



SOP: IRB Project Records Retention			
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1 PURPOSE

- 1.1 This procedure 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 PREVIOUS VERSION

- 2.1 Revised from previous version dated 01/21/2019.

3 POLICY

- 3.1 Study files are to be retained as long as required by University Policy and law, then destroyed.
- 3.2 Records may be maintained in paper form or electronically.
- 3.3 Protocols in which there was no subject enrollment or no research was conducted are to be retained according to the same standards 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 (USDOD) 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 USFDA regulations are to be accessible for inspection and copying by authorized representatives of USFDA at reasonable times and in a reasonable manner.
- 3.7 All IRB records relating to VA research are to be accessible for inspection and copying by the Veterans Administration (VA) Research and Development Committee at reasonable times and in a reasonable manner.

4 RESPONSIBILITIES

- 4.1 IRB Office staff members carry out these procedures.

5 PROCEDURE

- 5.1 Destroy protocol files for Veterans Administration (VA) research when approved by the National Archives and Records Administration (NARA). The original format of the record must be retained as the official recordkeeping copy until a proposed record retention and disposition schedule is submitted for review, appraisal, and approval by NARA.
- 5.2 Destroy protocol files for the US Department of Defense (USDOD) research when approved by the US Department of Defense. The agency may require submitting records to the US Department of Defense for archiving.

6 MATERIALS

- 6.1 [Research Data: Ownership, Retention and Access](#)
- 6.2 [Retention of University Records Policy](#)
- 6.3 [POLICY: Appendix A - Records Retention Schedule](#)
- 6.4 Data Security Plans for Identifiable Information Used in Clinical Research

7 REFERENCES

- 7.1 None.