



INVESTIGATOR GUIDANCE: Prompt Reporting Requirements

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1. PURPOSE

- 1.1. This policy describes the information to promptly report to GW's IRB when the research is subject to oversight by GW's local IRB.
- 1.2. For research overseen by an IRB other than GW's local IRB, investigators should follow the requirements of that IRB.

2. POLICY

- 2.1. Report the following information items to the IRB within 5 business days of knowledge of the event:
 - 2.1.1. New or increased risk, or a safety issue
 - 2.1.1.1. New information (ex: an interim analysis, data safety monitoring report, IND safety report, publications indicating a new risk, sponsor report, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
 - 2.1.1.2. An investigator brochure, package insert, or device labeling revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
 - 2.1.1.3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
 - 2.1.1.4. Protocol deviation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm or affects the integrity of the research data
 - 2.1.1.5. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
 - 2.1.1.6. Any changes or information significantly affecting the conduct or integrity of the research
 - 2.1.2. Any harm experienced by a subject or other individual, which in the opinion of the investigator, are unexpected and possibly related to the research procedures
 - 2.1.2.1. A harm is "unexpected" when its specific 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.
 - 2.1.2.2. A harm is "possibly related" to the research procedures if in the opinion of the investigator, the research procedures may have possibly caused the harm.
 - 2.1.3. Internal Serious Adverse Events
 - 2.1.3.1. Death, excluding death due to disease progression
 - 2.1.3.2. Life-threatening, or requires or prolongs inpatient hospitalization
 - 2.1.3.3. Results in persistent or significant disability/incapacity
 - 2.1.3.4. Constitutes a congenital anomaly or birth defect
 - 2.1.3.5. Medically significant and which the investigator regards as serious based on appropriate medical judgment
 - 2.1.4. <Finding of Noncompliance> with the federal regulations governing human research or with the requirements or determinations of the IRB, or <Allegation of Noncompliance>
 - 2.1.5. Protocol deviation made without prior IRB approval to eliminate an apparent immediate hazard to a subject
 - 2.1.6. Breach of confidentiality
 - 2.1.7. Unresolved subject complaint
 - 2.1.8. Incarceration of a subject in a research study not approved to involve prisoners

- 2.1.9. Unanticipated adverse device effect
 - 2.1.9.1. 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 (21 CFR 812.3(s))
 - 2.1.10. Suspension or premature termination by the sponsor, investigator, or institution
 - 2.1.11. Audit, inspection, or inquiry by a federal agency
 - 2.1.12. Written reports from a federal agency (e.g., FDA Form 483)
 - 2.1.13. State medical board or hospital medical staff actions
 - 2.1.14. Other information that the sponsor/CRO has directed the PI to report to the IRB, even if not on this list
- 2.2. When relying on an external IRB report the following information items to the OHR Office within 5 days:
 - 2.2.1. Audit, inspection, or inquiry by a federal agency
 - 2.2.2. Written reports of federal agencies (e.g., FDA Form 483)
 - 2.2.3. Written reports of study monitors
 - 2.2.4. Unauthorized disclosure of confidential information
 - 2.2.5. State medical board or hospital medical staff actions
- 2.3. Information not listed above should not be promptly reported to GW's local IRB but can be reported in summary form at time of Continuing Review.

3. REFERENCES

- 3.1. 21 CFR §56.108(b)
- 3.2. 45 CFR §46.103(b)(5)