

SOP: IRB Records Retention				
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1 PURPOSE

- 1.1 This procedure establishes the process to retain and destroy IRB records.
- 1.2 The process begins at the creation of a record.
- 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 IRB Records, as defined in 45 CFR 46.115, are to be retained as long as required by law and then destroyed.
- 3.2 Records may be maintained in printed form or electronically.
- 3.3 IRB Records in which there was no subject enrollment or no research was conducted are to be retained the same as IRB Records where research was conducted.
- 3.4 IRB Records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

4 RESPONSIBILITIES

- 4.1 Human Subjects Office staff members carry out these procedures.

5 PROCEDURE

- 5.1 Destroy IRB Records in accordance with Federal regulations (e.g., 45 CFR 46.115; 21 CFR 56.115; and 32 CFR 219).
- 5.2 In the case of multi-center or multi-site research where FSU is not acting as the Single IRB, the record retention period refers to FSU's involvement in the research, not the entire study.

6 MATERIALS

- 6.1 None

7 REFERENCES

- 7.1 None