UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-004
AAHRPP:	Element I.5.D., Element II.5.B. & Element III.2.D.
Date Adopted:	12/18/2015
Last Updated:	04/08/2020
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Reviewed By:	IRB; ORIO; Assistant Provost for Research Integrity
Procedure Title:	Non-compliance

1.0 Objective

1.1. To describe the policies and procedures that the Institutional Review Board (IRB) and the Office of Research Integrity and Outreach (ORIO) follow for handling allegations of non-compliance.

2.0 General Description

2.1. Federal regulations require the IRB to review proposed changes in any research activity and to ensure that the Principal Investigator (PI) does not initiate such changes in approved research without IRB review and approval except when necessary to eliminate apparent immediate hazards/risks to the subject [45CFR46.108(a)(3)(iii) and 21CFR56.108(a)(4)].

2.1.1. In assuming that responsibility, the IRB addresses allegations of non-compliance with IRB requirements and/or federal regulations governing the conduct of human research. Office of Research Integrity and Outreach (ORIO) staff, IRB members, or IRB consultants do not participate in alleged non-compliance reviews if they have a conflict of interest.

2.2. **Discovery of Non-compliance:** Investigators and performance sites will be instructed that suspected non-compliance shall be reported to the Research Compliance Administrator (RCA) or the IRB Chair. All performance site personnel, including but not limited to individuals involved in the conduct of research, such as investigators, study coordinators, and institutional officials, shall ensure prompt reporting to the IRB of any suspected non-compliance with the approved project or requirements of the University of Southern Maine (USM) IRB. A whistleblower with involvement or knowledge of a project with an allegation of non-compliance is a common means by which non-compliance may be discovered. The IRB shall do its diligence in protecting the whistleblower.

2.3. When appropriate, the USM IRB will decide whether or not additional reports, including but not limited to audits, complaints, protocol deviations, and unanticipated problems involving risks to participants or others, indicate non-compliance.

3.0 Definitions

3.1. **Non-compliance** is defined as conducting research in a manner that disregards or violates federal regulations, local or country laws, institutional policies, procedures applicable to human subject research, or requirements of the IRB.

3.1.1. Non-compliance does not include minor or technical violations, which result from inadvertent errors, inattention to detail, or failure to follow operational procedures, which do not pose risk to subjects and/or violate subjects' rights and welfare. These are outlined in *HRPP-002 Protocol Violations*.

3.2. **Continuing non-compliance** is a pattern of repeated failure to adhere to the laws, regulations, or policies governing human subject research.

3.3. **Serious non-compliance** may reasonably be regarded as:

3.3.1. Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or

3.3.2. Substantively compromising the effectiveness of human subject research protection or human subject research oversight programs.

3.3.3. A single instance of non-compliance may be deemed serious.

3.4. **Non-serious non-compliance**: Defined as non-compliance that does not meet the standards of serious or continuing non-compliance. While this type of non-compliance is not considered serious, it does still mean that the investigator has committed non-compliance and that the situation still warrants discussion by the IRB Chair or IRB and corrective action.

3.5. **Allegation** is a disclosure of possible non-compliance by a respondent to the Research Compliance Administrator (RCA) by any means of communication.

3.6. **Complainant** is a person who makes an allegation and need not be a member of the University of Southern Maine (USM) community.

3.7. **Respondent** is a person who is the subject of an allegation and must be a member of the USM community at the time the alleged non-compliance occurred.

4.0 Responsibility

4.1. It is the responsibility of the ORIO, RCA, IRB, investigators, and USM employees to execute this SOP.

5.0 Procedure

5.1. Submission and Screening of Allegations of Non-compliance

5.1.1. Anyone may submit allegations of non-compliance involving human subject research to the Research Integrity Officer (RIO) or RCA, verbally or in writing. Anyone who wishes to make an anonymous allegation should follow the procedure set forth in *RCR-101 Alleged Research Misconduct Policy* and *HRPP-039 Research Concerns*. The RIO/RCA/IRB shall maintain confidentiality regarding the identity of the person submitting the allegation to the extent possible.

5.1.2. The RIO or designatee screens the allegation of non-compliance to determine whether the protocol(s) affected is supported by federal funds.

