UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-039
AAHRPP:	Element I.4.A., Element I.5.C., & Element III.1.G.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Research Concerns

1.0 Objective

1.1. To describe policies and procedures for handling concerns, complaints, or questions received regarding a research study involving human subjects.

2.0 General Description

2.1. The right of research subjects to lodge a concern (e.g., allegation), complaint, or question and to be assured that the concern, complaint, or question is taken seriously and resolved in a timely manner is of prime importance. All members of the University of Southern Maine (USM) community should report observed, suspected, or apparent research misconduct or protocol violation to the Research Integrity Officer (RIO).

2.2. The RIO is responsible for investigating concerns, complaints, and questions from subjects and any improprieties involving investigators or their staff. Matters shall be handled in a timely manner, assuring protection of human subjects, and that the Institutional Review Board (IRB) holds any violators accountable to the applicable regulation.

2.3. A research subject (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human research study may raise concerns, complaints, or questions about a research project to the designated RIO. At any time, a USM community member may have confidential discussions and consultations about concerns of possible misconduct or violations with the RIO. The RIO will provide counsel regarding appropriate procedures for reporting allegations.

2.3.1. Research Misconduct Policies

2.3.1.1. RCR-101 Alleged Research Misconduct
2.3.1.2. RCR-102 Sequestration of Research Records
2.3.1.3. RCR-103 Anti-Retaliation Policy for Reporting of Misconduct in Research
2.3.1.4. https://usm.maine.edu/orio/responsible-conduct-research

3.0 Definitions

3.1. Research Misconduct means:

3.1.1. The knowing fabrication, falsification, or manipulation by a researcher of data or information;

3.1.2. The knowing theft by a researcher of data, materials, or information, including but not limited to plagiarism;

3.1.3. Implicit in this definition of misconduct is that a preponderance of the evidence proves that fabrication, falsification, or plagiarism; theft; non-compliance with legal requirements; or disregard of associate conduct was committed intentionally, knowingly, or recklessly, and not merely carelessly.

3.2. Protocol Violation is an accidental or unintentional deviation involving a single subject that is not approved by the IRB prior to its initiation or implementation. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data. These protocol violations may be major or minor violations.

3.2.1. **Major Protocol Violation** is any protocol violation that may impact subject safety, make a substantial alteration to risks to subjects, or any factor determined by the IRB Chair or designee as warranting review of the violation by the convened IRB.

3.2.2. **Minor Protocol Violation** is any protocol violation that does NOT impact subject safety or does not substantially alter risks to subjects.

3.2.3. *See* HRPP-002 Protocol Violations.

3.3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

3.4. USM Member or Member means a person who is employed by, affiliated with under a contract or agreement, or under the control of the USM. Members include, but are not limited to:

3.4.1. Students;

3.4.2. Faculty;

3.4.3. Administrators;

3.4.4. Support staff;

3.4.5. Principal Investigators (PI);

3.4.6. Research Staff; and

3.4.7. Technicians.

3.5. Research Integrity Officer (RIO): The RIO promotes the responsible conduct of research, research raining, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

4.0 Responsibility

4.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this Standard Operating Procedure (SOP).

5.0 Procedure

5.1. A research subject or anyone with a concern, complaint, or question regarding a research study involving human subjects may raise them with the RIO. Upon receipt of concern (e.g. allegation), complaint, or question, the RIO or designee gathers the following information from the complainant as appropriate:

5.1.1. If applicable, the subject's (or complainant's) name and contact information;

5.1.1.1. To report an allegation anonymously, the complainant may create a new e-mail account, such as Yahoo or Gmail, using pseudonyms and e-mailing the RIO directly; or

5.1.1.2. As an alternative method, sending ORIO an anonymous comment via the ORIO website located https://usm.maine.edu/orio/contact-us with the appropriate subject line; or

5.1.1.3. Fill in a text box through a Google form which is submitted directly to the RIO;

5.1.1.4. All submissions will be confidential and safe.

5.1.2. Study protocol title (or acronym) and the name of the PI;

5.1.3. Date(s) of the incident, and;

5.1.4. An explanation of the concern, complaint, or question.

5.2. The RIO or designee assures the individual (or complainant) that s/he will inquire into the circumstances and the RIO will take appropriate measures to address the issue. Furthermore, the RIO or designee informs the individual that a response to him or her

will be forthcoming as rapidly as possible provided that contact information is given. The RIO or designee also explains to the individual the limits to confidentiality.

5.3. The RIO or designee handles the concern, complaint, or question in a confidential manner to the extent allowed by law. ORIO limits access to information concerning the contact to employees with responsibilities that require knowledge of the concern, complaint, or question.

5.4. The RIO or designee conveys the information regarding the concern, complaint, or question to the PI of the study at issue in a timely manner.

5.5. The RIO or designee promptly investigates the concern, complaint, or question; evaluates the alleged impropriety on a case-by-case basis; and makes every effort to correct the issues(s) at the administrative level.

5.6. If the alleged impropriety involves potential harm to subjects or others, the RIO or designee notifies the IRB for immediate action pending a formal inquiry. The RIO or designee reports concerns, complaints, or questions involving serious issues immediately to the IRB Chair, the RCA, and IRB.

5.7. All records, inquiries, preparing related correspondence, and documentation will be kept in a secure room, accessible only to the RIO and their administrative staff. The RIO shall keep all records for at least seven years from completion of the inquiry or close out of the IRB file, whichever is longer before records are destroyed.

5.8. The IRB Chair or his or her designee, in collaboration with the RIO or designee, ensures appropriate response to each concern, complaint, or question and reports the action(s) taken to the IRB. If the complaint, concern, or question is of a minor nature, the RCA, the RIO, or designee may resolve the issue without bringing it forth for an IRB committee vote. All actions taken by the IRB are appropriate for the circumstances, and the final course of action is dependent on the nature, severity, and seriousness of the findings.

5.9. Depending on the nature of the event or circumstances, the IRB may take the following actions but is not limited to:

5.9.1. Further inquiry;

5.9.2. Administrative action;

5.9.3. Details and recommendations forwarded to the appropriate committee chairs; and/or;

5.9.4. Other actions as deemed appropriate.

5.10. The ORIO and IRB will monitor any concerns, complaints, or questions that an individual may lodge for issues of noncompliance. The RIO or designee brings issues involving non-compliance to the attention of the IRB Chair, and the IRB.

5.11. If the circumstances described by the individual do not meet the definition of research misconduct or animal protocol violation, the RIO can still refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

6.0 References

6.1. 45 CFR 46.116(a);

6.2. 21 CFR 50.25(a)