2022
Effective Date: 04/04/2022	**Review Date:** 04/04/2022

I. SCOPE: This standard operating procedure (SOP) applies to all personnel responsible for maintaining Institutional Review Board (IRB) records.

II. PURPOSE: This SOP describes the contents of IRB records.

III. QUALIFIED PERSONNEL: IRB staff, Regulatory Reviewers, IRB members

IV. TRAINING: IRB electronic system

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. Documents in a study file are to record the history of IRB actions related to the review.

B. IRB files are to include:

1. Study files
2. IRB meeting minutes
3. A resume or curriculum vitae for each IRB member
4. Current and previous versions of IRB member rosters
5. Current and previous versions of controlled documents, such as policies.
6. Correspondence to and from the IRB related to Human Research
7. IRB Authorization Agreements

C. Study files are to include the following information when it exists:

1. Correspondence and submissions to and from the IRB related to the study
2. Protocols or research plans, including the DHHS-approved sample protocol when applicable.
3. Investigator brochure
4. Scientific evaluations, when provided by an entity other than the IRB
5. Recruitment materials
6. Consent documents, including the DHHS-approved sample consent when applicable
7. Progress reports submitted by Investigators
8. Reports of injuries to subjects

9. Records of continuing review activities
10. Data and safety monitoring reports
11. Modifications
12. Unanticipated Problems Involving Risks to Subjects or Others
13. Documentation of Noncompliance
14. Significant new findings and statements about them provided to subjects
15. For initial and continuing review by the expedited procedure:
    a) The specific permissible category
    b) Description of action taken by the Designated Reviewer
    c) Any findings required by law
    d) If continuing review is not required by HRP-400 WORKSHEET - Criteria for Approval, but the Designated Reviewer determined that continuing review was required, the Designated Reviewer's rationale for that determination
16. For exemption determinations, the specific category of exemption
17. Required determinations and study-specific findings supporting those determinations for research involving:
    a) Waiver or alteration of the consent process
    b) Pregnant Women
    c) Neonates of Uncertain Viability
    d) Nonviable Neonates
    e) Prisoners
    f) Children
    g) Wards
    h) Adults lacking capacity
    i) Significant Risk Device/Non-significant Risk Device determinations
18. For each study's initial and continuing review, the frequency for the next continuing review or that continuing review is not required.

D. Records for FDA-regulated research are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

E. Records for research conducted, supported, or otherwise subject to regulation by a federal department or agency are to be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner. Records maintained that document compliance or Noncompliance with DOD regulations shall be

made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.

F. Upon request AdventHealth makes IRB records available to clients provided they are relevant to the client, such as sponsor, funder, regulatory authorities, etc. Such records may be excerpted or redacted to comply with AdventHealth's obligations to maintain confidentiality.

VII. DEFINITION(S):

For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

For abbreviations not defined in this policy, refer to CW AHC 102 Abbreviations in Research

VIII. EXCEPTION(S):

See CW AHC 101 Research Oversight

IX. REFERENCE(S):

Electronic Code of Federal Regulation (*e-CFR™*). (June 10, 2015). 21 CFR; §56.115: IRB Records. Retrieved from: Click here.
Electronic Code of Federal Regulation (*e-CFR™*). (June 10, 2015). 45 CFR, §46.115: IRB Records. Retrieved from: Click here.

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

- CW AHC 101 Research Oversight
- CW AHC 107 Definitions in Human Research
- CW AHC 102 Abbreviations in Research
- CW AHC 108 Human Research Protection Program
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-400 WORKSHEET – Criteria for Approval