OBJECTIVE

To describe the policies and procedures the Institutional Review Board (IRB) and the Office of Research Integrity (ORI) follow for handling allegations of noncompliance.

GENERAL DESCRIPTION

Noncompliance occurs when research involving human participants is conducted in a manner that disregards or violates federal regulations, the policies or procedures of the Institutional Review Board (IRB), or institutional policies governing human research. Noncompliance with respect to human research participant protection violates James Madison University's (JMU) Federalwide Assurance Registration (FWA). Even in the absence of intent, an unapproved or otherwise noncompliant research activity may place a research participant at unnecessary risk.

Under federal regulations at 45 CFR 46.113, IRBs must have written procedures for promptly reporting to appropriate institutional officials and agency heads any serious or continuing noncompliance of investigators with federal regulations and local IRB policy, and any suspension or termination of research studies resulting from noncompliance.

This SOP sets forth the definition and examples of noncompliance; the procedures for reporting an allegation of noncompliance to the IRB; and the procedures for the IRB's management of such allegations, and if appropriate, of confirmed noncompliance.

This SOP applies to all on-going and future human participant research projects conducted by JMU faculty, staff, or students or by anyone conducting a research activity supported by JMU or where JMU is considered to be engaged in the research.

DEFINITIONS

Allegation: An assertion made by a party which has not yet been proven or supported by evidence.

Noncompliance: Conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human research. Noncompliance with IRB policies and/or federal requirements may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations which pose risk to subjects and/or violations of their rights and welfare.

Confirmed Noncompliance: An allegation of noncompliance that has been verified as a result of an investigation and/or a for-cause audit.

Continuing Noncompliance: A repeated pattern or un-rectified instance of noncompliance by an individual investigator or research staff member either on a single protocol or multiple protocols.

Serious Noncompliance: Failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

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
2. Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

RESPONSIBILITY

Execution of SOP: Office of Research Integrity (ORI) Director and Staff, IRB Chair, IRB Members, Principal Investigator (PI)/Study Personnel

PROCEDURES

1. The IRB or ORI may become aware of an allegation of noncompliance or of circumstances indicating noncompliance upon the receipt of a complaint from a participant, researcher, JMU employee, or member of the public; from the interpretation of information received during a Continuation, Amendment, Unanticipated Problems Review; or from the findings of a random or for-cause audit or other quality control activities. Anyone may submit allegations of noncompliance or continuing noncompliance involving human subjects research to the ORI verbally or in writing. The ORI/IRB maintains confidentiality regarding the identity of the person submitting the allegation to the extent possible.

2. ORI will forward the allegation to the IRB Chair. The IRB Chair and the Director of ORI will make the following initial determinations: (a) whether noncompliance is alleged; and (b) whether the allegation indicates that an immediate action such as suspension by the IRB is warranted. If it is determined that immediate action by the IRB is warranted (e.g., suspension), then the IRB Chair will initiate those proceedings in accordance with SOP # 6: Termination or Suspension of Research by the IRB). ORI will then initiate an investigation of the circumstances alleged in the allegation.

3. The ORI Director screens the allegation/concern of noncompliance to determine whether the protocol(s) affected is supported by federal funds. The ORI Director also determines whether the protocol has issues pertinent to other research review committees, i.e., Institutional Biosafety Committee or Office of Sponsored Programs.

4. ORI may elect to investigate informally by reading relevant documents and communicating with the affected parties. If ORI and the IRB Chair determine that the allegation is not

credible or is unsubstantiated, then the inquiry ends. ORI will document this finding in a written report; place the report in the study file; and notify the IRB of the finding on the agenda of the next available meeting. If, however, the inquiry yields evidence that noncompliance has occurred, then ORI will present this information to the IRB Chair and submit a corresponding report to the full IRB for discussion at the next available meeting.

Confirming and Resolving Noncompliance

If it is determined that the noncompliance is neither serious nor continuing, the IRB Chair and ORI will devise a corrective plan, which generally will involve immediate remediation (e.g., obtaining signature of PI on submissions, providing missing documentation) and/or remedial education with the ORI Director or IRB Chair.

