



SOP: IRB Records Retention				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-072	7/9/2019	C.Gates	C.Gates	1 of 1

1 PURPOSE

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

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None
- 2.2 Revised timelines for record retention relating to HIPAA and documents stored in the HSRO electronic system.

3 GUIDING PRINCIPLES

- 3.1 HSRO files maintained in the electronic system (eProst) are retained indefinitely.
- 3.2 Records of research review are maintained in eProst.
- 3.3 All records required by an FDA or ORHP predicate rule that are not maintained in eProst will be maintained for at least three years after research for which the document is applicable has closed.
- 3.4 Records relating to the Federal Privacy Rule (HIPAA) will be maintained for at least six years.
- 3.5 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.
- 3.6 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.
- 3.7 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 HSRO staff members carry out these procedures.

5 PROCEDURE

- 5.1 Maintain all records of IRB Review [(See Section 3 of SOP IRB Records (HRP-070)] in eProst indefinitely.
- 5.2 Before any document is destroyed ensure:
- 5.3 The research has been closed for more than three years.
- 5.4 Six years have elapsed since a Waiver of Authorization for access to research records was employed.
- 5.5 Research for which an SOP, Worksheet or Checklist is applicable has been closed for at least three years.

6 MATERIALS

- 6.1 None

7 REFERENCES

- 7.1 None