Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 227	**SOP Name:** IRB Records Retention
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 IRB staff members

II. PURPOSE: This procedure establishes the process to retain IRB records. This procedure begins every seven months. This procedure ends when all records that are no longer required to be retained are destroyed.

III. QUALIFIED PERSONNEL: IRB staff members carry out these procedures.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. Study files designated by legal counsel as being on "legal hold" are not to be destroyed until the legal hold is removed.

B. Study files relating to research requiring continuing review, which was not conducted in a timely manner and therefore expired, are retained for at least 7 years after the last IRB action.

C. Study files relating to research requiring continuing review which has been conducted are retained for at least 7 years after completion of the research, regardless of whether there was subject enrollment.

D. Study files relating to research not requiring continuing review are retained for at least 7 years after the last IRB action.

E. Incomplete study files that were never finalized and sent to Committee Review or Non-Committee Review are retained for at least 7 years after the last IRB action.

F. The following documents are retained indefinitely:

1. IRB meeting minutes
2. A resume or curriculum vitae for each IRB member
3. Current and previous versions of IRB member rosters
4. Current and previous versions of controlled documents

G. Review the study files that can be destroyed.

1. Omit destruction of records on a legal hold.

2. Previously approved studies requiring continuing review: 7 years after the date on which all research sites overseen by AdventHealth's IRB have been completed either through closure, Termination of IRB Approval, disapproval, or lapse of approval
3. Research never approved and research not requiring continuing review: 7 years after the last IRB action or after withdrawal by the submitter

H. Shred paper documents and dispose the shredded materials securely.

I. Notify information technology to destroy electronic documents by either deleting the files or replacing the files with stub files documenting the date of deletion.

J. Document your name and the date of destruction with the following for each study file destroyed:

1. Study title
2. IRB ID
3. Date of completion
4. Paper, electronic, or both

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

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

IX. REFERENCE(S):
21 CFR §56.115
45 CFR §46.115

X. RELATED DOCUMENT(S) / ATTACHMENT(S):
- CW AHC 107 Definitions in Human Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program