If it is determined that the noncompliance is serious or continuing, ORI will conduct a for cause audit. If it is determined that an unanticipated problem has occurred, ORI and the IRB Chair will address it in accordance with SOP # 5: Unanticipated Problems Involving Risk to Human Research Participants or Others. The PI may request a meeting with the IRB Chair regarding their determination of serious or continuing noncompliance. As stated in SOP # 6: Termination or Suspension of Research by the IRB, a PI may decide voluntarily to suspend or terminate some or all of the research activities that may be under current review or investigation. The PI should inform ORI of this action, so that ORI can notify the IRB Chair and place the protocol on the agenda for the next available IRB meeting. The IRB will address the suspension or termination in accordance with SOP # 6.

ORI will distribute its for-cause audit report to the PI, the IRB Chair, the members of the IRB, and, if appropriate, the Institutional Official and/or appropriate Dean and/or Chair of the PI's Department. The PI may submit a response to the audit report in writing and/or may request to speak to the IRB at a convened meeting. ORI will place the report and any written response from the PI as discussion items on the agenda of the next available IRB meeting. The IRB will make a final determination as to whether the evidence supports a finding of serious or continuing noncompliance and, if so, will determine a corrective plan, including timeframe for correction, and will, if necessary, initiate suspension or termination proceedings in accordance with SOP # 6: Termination or Suspension of Research by the IRB.

In reviewing information to make a final determination of serious or continuing noncompliance, the IRB should consider:

a. Whether the audit report and any other available information sufficiently supports a determination of non-compliance.
b. Whether the audit report and any other available information supports suspension or termination of research in order to protect human participants or others.
c. Additional actions to protect the rights and welfare of currently enrolled participants.

d. Whether procedures for withdrawal of enrolled participants account for their rights and welfare.
e. Whether participants should be informed of the noncompliance and/or any of the corrective actions.

The IRB may invite the PI to a portion of the meeting to answer questions and to discuss the issue of noncompliance. If the PI requests, or is requested, to be present at the IRB meeting, he or she may be accompanied by a faculty representative, legal counsel, or another member of his or her department. The role of these individuals is limited to providing information and support to the PI; they will not participate in the discussion between the PI and the IRB.

The PI must implement the corrective plan within the required timeframe. ORI will monitor the PI's implementation of the corrective plan. A failure to implement the corrective plan on time will be reported by ORI to the IRB Chair and the Director of ORI for further action, including initiation of procedures for suspension or termination of IRB approval of the research protocol, in accordance with SOP 6: Suspensions and Terminations of IRB Approval of Research Protocols.

Upon full implementation of the corrective plan, ORI will draft a final noncompliance report for discussion by the IRB at the next available meeting. After the report is finalized by ORI and the Director of ORI, ORI will distribute this report to the following parties: (a) PI (b) Institutional Official (c) Department Chair, Center Director, and/or College Dean of the PI (d) Office of Sponsored Programs, when applicable (e) Sponsoring agency, when applicable (f) OHRP, when applicable.

While the IRB has the authority to take appropriate action concerning a research protocol, neither the IRB nor ORI has the authority to take disciplinary action against any individual relating to a finding of confirmed noncompliance. Instead, disciplinary action shall be the responsibility of the institution. The Director of ORI shall report any termination of research to the appropriate institutional officials, and the Director of ORI and the IRB Chair will, if requested, assist in any disciplinary action process taken by the appropriate academic unit.

Corrective Actions in Response to Noncompliance

The actions taken to correct noncompliance vary and depend on the nature and seriousness of the noncompliance. The IRB, in consultation with the Director of ORI, may take any of the following actions:

1. Take no action
2. Request a protocol and/or consent form modification
3. Require that all participants be re-consented
4. Require previous participants to be informed of any changes to the protocol and/or consent procedures

5. Require observation of consent procedures
6. Require more frequent review of the conduct of the research
7. Require additional training for the research team
8. Require follow-up audit(s)
9. Suspend the research
10. Terminate the research
11. Refer issues to other institutional entities (e.g., Institutional Official, Dean, Legal Counsel)
12. Any other action deemed appropriate by the IRB to protect the rights and welfare of research participants

Informed by any audit reports, corrective plans, and final noncompliance reports, ORI will develop and administer required and optional educational programs, as specified in corrective plans for the PI and for the research community generally.

Documentation Relating to Reporting and Resolution of Noncompliance

All documents relating to noncompliance will be maintained by ORI for a period of not less than 5 years.

These documents include but are not limited to: Adverse Event Report Form; correspondence with the PI; and documentation of implementation of corrective plans.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	7/28/2015
01	Revision of SOP	11/8/2019

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

45 CFR 46.113