HRPP Policy Number: 901 Version: 3.0 Effective Date: 08/14/25	Reporting Unanticipated Problems	Supersedes Document Dated: 12/01/16, 07/12/19
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9.1 Principal Investigator Reporting Requirements

9.1.1 Reporting Determinations

The Institutional Review Board (IRB) requires principal investigators (PI) to promptly report a summary of each unanticipated problem involving risks to subjects and others to the IRB using the **Reportable New Information (RNI) Form**. Unanticipated problems include, but are not limited to the following:

1. An actual unforeseen harmful or unfavorable occurrence to subjects or others that relates to the research protocol (injuries, side effects, deaths).
2. A problem involving data collection, data storage, privacy, or breach of confidentiality.
3. A subject complaint about IRB approved research procedures.
4. New information about a research study (e.g., a publication in the literature, interim findings, safety information released by the sponsor or regulatory agency, or safety monitoring report) that indicates a possible increase in the risks of the research.
5. Changes in approved research initiated without IRB review and approval to eliminate apparent immediate hazards to the subject.
6. Incarceration of a subject.
7. A sponsor-imposed suspension of a protocol due to possible increased risk.
8. A complaint from a subject when the complaint indicates potential increased risk or when the complaint cannot be resolved by the PI.
9. A protocol deviation that places one or more subjects at increased risk or has the potential to occur again.
10. An event that requires prompt reporting to the sponsor.
11. Adverse event if research is Food and Drug Administration (FDA)-regulated.

9.1.2 Reporting Unanticipated Problems

PIs are required to report unanticipated problems to the IRB **within five days of becoming aware of the problem**. However, if a protocol deviation or unanticipated problem meets any of the following criteria, the protocol deviation or unanticipated problem is **considered serious, and it must be reported to the IRB office within 24 hours**:

1. Was unanticipated and unexpectedly serious (in terms of nature, severity, or frequency) or life-threatening.
2. Resulted in hospitalization or prolongation of hospitalization or death.
3. Resulted in a persistent or significant disability/ incapacity.

4. Resulted in suspicions that exposure to an investigational drug/device prior to conception or during pregnancy resulted in an adverse outcome (congenital anomaly/birth defect) to a child.
5. Based on appropriate medical judgment, the protocol deviation or unanticipated problem may jeopardize the subject's health and may require medical/surgical intervention to prevent one of the other outcomes listed in 1-4 above.

9.2 Review of Reportable New Information Reports

9.2.1 Initial Review

Upon receipt, the IRB Compliance Analyst or other designated IRB staff member will screen the report. The report, with the IRB Compliance Analyst's or other staff's recommendation, is then reviewed by the IRB Chair. In consultation with the Research Integrity Director, a determination will be made on whether the report likely represents an unanticipated problem that meets the regulatory criteria requiring reporting to federal oversight agencies (Office for Human Research Protections (OHRP), FDA) and refer the report for review at a convened meeting of the IRB. If the reported problem does not meet the regulatory criteria for reporting to federal agencies, the issue will be returned to the ORIE to be handled administratively. All reports will also be reviewed to determine if there are issues of possible noncompliance.

9.2.2 Convened Meeting Review

If initial review indicates that the report is likely an unanticipated problem involving risks to subjects or others, a copy of the report, the protocol, and informed consent will be provided to the IRB members for review prior to the convened meeting. The IRB will consider whether the event meets the following regulatory criteria for an unanticipated problem involving risks to subjects or others:

1. The event was unforeseen.
2. The event is related or possibly related to the research.
3. The event caused harm to subjects or placed them at increased risk of harm.

Upon discussion, the IRB will determine whether the event does in fact represent an unanticipated problem involving risks to subjects or others, and if so, must be reported through the Institutional Official to the appropriate regulatory agency (OHRP or FDA).

However, if after reviewing the information, the IRB determines that the event was not an unanticipated problem, the issue will be returned to the ORIE to be handled administratively.

Deliberations and determinations of the IRB will be fully documented in the minutes.

9.3 Possible IRB Actions

Any unanticipated problem or an event that is determined by the IRB to be unanticipated and indicates that subjects or others are at increased risk will warrant consideration of substantive changes in the research protocol and/or consent document/process or other corrective actions to protect the safety, welfare, or rights of subjects or others. Some of the corrective actions that might need to be considered in response to an unanticipated problem include:

1. Changes to the protocol initiated by the PI prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects may need to be made a permanent part of the protocol.
2. Modification of inclusion/exclusion criteria to mitigate the newly identified risks.
3. Implementation of additional procedures for monitoring subjects, the consent process, and/or the research.
4. Suspension of enrollment of new subjects.

5. Suspension of research procedures on currently-enrolled subjects.
6. Modification of the protocol.
7. Modification of the continuing review schedule.
8. Modification of informed consent documents to include a description of newly recognized risks or any other information that should be disclosed during the consent process.
9. Notification of current subjects when such information may relate to subjects' willingness to continue.
10. Provision of additional information about newly recognized risks to previously enrolled subjects.
11. Require the investigator to re-consent current participants.
12. Termination of the protocol with consideration for health and well-being of currently enrolled subjects; and
13. Referral to other organizational entities.

9.4 University Reporting Requirements

In addition, any event that meets the criteria for an unanticipated problem involving risks to subjects or others listed in **Section 9.2.1** must be reported to the appropriate Federal agencies (OHRP, FDA) and sponsoring entities. Refer to HRPP Policy 2401: Institutional Reporting Requirements.

9.5 Notification of Principal Investigators

Upon completion of the review, the PI will be notified by letter. If the problem/event does not meet the criteria of unanticipated and indicates that subjects or others are not at increased risk, the letter will acknowledge the report. If the problem/event meets the criteria of being unanticipated and indicates that subjects or others are at increased risk, the letter will inform the PI that the IRB determined the problem/event to be an unanticipated problem involving risks to subjects or others, that the problem/event will be reported to the appropriate Federal agency, and provide a list of required actions and/or changes to the protocol or consent form.