1 PURPOSE

1.1 This procedure establishes the process to retain IRB records.

1.2 The process begins each year in June.

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 POLICY

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

3.2 All records not in protocol files are retained indefinitely.

3.3 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 to be retained the same as protocols where research was conducted.

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 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Destroy protocol files for the Department of Defense (DOD) research when approved by the Department of Defense. The agency may require submitting records to the Department of Defense for archiving.

5.2 Destroy all other protocol files when the protocol has been closed, withdrawn, or terminated more than three years unless otherwise required by law.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 None.

7 REFERENCES

7.1 None.