5.1.3. The RCA also determines whether the protocol has issues pertinent to other research review committees.

5.1.4. The RCA determines if there is immediate action needed to protect subjects and consults with the IRB Chair.

5.2. Preliminary Assessment of Allegation

5.2.1. The RCA reviews all allegations to determine whether the facts justify the allegation (i.e., there are supporting documents or statements).

5.2.2. If the RCA deems an allegation unjustified (i.e., finds no supporting documents or statements), the RCA communicates this determination in writing to the complainant (if the identity of the person is known) and to the investigator against whom the allegation was raised (respondent). Upon resolution of the issue, the RCA provides an oral and/or written summary of the resolution to the applicable IRB at the next convened IRB meeting.

5.2.3. If the RCA determines that an allegation is justified but is minor or administrative in nature, the RCA manages the concern through communications with the PI. The RCA communicates this determination in writing to the complainant (if the identity of the person is known) and to the investigator against whom the allegation was raised (respondent). Upon resolution of the issue, the RCA provides an oral and/or written summary of the resolution to the applicable IRB at the next convened IRB meeting.

5.2.4. If the RCA determines that an allegation is justified, the RCA forwards the allegation materials to the IRB Chair or designee for review.

5.2.5. If the IRB Chair deems the allegation unjustified, the RCA communicates this determination in writing to the complainant (if the identity of the person is known) and to the investigator against whom the allegation was raised (respondent). Upon resolution of the issue, the RCA provides an oral or written summary of the resolution to the applicable IRB at the next convened IRB meeting.

5.2.6. If the IRB Chair determines that an allegation is justified, the RCA initiates an inquiry into an allegation.

5.3. Initiating an Inquiry into an Allegation

5.3.1. If the IRB Chair determines that an allegation is justified, the RCA notifies the PI. If the allegation involves a co-investigator(s) or research assistant(s), the RCA also contacts these individuals by phone, email, or letter.

5.3.2. The IRB Chair appoints the RCA or designee to gather information pertaining to the nature of the allegation, the procedures approved in the IRB protocol, and the procedures followed in conducting the study.

5.3.3. The RCA interviews the complainant, or, in cases where the complainant requests anonymity, the individual who received the original allegation interviews the complainant. The interviewer prepares a summary of the interview and gives the complainant the opportunity to comment on the written summary. In some cases, the complainant may have already submitted a written complaint, which the RCA then verifies. The RCA may request additional information from the complainant.

5.3.4. The RCA interviews the respondent and gives the PI the opportunity to comment on the allegation and provide information. The RCA prepares a summary of the interview and gives the respondent the opportunity to comment on the summary. The respondent may submit a written rebuttal to the complaint, which the RCA verifies. The RCA may request additional information from the respondent.

5.3.5. Depending on the nature of the allegation and the information collected during the interviews, the RCA may interview other individuals. In addition, in conducting the review, the RCA may examine research data, both published and unpublished; informed consent/assent forms; medical records; inclusion/exclusion criteria; the applicable approved IRB protocol; and any other pertinent information.

5.3.6. When appropriate, the RCA prepares a summary report for the convened IRB. The report may consist of a summary of the allegations, interview summaries, and copies of pertinent information or correspondence. The report may or may not include recommendations for IRB action. In some cases, the RCA simply

provides the convened IRB with a summary of the allegations, the interview summaries, and copies of pertinent information without an accompanying written report.

5.4. Review Procedures

5.4.1. The RCA advises the IRB regarding the applicable University and federal regulations, assists the IRB in documenting the review, answers questions about the review process, maintains the records as required by state and federal laws, and serves as a liaison with the funding agency or agencies.

5.4.2. The IRB reviews the material presented by the IRB representative at a convened meeting at which a quorum is present. The materials provided include the summary report of the non-compliance, the protocol if applicable and the informed consent document if applicable. The convened IRB determines whether to request additional information or whether to interview additional witnesses. The IRB may give the respondent the opportunity to meet with the convened IRB before it takes final action.

