UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	RCR-102
Date Adopted:	November 20, 2013
Last Updated:	December 31, 2025
Prepared By:	Associate Provost for Research
Reviewed By:	Provost, Federal Office of Research Integrity, IRB University of Southern Maine Human Resources
Title:	**Sequestration of Research Records**

1.0 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 "RCR 101 Alleged 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.

2.0 Scope: These Procedures apply to:

2.1. These Procedures apply to:

2.1.1. A person who, at the time of the alleged research misconduct, held a University appointment or was a graduate student engaged in the design, conduct, or reporting of research, whether or not the research is funded; and

2.1.2 Anyone engaged in the design, conduct, or reporting or research through a Sponsored Program at USM, to the extent of that research.

2.2. Except for research misconduct in the context of a Sponsored Program, allegations of research misconduct by undergraduate students shall be dealt with pursuant to the Code of Student Rights, Responsibilities, and Conduct.

2.3. The Deciding Official (DO) may, in consultation with the Research Integrity Officer (RIO), determine that an allegation of research misconduct on the part of a graduate student is more appropriately referred to the disciplinary channels provided in the Code of Student Rights, Responsibilities, and Conduct or such other disciplinary process duly established by a campus or academic unit.

2.4. This statement of policy and procedures is intended to carry out USM's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. These policies and procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling research misconduct involving non-PHS supported research. They do not replace the PHS regulation, and in case of any conflict between this document and 42 CFR Part 93, the PHS regulation will prevail. These policies and procedures are intended to enable the University to comply with the requirements of the PHS regulations as the policies and procedures apply to allegations of research misconduct involving:

2.4.1. Applications or proposals for PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training.[1]

2.4.2. PHS-supported biomedical or behavioral research.[2]

2.4.3. PHS-supported biomedical or behavioral research training programs.[3]

2.4.4. PHS-supported activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information.[4]

2.4.5. Research records produced during PHS-supported research, research training, or activities related to that research or research training.[5]

2.4.6. Research proposed, performed, reviewed, or reported, as well as any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in an awarded grant, contract, cooperative agreement, subaward, or other form of PHS support.[6]

2.5. This statement of policy and procedures does not apply to authorship or collaboration disputes. It applies only to allegations of research misconduct that occurred within six years of the date the University or HHS received the allegation, subject to the following exceptions:

2.5.1. The six-year time limitation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of, republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent ("subsequent use exception"). For alleged research misconduct that appears subject to this subsequent use exception, but the University determines is not subject to the exception, the institution will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven years after completion of the institutional proceeding or the completion of any HHS proceeding.

2.5.2. The six-year time limitation also does not apply if the Officer of Research Integrity (ORI) or the University, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

3.0 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.

---

[1] § 93.102(b)(1).
[2] § 93.102(b)(2).
[3] § 93.102(b)(3).
[4] § 93.102(b)(4).
[5] § 93.102(b)(5).
[6] § 93.102(b)(6).

4.0 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 a disclosure of possible Research Misconduct through any means of communication and brought directly to the attention of the Research Integrity Officer (RIO) or to any University Official.

4.3. **"Complainant"** means an individual who in good faith makes an allegation of research misconduct.

4.4. **"Evidence"** means anything offered or obtained during a Misconduct Proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony. This could include, depending on the Allegation, materials such as:

4.4.1. proposals, grant applications, and comments thereon,
4.4.2. relevant research data and related records,
4.4.3. laboratory notebooks and computer files,
4.4.4. telephone logs and memos of calls,
4.4.5. correspondence, or
4.4.6. 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. The Inquiry Panel shall select one of its members to act as its chairperson.

4.7. **"Institutional Member"** means an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional Members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.

4.8. **"Institutional Record"** comprises: (a) The records that the institution compiled or generated during the Misconduct Proceeding, except records the institution did not consider or rely on. These records include but are not limited to (1) documentation of

the assessment as required by § 93.306(c); (2) if an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c); (3) if an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution; (4) decision(s) by the Deciding Official, such as the written decision from the Deciding Official under § 93.314; (5) the complete record of an internal appeal from a finding of Research Misconduct consistent with § 93.315; (b) a single index listing all the research records and evidence that the institution compiled during the Misconduct Proceeding, except records the institution did not consider or rely on; and (c) a general description of the records that were sequestered but not considered or relied on.

4.9. "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.

4.10. "Investigative Committee" means a group of at least three persons appointed by the Responsible Administrator to conduct an Investigation.

4.11. "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.

4.12. **"Research Record"** means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

4.13. "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.

5.0 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)

6.0 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. Data Retention. Research Misconduct Institutional Records will be kept in a secure room, accessible only to the RIO and their administrative staff. The RIO shall keep all Misconduct Proceeding Records for at least seven years after the completion of the Misconduct Proceedings to which they relate, or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS.[7] RIO shall keep assessment reports and related Misconduct Proceeding Records for three years after the completion of the assessment to which they relate and then destroy them.

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.

6.5.1. **Records to Agency.** When the alleged Research Misconduct involves Research supported by a federal funding source, the RIO shall make available to its authorized personnel any Institutional Records that such personnel request.

6.5.1.1 Public Health Service (PHS) funded research. The institution will provide information related to the alleged research misconduct and proceedings to ORI upon request and transfer custody or provide copies of the Institutional Record or any component of it and any sequestered evidence to HHS, regardless of whether the evidence is included in the Institutional Record.[8] Additionally, the institution will promptly notify ORI of any special circumstances

[7] § 93.318.
[8] § 93.318(b).

that may arise.[9]

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.

[9] § 93.305(g).