UNIVERSITY OF MIAMI

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 ends when records that no longer need to be retained are destroyed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

3.1 HSRO files maintained in the electronic IRB system are retained indefinitely.
3.2 Records of research review are maintained in the electronic IRB system.
3.3 Other records may be maintained in printed form or electronically.
3.4 Protocols in which there was no subject enrollment or no research was conducted are retained the same as protocols where research was conducted.
3.5 All records required by an FDA or ORHP predicate rule that are not maintained in electronically will be maintained for at least three years after research for which the document is applicable has closed.
3.6 Records relating to the Federal Privacy Rule (HIPAA) will be maintained for at least six years.
3.7 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.
3.8 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.
3.9 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 in the IRB electronic system indefinitely.
5.2 Before any document is destroyed ensure:
- 5.2.1 The research has been closed for more than three years.
- 5.2.2 Six years have elapsed since a Waiver of Authorization or an IRB-approved waiver of authorization for use and disclosure of protected health information employed.
- 5.2.3 Research for which an SOP, Worksheet or Checklist is applicable has been closed for at least three years.

5.3 Destroy protocol files for the Department of Defense (DOD) research only when approved by the Department of Defense. The agency may require submitting records to the Department of Defense for archiving.
5.4 Destroy all other protocol files only when the protocol has been closed, withdrawn, or terminated more than three years unless otherwise required by law.
- 5.4.1 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 None

7 REFERENCES

7.1 AAHRPP elements I.1.A, I-9, II.5.A, 11.5B