1 PURPOSE

1.1 This procedure establishes the process to retain IRB records.

1.2 The process begins when an application has been submitted to the IRB Office.

1.3 The process ends when records no longer need to be retained.

2 REVISIONS FROM PREVIOUS VERSION

2.1 7/1/2020.

3 POLICY

3.1 Protocol files are to be retained as long as required by law.

3.2 Records may be maintained in printed form or electronically.

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 5.1 Paper files are archived indefinitely. Electronic files remain in eIRB+ indefinitely.

6 MATERIALS

6.1 None.

7 REFERENCES

7.1 46 45 CFR 115 (a)-(b) 21 CFR 56.115 (a)-(b).

7.2 30.4.5 Records Management Rutgers Policy Library.

7.3 HRPP Guidance: Record Retention.