

	SOP: Records Retention		
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1 PURPOSE

- 1.1 This SOP establishes the process to retain IRB records.
- 1.2 The process begins at the creation of a record.
- 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 SOP Statement

- 3.1 Study files are to be retained as long as required by law or as stated in the clinical trial agreement but no less than 3 years after completion of the research and then destroyed in accordance with Texas A&M University SAP 15.99.03.M1.03 The Responsible Stewardship of Research Data.
- 3.2 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.
- 3.3 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.
- 3.4 The following documents are retained indefinitely:
 - 3.4.1 IRB meeting minutes
 - 3.4.2 A resume or curriculum vitae for each IRB member
 - 3.4.3 Current and previous versions of IRB member rosters
- 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 IRB protocol files for the Department of Defense (DOD) research when approved by the Department of Defense. The agency may require that research records be transferred to the DOD component for archiving.
- 5.2 Destroy all other IRB protocol files when the protocol has been closed, withdrawn, or terminated more than three years unless otherwise required by law.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 organization's involvement in the research, not the entire study.

6 MATERIALS

- 6.1 Texas A&M University SAP 15.99.03.M1.03

7 REFERENCES

- 7.1 21 CFR §56.115
- 7.2 45 CFR §46.115
- 7.3 AAHRPP II.5.A