



SOP: IRB Records Retention

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1. PURPOSE

- 1.1. This procedure establishes the process to retain IRB records.
- 1.2. This procedure begins every three months.
- 1.3. This procedure ends when all records that are no longer required to be retained are destroyed.

2. POLICY

- 2.1. Study files designated by legal counsel as being on “legal hold” are not to be destroyed until the legal hold is removed.
- 2.2. Study files relating to research requiring continuing review which has not been conducted are retained for at least 3 years after the last IRB action.
- 2.3. Study files relating to research requiring continuing review which has been conducted are retained for at least 3 years after completion of the research, regardless of whether there was subject enrollment.
- 2.4. Study files relating to research not requiring continuing review are retained for at least 3 years after the last IRB action.
- 2.5. Incomplete study files that were never finalized and sent to <Committee Review> or <Non-Committee Review> are retained for at least 3 years after the last IRB action.
- 2.6. The following documents are retained indefinitely:
 - 2.6.1. IRB meeting minutes
 - 2.6.2. A resume or curriculum vitae for each IRB member
 - 2.6.3. Current and previous versions of IRB member rosters
 - 2.6.4. Current and previous versions of controlled documents

3. RESPONSIBILITY

- 3.1. HRPP staff members carry out these procedures.

4. PROCEDURE

- 4.1. Review the study files that can be destroyed.
 - 4.1.1. Omit destruction of records on a legal hold.
 - 4.1.2. Previously approved studies requiring continuing review: Three years after the date on which all research sites overseen by the [Organization]’s IRB have been completed either through closure, <Termination of IRB Approval>, disapproval, or lapse of approval
 - 4.1.3. Research never approved and research not requiring continuing review: Three years after the last IRB action or after withdrawal by the submitter
- 4.2. Shred paper documents and dispose the shredded materials securely.
- 4.3. Notify information technology to destroy electronic documents by either deleting the files or replacing the files with stub files documenting the date of deletion.
- 4.4. Document the date of destruction with the following for each study file destroyed:
 - 4.4.1. IRB ID
 - 4.4.2. Protocol ID
 - 4.4.3. Date of completion
 - 4.4.4. Paper, electronic, or both

5. REFERENCES

- 5.1. 21 CFR §56.115
- 5.2. 45 CFR §46.115