

 UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-072 SOP: OIA Records Retention				
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1 PURPOSE

- 1.1 This procedure establishes the process to retain Office of IRB Administration (OIA) records.
- 1.2 The process begins when OIA records are created.
- 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 REQUIREMENTS

- 3.1 Protocol files are to be retained for the time period required by law, regulation, or policy, whichever is longer. The same retention requirements apply to protocol files for which no subjects were enrolled or no research was conducted.
 - 3.1.1 Protocol files which are no longer required to be retained may be destroyed.
- 3.2 All records other than protocol files are retained indefinitely.
- 3.3 All records for research conducted or funded by a Common Rule department or agency, or records for research subject to Food and Drug Administration (FDA) regulations, are to be accessible for inspection and copying by authorized representatives of those agencies, respectively, 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 Protocol files are maintained within the OIA electronic submission system. The electronic submission system is maintained on server banks in geographically diverse areas of the U.S. to prevent data loss and down time during even the worst disasters and to promote continuity.
- 3.6 All records other than protocol files are stored on UCSD provided cloud services which adhere to the UCSD disaster preparedness plan and are backed up to prevent data loss and down time during even the worst disasters and to promote continuity.

4 RESPONSIBILITIES

- 4.1 OIA staff members carry out these procedures.

5 PROCEDURE

- 5.1 Protocol files must be retained for a minimum of 10 years after the end of the calendar year in which the research has been completed, unless retention is otherwise required by law, regulation, policy, contract, or grant terms.
 - 5.1.1 In the case of multi-center research, ten years is referenced to the institution's involvement in the research, not the entire study.

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*

7 REFERENCES

- 7.1 [21 CFR 56.115](#)
- 7.2 [32 CFR 219.115](#)
- 7.3 [45 CFR 46.115](#)
- 7.4 [45 CFR 164.530\(j\)\(2\)](#)
- 7.5 [UC Record Retention Schedule](#)