Oklahoma State University Institutional Review Board Standard Operating Procedures		
Unanticipated Problem/Adverse Event Reporting	SOP #	RR 409
	Effective Date	1/1/2012
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	Revision #	3
	Approval: IRB	4/9/2025

1. POLICY

All adverse events and unanticipated problems involving risks to research participants (i.e. human subjects) or others will be reported promptly to the Institutional Review Board (IRB) and then by the IRB to the appropriate institutional officials and federal officials as appropriate. The purpose of this standard operating procedure is to establish the reporting requirement and identify problems that an Investigator must report to the IRB.

Specific Procedures

1.1 Definitions

1.1.1 Unanticipated problem: Any incident, experience, or outcome that is:

- unexpected (in terms of nature, severity or frequency) given the research procedures described in the approved IRB protocol and *via* the informed consent document(s) or process (whichever is applicable) and the characteristics of the subject population being studied;
- related or possibly related to participation in the research; and
- places the research subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

1.1.2 Adverse Event: Any untoward or unfavorable medical occurrence (i.e. physical or psychological harm) in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

1.2 Problem Reporting

1.2.1 The Investigator must promptly report to the IRB all unanticipated problems and adverse events, including any of the following incidents, experiences, outcomes, or events, regardless of whether they occur during the study, after study completion, or after subject withdrawal from or completion of the study:

- Any incident (including on-site and off-site adverse events, side effects, deaths or other problems, regardless of whether the event was serious), which in the opinion of the Investigator was unanticipated and related to the research procedures;
- Any incident that requires prompt reporting according to the research sponsor (if any);
- Any accidental or unintentional change to the IRB-approved protocol that involved risks to subjects or has the potential to recur;
- Any change to the approved protocol made without prior IRB approval to eliminate apparent immediate harm to subjects or others;

- Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research;
- Any complaint of a subject that indicates an unanticipated problem or risk; or
- Any breach of privacy/confidentiality/data security or loss of study data or the destruction of study data due to nefarious action(s).

1.2.2 The Investigator must submit a report to the IRB within 48 hours of initially learning of the event. The report must be submitted within the OneAegis system using the IRB Unanticipated Problem/Adverse Event Report form. Investigators should include the following information when reporting unanticipated problems and adverse events:

- the date of the event
- a detailed description of the adverse event, incident, experience, or outcome;
- If they are aware of research project still continuing and if participant(s) were involved, do they plan to continue participation
- an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and
- a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

The following will automatically be included on the report within the system:

- appropriate identifying information for the research protocol; such as title; investigator's name' and the IRB protocol number

1.3 Review of the Event or Problem

1.3.1 The IRB Chair and the IRB Manager will initially review all Unanticipated Problem/Adverse Event Report forms. If appropriate to the event or problem, the IRB Chair and Manager will also review the protocol, current informed consent form and/or process, and any other relevant documents pertaining to the incident or problem. After initial review, the IRB Chair and IRB Manager will make one of the following determinations:

The problem is NOT an unanticipated problem involving risks to subject(s) or others (because the event was either anticipated or does not indicate that subjects are at increased risk of harm). If this is the case, the IRB Chair will take no action, document the review, and add the item to the IRB agenda for reporting purposes.

OR

The problem is considered an unanticipated problem involving risks to subjects or others because the problem is (1) unanticipated and (2) indicates that subjects are at increased risk of harm. If so:

- The IRB Chair may determine that immediate action is needed to ensure the subjects' safety; the IRB Chair, in consultation with the IRB Manager and Assistant Vice President for Research Compliance, may request that the investigator suspend some or all of the research pending review of the matter at the next convened IRB meeting. Suspensions ordered by the IRB Chair will follow IRB procedures outlined in SOP RR410 - Suspension and Termination of IRB Approval.

