OBJECTIVE

To describe policies and procedures for ensuring prompt Institutional Review Board (IRB)/Office of Research Integrity (ORI) reporting of events to institutional official(s), sponsor, coordinating center, and the appropriate federal regulatory agency as required in federal regulations.

GENERAL DESCRIPTION

Federal regulations and James Madison University's (JMU) Federalwide Assurance Registration (FWA) require the Institutional Review Board (IRB) to report the following promptly to appropriate institutional officials; federal departmental or agency heads at the Office of Human Research Protections (OHRP); and sponsors:

(1) unanticipated problems involving risk to human research participants or others (see SOP # 5);
(2) suspensions or terminations of IRB approval of research protocols (see SOP # 6); and
(3) instances of serious or continuing noncompliance (see SOP # 7).

The Institutional Official has delegated this reporting authority to the Director of Office of Research Integrity (ORI). This policy sets forth the procedures for complying with federally mandated reporting requirements concerning unanticipated problems, noncompliance, and suspensions and terminations involving human research protocols previously approved by the IRB.

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.

RESPONSIBILITY

Execution of SOP: IRB Chair, IRB, ORI Staff, ORI Director, Vice President and Chief Research Officer, Division of Research, Economic Development and Innovation (VPREDI), Office of Sponsored Programs (OSP), Principal Investigator/Study Personnel

PROCEDURES: REPORTING RESPONSIBILITIES & REQUIREMENTS

Content of Reports

Final Reports: A final report should include the following information:

1. the name of the PI;
2. the IRB's OHRP registration number, JMU's FWA number;

3. protocol title;
4. sponsor of the study;
5. any applicable grant numbers;
6. the dates(s) and nature of the event(s);
7. details concerning how the event was discovered; (8) the IRB's and the Director of ORI's response to the event;
8. the PI's response to the event;
9. investigatory/audit findings;
10. IRB's actions and rationale and any response by the PI;
11. details of the corrective plan;
12. any pertinent details concerning the PI's implementation of the corrective plan;
13. participants' response to corrective measures;
14. IRB plan for monitoring the outcome of the event;
15. certification of destruction of data resulting from un-approved research activities, if applicable;
16. outcomes of withdrawal and follow-up of participants, if applicable; and
17. any general educational activities inspired by the incident.

Initial Reports: While this information is being compiled for the final report and the corrective plan is being implemented, the IRB and the Director of ORI may elect to have ORI submit an initial report to OHRP in order to ensure prompt reporting. An initial report should include as much of this information as is available.

Drafting, Approval, and Distribution of Reports: ORI will draft initial and final reports, and the Director of ORI will be responsible for signing and finalizing them. After initial and final reports are signed and finalized, ORI will distribute them to all required recipients.

Required Recipients of Reports:

Final Reports: Copies of final reports concerning serious adverse events, other unanticipated problems, noncompliance, suspension or termination, will be sent to OHRP, as well as to the PI, appropriate institutional officials, department chair/center director/college dean of the PI, Office of Sponsored Programs, and if appropriate, the sponsor. The sponsor should always receive a final report relating to serious adverse events; serious or continuing noncompliance; and/or terminations of IRB approval of a research protocol. A final report concerning non-serious and non-continuing noncompliance will not be sent to OHRP or other federal sponsoring agency.

Initial Reports: Copies of initial reports will be sent to OHRP and to the other aforementioned parties, including, if appropriate, the sponsor.

Serious Adverse Events (see SOP # 5): The timing of the notification of a serious adverse event to OHRP depends on the nature of the risk, the availability of relevant information and evidence, and the estimated timeframe for full implementation of a corrective plan. Where a serious

adverse event has occurred, the IRB Chair and the Director of ORI may require ORI to notify OHRP with an initial report following suspension of the protocol by the IRB Chair, see SOP # 6, but at some point before ORI's for-cause audit, the IRB's issuance of a corrective plan, or the PI's implementation of the corrective plan. Where the IRB Chair and the Director of ORI estimate that full implementation of the corrective plan will require more than 75 days, an initial report is recommended. Upon full implementation of the corrective plan, ORI will draft a final report for comment by the IRB at the next available meeting. The final report should be distributed by ORI to all required recipients within 75 days of any official action taken by the IRB, including its issuance of a corrective plan.

Other Unanticipated Problems (see SOP # 5): In the case of unanticipated problems that are not serious adverse events, formal notification to OHRP generally will be made after completion of an investigation or formal audit by ORI, if appropriate, and implementation of the IRB's corrective plan. Upon full implementation of the corrective plan, ORI will draft a final report for comment by the IRB at the next available meeting. The final report should be distributed by ORI to all required recipients, within 75 days of any official action taken by the IRB, including its issuance of a corrective plan.

Suspensions and Terminations (see SOP # 6): Upon the PI's implementation of the corrective plan following a suspension notice or upon the IRB's termination of a research protocol, ORI will submit a final suspension or termination report to OHRP and other required recipients. The final report should be distributed by ORI to all required recipients within 75 days of a suspension or termination. However, where the IRB votes for termination, ORI may be instructed by the IRB Chair and the Director of ORI to notify OHRP with an initial report at some point before ORI's for-cause audit, the IRB's issuance of a corrective plan, or the PI's implementation of the corrective plan. Where the IRB Chair and the Director of ORI estimate that full implementation of a corrective plan (including any required withdrawal or follow-up of participants) in response to a suspension or termination will require more than 75 days, an initial report is recommended. The IRB Chair or the Director of ORI may also instruct ORI to draft an initial report in the case of a suspension, if the circumstances so warrant.

Serious or Continuing Noncompliance (see SOP # 7): The timing of the notification to OHRP of a finding of serious or continuing noncompliance as per SOP # 7, depends on the nature of the risk, the availability of relevant information and evidence, and the estimated timeframe for full implementation of a corrective plan. Where serious or continuing noncompliance has occurred, the IRB Chair and the Director of ORI may instruct ORI to notify OHRP with an initial report at some point before ORI's for-cause audit, the IRB's issuance of a corrective plan, or the PI's implementation of the corrective plan. Where the IRB Chair and the Director of ORI estimate that full implementation of the corrective plan will require more than 75 days, an initial report is recommended. Upon full implementation of the corrective plan, ORI will draft a final report for comment by the IRB at the next available meeting. The final report should be distributed by ORI to all required recipients within 75 days of any official action taken by the IRB, including the issuance of a corrective plan.

Follow-up Communications with OHRP:

ORI is responsible for drafting and sending responses to any comments by federal officials or sponsors on the final reports after coordination with the PI, IRB, Institutional Official, and other as appropriate.

DOCUMENTATION RELATING TO REPORTING

All documents relating to reporting unanticipated problems, noncompliance, suspensions, and terminations will be maintained by ORI for at least 5 years. These documents include but are not limited to: the Incident Form; correspondence with the PI; documentation of implementation of corrective plans; audit reports; preliminary notification reports; and final notification reports.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	12/02/2015
01	Revision of SOP	11/8/2019
02	Updated title of Vice President for Research, Economic Development and Innovation (VPREDI). Removed Provost and Senior Vice President for Academic Affairs. Changed Adverse Event/ Unanticipated Problem Form to Incident Form. Clarified retention period. Updated hyperlink.	3/12/2025

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

45 CFR 46.108(a)(4)