James Madison University Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
TITLE: Unanticipated Problems Involving Risk to Human Research Participants or Others: Procedures for Reporting to, and Review by, the IRB			
SOP # 5	**Revision # 1**	**Effective Date: 11/8/19**	**Page 1 of 4**

OBJECTIVE

To describe the policies and procedures for complying with federally mandated reporting requirements concerning unanticipated problems and adverse events involving human research protocols previously approved by the Institutional Review Board (IRB).

GENERAL DESCRIPTION

Regulatory guidance provided in 45 CFR 46.103(b)(5) requires the IRB to have in place written procedures for ensuring prompt reporting to the IRB, appropriate University officials, and applicable regulatory agencies of any unanticipated problems involving risk to human subjects or others.

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

Unanticipated problem: Involves risks to participants or others are defined as any incident, experience, or outcome that meets all of the following criteria:

- Unforeseen (not expected by the researcher or the research participant) given the research procedures and the subject population being studied;
- Related or probably related to participation in the research or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

Unexpected adverse event: Is any adverse event occurring in one or more subjects participating in a research protocol, whose nature, severity, or frequency is not consistent with, either:

- The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol related-documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and other relevant sources of information, such as product labeling and package inserts; or
- The expected natural progression of any underlying disease or condition of the subject(s) experiencing the adverse event.

RESPONSIBILITY

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

PROCEDURES

JMU Basic Reporting Requirements for Prompt Reporting of Problems/Adverse Events

1. The PI reports all problems/adverse events using the applicable JMU Adverse Event Report Form through the electronic Research Administration (eRA) software system.
2. It is the responsibility of the Principal Investigator to report all adverse events / unanticipated problems regarding an approved protocol to the IRB **within (3) working days** after the adverse event/unanticipated problem.

Submissions/Screening and Review of Internal Problems/Events: Prompt Report

1. The submission is assigned by ORI staff to the IRB chair for review and evaluation.
2. The IRB Chair may request clarifications, corrections, or revisions to the report from the PI if further information is needed to evaluate the event.
3. If the IRB Chair determines that the problem is not an unanticipated problem involving risks to participants or others as defined in this SOP, the Chair completes an evaluation indicating the event is not considered to be an unanticipated event involving risks to participants. ORI staff notifies the PI and advisor, if student, through eRA. No further action is taken.
4. If the IRB Chair determines the problem might be an unanticipated problem involving risks to participants or others as defined by this SOP, the event is referred to the convened IRB for review.
5. When problem reports are reviewed by the convened IRB, the IRB staff ensures board members are notified and the documents listed below are made available on the secure IRB members' only website prior to the meeting. All IRB members are expected to review the information and be prepared to discuss it at the meeting.
6. Based on the nature of the event and the expertise required to assess it, the IRB Chair or designee acts as the primary reviewer and presents their findings to the convened IRB. The convened IRB evaluates the event by considering whether the problem is an unanticipated problem involving risks to participants or others as defined by this SOP. The convened IRB votes on whether the report is an unanticipated problem involving risks to participants or others. IRB staff records the discussion, rationale for any action, and vote in the minutes.

7. If the convened IRB determines that the problem is not an unanticipated problem involving risks to participants or others as defined by this policy the convened IRB acknowledges the event as submitted, indicating the event is not considered to be an unanticipated event involving risks to participants. ORI staff notifies the PI and advisor, if student, through eRA. No further action is taken.
8. If the convened IRB determines that the problem is an unanticipated problem involving risks to participants or others as defined by this policy, the convened IRB may consider any of the following actions, but is not limited to:

    - modification of the protocol,
    - modification of the information disclosed during the consent process provided by the investigator,
    - providing additional information to current participants (this must be done whenever the information may relate to the participant's willingness to continue participation),
    - providing additional information to past participants,
    - requiring current participants to re-consent to participation,
    - alteration of the frequency of continuing review,
    - observation of the research or the consent process,
    - requiring additional training of the investigator,
    - notification of investigators at other sites,
    - obtaining additional information, or
    - administrative hold, termination or suspension of the research.

9. Following a final determination of an action with respect to the Adverse Event Report Form, the IRB Chair or their designee will draft and email a letter to the PI and advisor, if student, setting forth the IRB actions and any required modifications. Suspensions or terminations of research will be carried out in accordance with SOP # 6: Termination or Suspension of Research by the IRB. The PI will provide written notification to the IRB when they have made the required modifications.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	7/20/2015
01	Revision of SOP	11/8/2019

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

45 CFR 46.103(b)(5)