

UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	RCR-102
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Prepared By:	Assistant Provost for Research Integrity
Reviewed By:	Provost, Federal Office of Research Integrity, IRB University of Southern Maine Human Resources
Title:	Sequestration of Research Records

1. **Purpose:** The standard operating procedures (SOP) for Sequestration of Research Records in order to obtain custody of all the Evidence needed to conduct the review of an [Allegation under the “Research Misconduct Policy,”](#) inventory the Evidence, and sequester it in a secure manner, except where the Evidence encompasses scientific instruments shared by a number of users.
2. **Scope:** These Procedures apply to all members of the University of Southern Maine (USM) community, including students, who engage in Research.
3. **Responsibility:**
 - 3.1. USM has designated the USM Research Integrity Officer (RIO) to establish and implement this SOP. The RIO also serves as a liaison between USM and the sponsoring agency and will prepare and submit all reports to the research sponsor.
4. **Definitions:**
 - 4.1. **“Adverse action”** means any action taken by a member of USM which negatively affects the terms or conditions of the whistleblower's status at the University, including but not limited to his or her employment, academic matriculation, awarding of degree, or University relationship established by grant, contract, or cooperative agreement.
 - 4.2. **“Allegation”** means any disclosure, whether by written or oral statement, or any other communication, to USM, a governmental or other sponsoring agency official who receives the allegation while acting in their official capacity, that USM or member thereof has engaged in research misconduct.
 - 4.3. **“Complainant”** means a person who makes an Allegation. A Complainant need not be a member of the USM community.
 - 4.4. **“Evidence”** means any document, tangible item, or testimony that is received, or that may be offered, as evidence during a Research Misconduct Proceeding to prove or disprove the existence of a fact relevant to the Allegation at issue in that Research Misconduct Proceeding. This could include, depending on the Allegation, materials such as:
 - proposals, grant applications, and comments thereon,
 - relevant research data and related records,
 - laboratory notebooks and computer files,
 - telephone logs and memos of calls,
 - correspondence, or
 - manuscripts, posters, publications, and tapes of oral presentations.

- 4.5. **“Inquiry”** means information gathering and initial fact finding to determine whether an Allegation warrants an Investigation.
 - 4.6. **“Inquiry Panel”** means a group of at least three persons appointed by the Responsible Administrator to conduct an Inquiry. While Inquiry Panels will usually be composed of USM faculty, they may also include persons other than USM faculty when the Responsible Administrator determines that such persons have experience or expertise useful to the Inquiry. When a student is the Respondent, at least one student shall be a member of the Inquiry Panel. The Inquiry Panel shall select one of its members to act as its chairperson.
 - 4.7. **“Investigation”** means the formal, thorough examination and evaluation of all facts relevant to an Allegation to determine if Misconduct occurred and to assess its extent, gravity, and actual and potential consequences.
 - 4.8. **“Investigative Committee”** means a group of at least three persons appointed by the Responsible Administrator to conduct an Investigation.
 - 4.9. **“Research Misconduct”** Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.
 - 4.10. **“Research Record”** means the record of data or results from scholarly inquiry, including, without being limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, books, and other publications of any kind in any media and any material in any media necessary to support the content of any such document, presentation, or publication.
 - 4.11. **“Research Integrity Officer (RIO)”** means the official designated by and reporting to the Provost to establish and implement USM’s Anti-Retaliation Policy for Reporting of Misconduct in Research.
 - 4.12. **“USM member, or member”** means a person who is employed by, affiliated with under a contract or agreement, or under the control of USM. USM members include but are not limited to faculty, students, administrators, teaching and support staff, researchers, technicians, and fellows.
5. **Applicable Documents:**
 - 5.1. **42 CFR 50 and 93 applies to all HHS research**
 - 5.2. Title 42, Part 50, Subpart A of the Code of Federal Regulations - 42 CFR 50, Subpart A
 - 5.3. Federal Sentencing Guidelines – Chapter 8 Part B – Remedying Harm from Criminal Conduct, and Effective Compliance & Ethics
 - 5.4. America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act - 42 U.S.C. §1862 et seq. (2007)
 6. **Procedure:**
 - 6.1. **Immediate Sequestration.** If the relevant Research Records have not been secured at the assessment stage, the RIO shall immediately locate, collect, inventory, and secure them to prevent the loss, alteration, or fraudulent creation of Evidence. In addition to securing Research Records under the control of the Respondent (see below), the RIO may need to sequester records from other individuals, such as coauthors, collaborators, or Complainants.

