FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY POLICY

# Records Retention Schedule for Sponsored Project Documents # 2350.065

| INITIAL EFFECTIVE DATE: | LAST REVISION DATE: | RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT |
|---|---|---|
| February 11, 2004 | March 30, 2021 | Office of Research and Economic Development/ Post-Award |

## POLICY STATEMENT

All documents relating to sponsored projects must be maintained for the length of time required by applicable federal or Florida law and regulations.

## REASON FOR POLICY

To set forth the length of time that documents relating to sponsored projects must be maintained by University personnel.

## DEFINITIONS

| TERM | DEFINITIONS |
|---|---|
| N/A | N/A |

## ROLES AND RESPONSIBILITIES

PIs must ensure that they maintain the sponsored project records in their control, including the programmatic and fiscal documents, for the required length of time.

Post-Award will ensure that the file of fiscal documents will be maintained for the required length of time.

## RELATED RESOURCES

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR Part 200 (the "Uniform Guidance")

State of Florida Department of State General Records Schedule GS5 for Universities and Colleges, February 19, 2015, available at https://dos.myflorida.com/media/693588/gs05.pdf.

State of Florida General Records Schedule GS1-SL for State and Local Government Agencies, August 2017, available at https://dos.myflorida.com/media/698312/gs1-sl-2017-final.pdf

**CONTACTS**

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**HISTORY**

**Initial Effective Date:** February 11, 2004; Office of Sponsored Research Administration Faculty/Staff Guide for the Administration of Externally Funded Projects, INTERIM VERSION
**Review Dates** (*review performed, no updates*): N/A
**Revision Dates** (*updates made to document*): March 23, 2007, July 3, 2008, June 20, 2013, July 30, 2014, October 10, 2018, and April 22, 2020; March 30, 2021

FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY PROCEDURE

# Records Retention Schedule for Sponsored Project Documents # 2350.065a

| INITIAL EFFECTIVE DATE: | LAST REVISION DATE: | RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT |
|---|---|---|
| February 11, 2004 | March 30, 2021 | Office of Research and Economic Development/ Post-Award |

## PROCEDURE STATEMENT

All records are subject to audit and any authorized representative of the project sponsor, the State of Florida, the Inspector General, the Comptroller General of the United States or the University's cognizant federal agency, the U.S. Department of Health and Human Services, may inspect documents relating to the award. University faculty and staff must ensure that they retain records in accordance with the Records Retention Schedule set forth below. ORED documents shall be stored in an electronic format using a secure server in accordance with the requirements of the FIU Library and the State of Florida for electronic storage of documents and such electronically stored documents shall be the record documents of ORED. Once the ORED document has been imaged, and the image quality verified, ORED will destroy the hard copy of the document. Destruction of any records must be done in accordance with the policy established by the State of Florida.

If a type of record falls under more than one retention period set forth below, the record must be maintained for the longer retention period that is applicable.

I. General Retention Period for Sponsored Project Documents:

(a) Regardless of the project sponsor and unless the award document contains a longer period for retention of records, the sponsored project records must be maintained for five (5) fiscal years after the expiration or termination of the sponsored project so long as there is no pending audit or litigation relating to the sponsored project. If there is any pending audit or litigation, then the records must be maintained until the audit and/or litigation are finalized and closed. See retention period below for sponsored projects involving human subjects. (See General Records Schedule GS1-SL for State and Local Government Agencies Item #422: Grant Files: Recipient).

II. State of Florida Requirement for Final Close-Out Report:
Post-Award, shall retain the record copy of the final close-out reports for federal grants for 10 fiscal years (provided applicable audits have been released and there is no pending legal action) as required by Florida records retention requirements. (see General Records

Schedule GS1-SL for State and Local Government Agencies Item #341: Disbursement Records: Summary).

III. Sponsored Projects Involving Human Subjects:

The retention period is as follows for the documents noted below.

Office of Human Research Protections (OHRP) requires research records to be retained for at least 3 years after the completion of the research. (See 45 CFR 46.115(b))

HIPAA Requirements: Any research that involves collecting protected health information (PHI) is subject to the requirements of the Health Insurance Portability and Accountability Act (HIPAA) which requires that such records be retained for a minimum of 6 years after each subject signed the HIPAA authorization. (See 45 CFR Part 164, Subpart A - §164.105)

FDA Requirements (Drugs): Any research that involves drugs being tested on humans must have records retained for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and the Federal Drug Administration (FDA) is notified. Please note - this length of time can be much greater than 2 years. You should receive written confirmation from the sponsor and/or the FDA granting permission to destroy the records. (See 21 CFR 312.62.c)

FDA Requirements (Devices): Any research that involves devices being tested on humans must be maintained during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. You should receive written confirmation from the sponsor and/or the FDA granting permission to destroy the records. (See 21 CFR 812.140.d)

FDA Requirements (Biologics): Any research that involves biologics being tested on humans shall be retained for such interval beyond the expiration date as is necessary for the individual product, to permit the return of any clinical report of unfavorable reactions. The retention period shall be no less than (5) five years after the records of manufacture have been completed or six months after the latest expiration date for the individual product, whichever represents a later date. You should receive written confirmation from the sponsor and/or the FDA granting permission to destroy the records. (See 21 CFR 600.12.b)

Sponsor Requirements (Grant or Contract): You must ensure that you comply with any terms for records retention detailed in the award document with the sponsor. Some sponsors may require researchers to keep records until notified by the sponsor. If a longer period is not required by the sponsor, the research records must be maintained for five (5) years as set forth in Section I above.

Professional Association Requirements: If your research falls within the guidelines of a particular profession (e.g. American Psychological Association), you may be required to retain records based on the association's practices.

Occupational Safety and Health Administration (OSHA): OSHA requires employers to keep records of both medical and other employees who are exposed to toxic substances and harmful agents. Employers must maintain these records for the duration of the employee's employment plus 30 years. (See Title 29 of the Code of Federal Regulations (CFR) Part 1910.1020)

For any questions regarding records retention for humans subject research, please contact the Office of Research Integrity of the Office of Research and Economic Development or the Office of the General Counsel.

IV. Records Related to Intellectual Property Licensing:

The retention period for license agreements is five (5) fiscal years (See General Records Schedule GS1-SL for State and Local Government Agencies Item #65: CONTRACTS/LEASES/AGREEMENTS: NON-CAPITAL IMPROVEMENT).