Policy Title: Research Data Retention
Category: Research
Sponsor: Executive Vice President for Research
Effective Date: 04/11/2023

INTRODUCTION AND PURPOSE.

Accurate record keeping of Research Data is an essential component of the research enterprise. This ensures rigor and accountability, protects intellectual property rights, and is necessary to remain in compliance with federal regulations and other RFUMS policies.

The purpose of this policy is to outline the obligations and responsibilities of the University, the Principal Investigator (PI), and any other researchers regarding the preservation and availability of primary Research Data and Materials.

SCOPE AND APPLICABILITY.

This policy is applicable to all RFUMS faculty, staff, students, visiting scholars, postdoctoral fellows, and any other persons affiliated with RFUMS who participate in the creation, acquisition, access, use, management, sharing, retention, and disposal of Research Data and Research Materials, either on behalf of or at RFUMS. This policy applies to all research activities, regardless of funding status or funding source, except where specific sponsor requirements take precedence.

POLICY STATEMENTS.

Research Data Ownership and Sharing

RFUMS retains ownership of, and possesses unrestricted access to, Research Data and Research Materials for projects carried out at the University, under the University's jurisdiction, or supported by university resources. Principal Investigators (PIs) are custodians of Research Data and remain accountable to the University for the stewardship of Research Data.

When sharing Research Data or Research Materials, PIs must remain in compliance with all legal agreements, including, but not limited to Research Agreements, Material Transfer Agreements, License Agreements, and Confidentiality Disclosure Agreements. PIs must ensure they remain in compliance with all policies imposed by federal and non-federal funding bodies governing data sharing, model organisms, and the dissemination of research findings.

Research Data Retention

Research Data must be retained for a minimum of seven years after the closeout of the grant or contract agreement. Please note that the grantor institution may have additional policies and procedures regarding the custody, distribution, and required retention period for data produced under research awards.

Research Data from human subject research studies must be maintained in a manner consistent with the approved IRB protocol and the subsequent study closure plan. In the case of a Food and Drug Administration (FDA) Clinical Investigation, researchers must comply with the FDA's Investigator Recordkeeping and Retention Requirements.

Longer periods of retention may be required under the following circumstances:

- To protect any intellectual property during ongoing patenting and licensing procedures resulting from the work.
- If litigation or other dispute resolution procedures, claims, financial management reviews, or audits related to the research project are started before the expiration period.
- In cases where an allegation of research misconduct is made.
- Research Data for any project to which a student has contributed, and which are necessary for the student to fulfill a degree requirement, must be retained until the student's degree is awarded.
- If the terms of an award or contract regarding ownership, retention, and access to technical data conflict with or exceed the terms of this Policy, the provisions of the agreement will take precedence over this Policy.

Research Data Destruction

The destruction of Research Data after the applicable retention period is at the discretion of the PI. Data destruction should conform to secure data removal techniques and be appropriately documented by the laboratory or department.

Research Data Transfer

A PI wishing to transfer Research Data to another institution should contact the Office of Sponsored Research to coordinate the transfer.

Copies of Research Data associated with finished projects that have not exceeded the retention period, must be retained at RFUMS. With respect to Research Data and materials associated with active projects, ownership of the original data may be transferred to the PI's new institution subject to the approval of the Executive Vice President for Research and written agreement from the PI's new institution that guarantees (a) its acceptance of ongoing custodial responsibilities and (b) that RFUMS can access the original data if necessary, and (c) relevant confidentiality restrictions will be implemented where appropriate.

Regardless of project status or minimum retention period, PIs must seek IRB approval to transfer any non-deidentified human subject Research Data.

When individuals other than the PI involved in research projects at RFUMS leave the University they may take copies of Research Data for projects on which they have worked, subject to the conditions described above.

DEFINITIONS.

Research Data: Information that is created or collected in the process of performing research regardless of how it is recorded or stored. This includes both tangible data (recorded notes; films,

instrument printouts, digital storage devices, etc.) and intangible data (analyses, statistics, etc.), as well as any other documentation that can be used to reconstruct published research findings.

Research Materials: Includes, but are not limited to, new, modified or unmodified biological specimens, animal models or chemical compounds, computer software.

POINTS OF CONTACT.

The Executive Vice President for Research, RFUMS has authority for compliance with this Policy and is responsible for its implementation. The Research Data Management Coordinator serves as the subject matter expert and contact for questions about interpretation and implementation of this Policy.

REFERENCES AND RELATED POLICIES.

Manual on Responding to Allegations or Evidence of Possible Research Misconduct

Guidelines for the New NIH Data Sharing Policy

RESOURCES

8.4.2 Record Retention and Access (NIH policy on data retention).

312.62 Investigator recordkeeping and record retention (FDA Investigator Recordkeeping and Retention Requirements).

2 CFR § 1136.205 (Record retention for federal grants, Code of Federal Regulations).

NOT-OD-21-013 (NIH Policy for Data Management and Sharing).

POLICY HISTORY.

Policy issue date: April, 2023

Policy updates: N/A