- 6.1.1. **Obtaining Research Records from electronic devices.** USM shall secure relevant evidence from computer CPUs or physically secure the CPUs directly. USM will check for and secure all system backups.
- 6.2. **Sequestration of Records from Respondent.** The RIO should notify the Respondent that an Inquiry is being initiated simultaneously with, and in any event no earlier than, the sequestration to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the Respondent of tampering with or fabricating data or materials after the notification. The RIO should obtain the assistance of the Respondent's supervisor and UMS Counsel in this process, as necessary. If the Respondent is not available, sequestration may begin in the Respondent's absence.
- 6.3. **Inventory of the Records.** The RIO and the person from whom Research Records is collected should sign a dated receipt, and a copy of the receipt should be given to the person from whom such records are taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the Research Records was collected.
 - 6.3.1. As soon as practicable, a copy of each sequestered Research Record should be provided to the individual from whom the Record was taken, if requested. Where the Research Records constitute scientific instruments or other materials shared by a number of users, custody may be limited to copies of the data or Evidence on such instruments, or copies of the other materials, so long as those copies are substantially equivalent to the originals.
 - 6.3.2. The RIO will arrange for preparation of clear "working copies" of the most important Evidence. The working copies are conforming copies, which include all elements on the sheet from margin to margin, any covered elements, and with the reverse checked and copied if informative. On the "master copy," investigative labels for each notebook, folder, chart, etc., will be added, as well as numbers to each page along with annotations of any relevant observations, such as whether an item is original handwriting or a photocopy.
 - 6.3.2.1. Working copies will be provided to the Inquiry Panel, the Investigative Committee, the Review Panel, experts, and portions as appropriate to witnesses to ensure accurate and easy communication about the evidence and to reduce handling of the original evidence.
 - 6.3.2.2. As the committee organizes the issues and new items of Evidence become relevant to the investigation, the RIO will continue to make working copies
- 6.4. **Security and Chain of Custody.** The RIO shall keep original Evidence in a secure place accessible only by ORIO staff. The Evidence shall be checked against the inventory list immediately after they are placed in the secure site.
 - 6.4.1. Upon request, and to the extent feasible, the persons from whom Research Records are collected may be given access to their own original Records under the direct and continuous supervision of a USM official. Questions about maintaining the chain of custody of records should be addressed to UMS Counsel.
 - 6.4.2. Committee members, respondent, and appropriate witnesses will arrange through the

RIO to have access to the detailed inventory and copies of pertinent evidence.

- 6.5. **Data Retention.** The RIO shall keep all Research Misconduct Proceeding Records for at least seven (7) years after the completion of the Research Misconduct Proceedings to which they relate, except that the RIO shall keep Preliminary Assessment reports and related Research Misconduct Proceeding Records for three (3) years after the completion of the Preliminary Assessment to which they relate and then destroy them, unless a longer period is specified by the sponsor.
 - 6.5.1. **PHS funded research.** USM will retain the evidence in custody until all PHS actions are complete. The Office of Research Integrity (ORI) may request copies of the relevant evidence, if not already appended to the report, and it may be necessary to turn over custody of the original evidence to Federal officials. In that case, the custodian will be prepared with custody documentation and testimony.
 - 6.5.2. **Data Return.** When notified of completion of the final action, evidence will be returned to the proper individual and a receipt for its return will be obtained.