

SOP: IRB Records Retention

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1 PURPOSE

- 1.1 This procedure establishes the process to retain IRB records.
- 1.2 The process begins each year in June.
- 1.3 The process ends when records that no longer need to be retained are destroyed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Protocol files are to be retained as long as required by law and then destroyed.
- 3.2 All records not in protocol files are retained indefinitely.
- 3.3 Protocols in which there was no subject enrollment or no research was conducted are to be retained the same as protocols where research was conducted.
- 3.4 All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.
- 3.5 Records maintained that document compliance or non-compliance with Department of Defense (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.
- 3.6 All records for research subject to FDA regulations are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Destroy protocol files for the Department of Defense (DOD) research when approved by the Department of Defense. The agency may require submitting records to the Department of Defense for archiving.
- 5.2 Destroy all other protocol files when the protocol has been closed, withdrawn, or terminated more than three years unless otherwise required by law.
 - 5.2.1 In the case of multi-center research, three years is referenced to the institution's involvement in the research, not the entire study.

6 MATERIALS

- 6.1 None

7 REFERENCES

- 7.1 None