5.5. Review Outcomes/IRB Actions

5.5.1. The convened IRB makes the determination whether the allegation is substantiated, and if so, whether the non-compliance is serious or continuing based on the materials compiled during the inquiry. If the non-compliance is serious or continuing and the research federally funded, the IRB, with the assistance of the RCA and RIO, reports the incident(s) to the applicable agency.

5.5.2. The convened IRB must consider the following range of possible actions, depending on the outcome of the review:

5.5.2.1. Suspension of IRB approval of the research;
5.5.2.2. Termination of IRB approval of the research; and/or
5.5.2.3. Notification of current participants when such information might relate to participants' willingness to continue to take part in the research.

5.5.3. The convened IRB may take a variety of additional actions, depending on the outcome of the review, including, but not limited to, the following:

5.5.3.1. Approve continuation of research without changes;
5.5.3.2. Request formal educational intervention;
5.5.3.3. Request minor or major changes in the research procedures and/or consent documents;
5.5.3.4. Modify the continuing review schedule;
5.5.3.5. Require monitoring of research;

5.5.3.6. Require monitoring of the consent process;
5.5.3.7. Require audits of other active protocols of the investigator;
5.5.3.8. Disqualify the investigator from conducting research involving human subjects at USM;
5.5.3.9. Determine that the investigator may not use the data collected for publication;
5.5.3.10. Require that the investigator contact subjects previously enrolled in the study and provide them with additional information and/or re-consent them; and/or
5.5.3.11. Request that the investigator inform publishers and editors if PI has submitted or published manuscripts emanating from the research; and/or

5.5.4. The RCA communicates the IRB decision in writing to the person raising the allegation (if the identity of the person is known) and to the respondent.

5.5.5. The RCA informs the following individuals of the allegation, the review process, and the findings of the review, if appropriate, in accordance with *HRPP-034 Mandated Reporting to External Agencies*:

5.5.5.1. Investigator;
5.5.5.2. Complainant;
5.5.5.3. Research Integrity Officer;
5.5.5.4. Department Chair;
5.5.5.5. Dean;
5.5.5.6. Vice President for Research;
5.5.5.7. Provost;
5.5.5.8. Office for Human Research Protections
5.5.5.9. Sponsor, if appropriate;
5.5.5.10. Other administrative personnel as appropriate

5.5.6. Reporting Times:

5.5.6.1. For a more serious incident, this reporting should occur within days. For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report and indicate that a follow-up or final report will follow by a specific date, or when an investigation has been completed or a corrective action plan has been implemented. The time frame for reporting must never be greater than one month.
5.5.6.2. For serious or continuing non-compliance, reports to regulatory agencies will include:
5.5.6.2.1. Name of the institution conducting the research;
5.5.6.2.2. Title of the research project and/or grant proposal in which the non-compliance occurred, or, for IRB or institutional non-compliance, the IRB or institution involved;

5.5.6.2.3. Name of the principal investigator on the project, if applicable;
5.5.6.2.4. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
5.5.6.2.5. A detailed description of the non-compliance; and
5.5.6.2.6. Actions the institution is taking or plans to take to address the non-compliance (e.g., educate the investigator, educate all research staff, suspend the project, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

5.5.7. The RCA resolves questions or concerns raised by a PI regarding the outcome of a specific IRB non-compliance review through direct communication with the PI.

5.5.8. The PI submits concerns in writing to the IRB within thirty (30) days of the date that the IRB issues the final decision. The IRB limits concerns to a review of the procedures employed to reach the decision (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect) or grievances against sanctions imposed as a result of a finding of non-compliance. The PI specifies the nature of any claimed procedural error or the perceived unfairness of sanctions issued.

5.5.9. The record for the purpose of the concern raised shall be the record established during the protocol review. All IRB information, materials, determinations and decisions by the IRB will be documented in the minutes and IRB records.

5.8.10 In some cases non-compliance may also reveal scientific misconduct; in those instances, referrals will also be made to the Research Integrity Officer and/or other appropriate administrative officials (e.g., Institutional Official).

6.0 References

6.1. 45 CFR 46.103

6.2. 21 CFR 56.108

6.3. 45 CFR 46.112

6.4. 21 CFR 56.112