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1 PURPOSE

- 1.1 This SOP establishes the process to identify new information that requires reporting to the IRB.
- 1.2 The process begins when an individual receives an information item.
- 1.3 The process ends when the item is submitted to the IRB for review.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 SOP Statement

- 3.1 New Information Items are to be reported to the IRB within 5 business days or less.
- 3.2 The IRB will manage the new information item in accordance with SOP: New Information Process (HRP - 024).

4 Responsibility:

- 4.1 Investigators or other individuals receiving reportable new information items carry out these procedures.

5 Procedure

- 5.1 Report information items that fall into one or more of the following categories to the IRB within five (5) business days.
 - 5.1.1 Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **related** to the research procedures including unanticipated problems.
 - 5.1.1.1 A harm is “**unexpected**” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
 - 5.1.1.2 A harm is “**related**” or possibly related to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
 - 5.1.2 Information that indicates a new or increased risk, or a new safety issue including unanticipated problems. For example:
 - 5.1.2.1 New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor correspondence or report, CRO report, or investigator finding) that may indicate an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
 - 5.1.2.2 An investigator drug brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
 - 5.1.2.3 Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
 - 5.1.2.4 Protocol deviation/violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
 - 5.1.2.5 Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
 - 5.1.2.6 Any changes significantly affecting the conduct of the research
 - 5.1.3 Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB or the institution or an allegation of such non-compliance.
 - 5.1.4 Audit, inspection, or inquiry by a federal agency or any other outside entity and any resulting reports (e.g. FDA Form 483.)
 - 5.1.5 Written reports of study monitors.

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- 5.1.6 Failure to follow the protocol due to the action or inaction of the investigator or research staff whether planned or unplanned.
- 5.1.7 Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- 5.1.8 Breach of confidentiality (inappropriate disclosure of or access to confidential information).
- 5.1.9 Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- 5.1.10 Complaint of a subject that cannot be resolved by the research team.
- 5.1.11 Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
- 5.1.12 Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)
- 5.2 Use the IRB electronic submission system (iRIS) or equivalent to submit the reportable new items.
 - 5.2.1 Select the tab for Reporting New Information.
 - 5.2.2 Provide the date you became aware of the problem.
 - 5.2.3 Provide a description of the problem and determine the following:
 - 5.2.3.1 Does this information indicate a new or increased risk, or a safety issue?
 - 5.2.3.2 Does the study need revision?
 - 5.2.3.3 Does the consent document need revision?
- 5.3 Provide a list of all studies related to the reportable new information.
- 5.4 Attach supporting documentation and a description of any corrective actions when required.
- 5.5 Submit the item to the IRB when your description of the reportable new information is complete.

6 MATERIALS

- 6.1 SOP: New Information Process (HRP – 024).


7 REFERENCES

- 7.1 21 CFR §56.108(b)
- 7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)
- 7.3 AAHRPP I.5.D, II.2.F, II.2.G, II.4.A, II.4.B

Guidance on determining Unanticipated Problems

Unanticipated problems, in general, include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. is related or possibly related to the research (this means that it is more likely than not, the incident, experience, or outcome was caused by the procedures involved in the research); and
3. 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.

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There are other types of incidents, experiences, and outcomes that occur during the conduct of human subjects research that represent unanticipated problems but are not considered adverse events. For example, some unanticipated problems involve social or economic harm instead of the physical or psychological harm associated with adverse events. In other cases, unanticipated problems place subjects or others at increased *risk* of harm, but no harm occurs.

Unanticipated Problem Flow Chart

Ask all three questions