- The IRB Chair or designee will present the problem to the IRB at the next convened meeting. IRB members will be provided a copy of the report form and all appropriate documentation, including the current protocol and informed consent information. The IRB will deliberate and vote to determine whether the situation represents an unanticipated problem involving risks to subjects or others based on whether the situation was (1) unanticipated and (2) placed subjects at increased risk of harm. If the situation is determined to be an unanticipated problem involving risks to subjects or others, the IRB will deliberate and vote to approve one of the following actions, including, but not limited to:

    - No action;
    - Modification of the research protocol;
    - Modification of the information provided during the consent process to include information about the newly recognized risks;
    - Additional information provided to enrolled and/or past subjects, including those who withdrew from the study, if deemed appropriate;
    - Notification of current subjects (required when such information may relate to subjects' willingness to continue to take part in the research);
    - Require that current subjects re-consent to participate in the research;
    - Adjustment of the continuing review schedule;
    - Alteration of project inclusion and/or exclusion criteria;
    - Suspension of enrollment of new subjects;
    - Increased monitoring of the research;
    - Monitoring of the consent process;
    - Suspension of the research;
    - Termination of the research;
    - Request for more information pending a final decision;
    - Refer to other organizational entities (e.g. legal counsel, institutional official); or
    - Other actions as appropriate.

The determination and vote will be reported in the IRB meeting minutes and the Investigator will be notified in writing.

1.4 Notification

1.4.1 No action required: If the situation is not an unanticipated problem posing risks to subjects or others, the investigator will receive a letter indicating that the IRB has received the report and that no other action pertaining to the matter will be required.

1.4.2 Full Committee Review: The Investigator will be notified by the IRB Manager within 5 working days of the IRB meeting of the committee's decision and action(s).

If the problem is an unanticipated problem involving risks to subjects or others, the IRB will inform the following individuals internal to the university of the problem and the recommended action(s)

- Department Head(s);
- College Research Dean(s);
- Assistant Vice President for Research Compliance
- Institutional Official (Vice President for Research).

If the research is supported by an external sponsor, they will also be notified.

For all <u>non-exempt</u> research, if the IRB determines that the problem is an unanticipated problem involving risks to subjects or others, the incident must be promptly reported by the IRB Manager

or Chair to the Office for Human Research Protections (OHRP). The report should be prepared according to the OHRP Guidance on Reporting Incidents to OHRP and must include the following;

- Name of the institution;
- Title of the research project/grant in which the problem occurred;
- Name of the principal investigator;
- IRB number and (if appropriate) the number of any applicable federal award;
- A detailed description of the problem; and
- Actions the institution is taking or plans to take to address the problem.

A copy of this report will also be disseminated to IRB members at the next convened IRB meeting.

2. SCOPE

This SOP applies to all research approved by the OSU IRB.

3. RESPONSIBILITY

The investigator is responsible for prompt submission of all reports of any unanticipated problem or adverse event to the IRB.

The IRB Chair and IRB Manager will review all Unanticipated Problem/Adverse Event forms to determine if suspension of the protocol is warranted, and present the matter to the IRB at a convened meeting.

If deemed applicable, IRB members are responsible for determining if the problem represents an unanticipated problem involving risks to subjects or others or is an adverse event.

The IRB Manager is responsible for sending letters to Investigators and appropriate individuals and agencies.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108(A)(4) AND 45 CFR 46.113

5. REFERENCES TO OTHER APPLICABLE SOPS

RR 408, RR 410

6. IMPLEMENTATION OF PROCEDURES

Who	Task
IRB Manager	Receives submitted Unanticipated Problem/Adverse Event Report forms. Reviews for sufficient information. Provides to IRB Chair for review and appropriate action. Prepares and sends appropriate correspondence.

IRB Chair	Reviews reports. Makes initial determination if problem is an adverse event or unanticipated problem involving risk to subjects, as defined in this policy, and others. If yes, determines if immediate suspension of protocol is needed. Presents problem to the convened IRB for final determination and disposition.