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 Revisions for AAHRPP accreditation; replaces version dated 09/23/2009.

3 POLICY

3.1 Documents are to be retained as long as required by law and then destroyed.
3.2 Protocols in which there was no participant enrollment or no research was conducted are to be retained the same as protocols where research was conducted.
3.3 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.
3.4 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.
3.5 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
5.2 Destroy IRB member rosters that are more than five years old.
5.3 Destroy policies and procedures that were replaced with revised policies and procedure more than five years ago.
5.4 Destroy information in investigator files more than five years old.
5.5 Destroy protocol files when the protocol was closed, withdrawn, or terminated more than five years ago.¹
5.6 Destroy information in IRB member files more than five years old.

6 MATERIALS

6.1 None.

7 REFERENCES

7.1 None.

¹ This assumes that HIPAA records are maintained separately.