

Policies and Procedures

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1. PURPOSE

This policy establishes requirements for Principal Investigators on what types of new information are to be reported to the Creighton University IRB. The Principal Investigator for reporting any reportable new information.

2. INFORMATION REQUIRED TO BE REPORTED TO THE IRB

- 2.1. Any harm (i.e., any physiological, emotional, psychological, financial, or legal damage to an individual) experienced by a subject or other individual which in the opinion of the investigator are unexpected and at least probably related to the research procedures.
 - 2.1.1. A harm is “unexpected” when its specificity and severity are not accurately reflected in the consent document.
 - 2.1.2. A harm is “at least probably related to the research procedures” if in the opinion of the investigator, the research procedures more likely than not caused the harm.
- 2.2. Information that indicates a new or increased risk, or a safety issue; for example:
 - 2.2.1. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) which indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk
 - 2.2.2. An investigator 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
 - 2.2.3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
 - 2.2.4. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
- 2.3. Noncompliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such noncompliance.

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- 2.4. Audit, inspection, or inquiry by a federal agency.
- 2.5. Written reports of study monitors.
- 2.6. Failure to follow the protocol due to the action or inaction of the investigator or research staff (protocol violation)
- 2.7. Breach of confidentiality
- 2.8. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- 2.9. Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- 2.10. Complaint of a subject that cannot be resolved by the research team.
- 2.11. 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)."

3. REPORTING REQUIREMENTS

The Principal Investigator shall report new information that may arise during the course of a research project; the Principal Investigator shall use IRB Document 134.1, "[Reporting Form for Reportable New Information](#)." This form must be submitted to the IRB within 5 working days after the information is received by the Principal Investigator, except in the case of study monitor reports, which must be submitted as soon as practicable, but no more than 30 days, after they are received from the monitoring agency. For such study monitor reports, the Principal Investigator's designee may sign and submit the form.

3.1. Information not required to be submitted to the IRB

- 3.1.1. IND reports submitted to the Principal Investigator by the sponsor that do not include a plan of action.

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- 3.1.2. Serious adverse events reported to the sponsor unless the event meets the definition of a problem to be reported, as detailed in section 2 of this policy.
- 3.1.3. Deviations that do not constitute a safety risk to the subject (e.g.; out-of-window visits, study medication containers not returned by subject, etc.) shall be reported on the next Progress Report for Continuing/Termination of Project filed with the IRB.

4. IRB REVIEW OF REPORTABLE NEW INFORMATION

All Reporting Forms for Reportable New Information shall be reviewed initially by the IRB administrative staff within three (3) business days of receipt by the IRB office to check for completeness of the reporting form and to determine whether the problem involves:

- 4.1. An unanticipated problem involving risks to subjects or others (see IRB Policy 120, "[Unanticipated Problems Involving Risks to Participants or Others](#)")
- 4.2. Suspension or termination of IRB approval (see IRB Policy 135, "[Suspensions and Terminations](#)")
- 4.3. Serious noncompliance (see IRB Policy 131, "[Noncompliant Conduct](#)")
- 4.4. Continuing noncompliance (see IRB Policy 131, "[Noncompliant Conduct](#)")
- 4.5. Noncompliance that is neither serious nor continuing (see IRB Policy 131, "[Noncompliant Conduct](#)")
- 4.6. None of the above

If the problem involves any of the first four items on this list, it shall be referred to a convened IRB meeting, per the policies listed above. For noncompliance that is neither serious nor continuing or a problem that does not meet any of the categories listed (none of the above), no further action is required.

The IRB shall notify the Principal Investigator in writing of the IRB administrator's determination.