SOP: IRB Records Retention

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 In accordance with UC Office of the President policy, research records must be retained for 10 years after the end of the calendar year in which the research is completed unless otherwise specified in the award agreement. RB records are stored for 10 years beyond the end of the calendar year in which the study is closed in both onsite and off-site locations. Records are stored electronically and on paper.

3.1.1 IRB paper files for currently active or archived studies are stored offsite at an Iron Mountain Storage Facility.

3.1.2 IRB minutes and rosters are stored off-site at an Iron Mountain Storage Facility with the more recent documents (post-2019) being stored in UCI's electronic IRB database.

3.2 Completion of a study occurs when the Lead Researcher submits a closing report or 30 days after IRB approval of the study expires, whichever comes first.

3.3 If a study is canceled without participant enrollment, records also are still maintained for 10 years beyond the end of the calendar year in which the study is closed.

3.4 All records not in protocol files are retained indefinitely.

3.5 Records may be maintained in printed form or electronically.

3.6 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.

3.7 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.

3.10 Administrative records (e.g., minutes, member lists, and budgets) are maintained indefinitely.

3.11 Access to UCI's electronic IRB database is limited to Office of Research, OR staff and UCI partners as needed for business purposes (e.g., School of Medicine). Electronic systems are frequently backed up and have a data recovery and disaster management plan.

3.12 All records are to be accessible for inspection and copying by the Veterans Administration (VA) Research and Development Committee at reasonable times and in a reasonable manner.

3.13 Veterans Administration (VA) IRB records are retained in accordance with VHA's Records Control Schedule.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Destroy protocol files for Veterans Administration (VA) research per Records Control Schedule 10-1 (VHA RCS 10-1).

5.2 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.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 VHA Directive 1200.05 dated January 7, 2019

7.2 DoDI 3216.02