Governors State University

Institutional Review Board
Room G353
1 University Parkway
University Park, IL 60484
www.govst.edu/irb

SOP: Prompt Reporting

1. **PURPOSE**
   1.1. This guidance clarifies events that must be promptly reported to the Governors State University (GovState) Institutional Review Board (IRB).
2. **GUIDANCE**
   2.1. The federal regulations require that investigators promptly report to the IRB events that may impact the rights, welfare, and safety of research participants or affect the scientific integrity of the research.
   2.2. The GovState IRB has categorized these events as follows:
      2.2.1. Any adverse events (internal or external) that meet all of these criteria:
         2.2.1.1. Unexpected.
         2.2.1.2. Possibly, probably, or definitely related to the research.
         2.2.1.3. Suggests the research places research participants or others at a greater risk of physical or psychological harm than was previously known or recognized.
      2.2.2. Adverse events most commonly occur in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research. Examples of adverse events include but are not limited to the following:
         2.2.2.1. Abnormal physical exam or laboratory finding.
         2.2.2.2. Symptom or disease temporally associated with the subject's participation in the research, whether considered related to the subject's participation in the research.
         2.2.2.3. Loss of employability, social standing, or reputation.
         2.2.2.4. Severe emotional distress, i.e., distress greater than that which one would experience in day-to-day life and that could not be addressed through the resources provided by the PI.
      2.2.3. Unanticipated problems or any incident, experience, or outcome that meets all of the following criteria:
         2.2.3.1. Unexpected with reference to procedure/risks defined in initial IRB application.
         2.2.3.2. Possibly, probably, or definitely related to participation in the research project.
         2.2.3.3. Suggests the research places subjects or others at greater risk of harm than was previously known or recognized.
      2.2.4. Examples of unanticipated problems include but are not limited to:
         2.2.4.1. Breach of privacy or confidentiality including lost or stolen project records that contain private identifiable subject information.

2.2.4.2. Any other problem that the investigator considers to be unanticipated and indicates that subjects or others are at increased risk of harm.

2.2.4.3. Incarceration of a subject in a protocol not approved to enroll prisoners.

2.2.4.4. Complaints of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team.

2.2.5. Protocol deviations that include but are not limited to the following:

2.2.5.1. Any departure from the protocol (deviation or violation) that harmed subjects or others; that indicates subjects or others might be at increased risk of harm; or that compromises the integrity of the research data.

2.2.5.2. Any change made to the research without prior IRB approval to eliminate apparent immediate harm.

2.2.6. Examples of protocol deviations include but are not limited to the following:

2.2.6.1. Enrolling a subject who does not meet eligibility criteria.

2.2.6.2. Not performing a specific screening procedure for a patient as indicated in the protocol.

2.2.7. Non-Compliance with IRB policies and/or procedures including any allegation of non-compliance with protocol requirements (including protocol deviations or violations) or IRB policies.

3. **PROCEDURES**

3.1. A prompt report must be submitted to the IRB within 5 calendar days of when the Principal Investigator (PI) learns of the reportable event.

3.2. The prompt report form must be submitted through Cayuse.

3.3. The GovState IRB review of prompt reports will follow the process outlined in the IRB SOP "Noncompliance."

3.4. The IRB will follow the process outlined in SOP "Reportable Events" to notify the GovState Institutional Official or designee (Director, Office of Sponsored Programs and Research) of the events that constitute unanticipated problems involving risks to subjects and others, serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB, or suspension or termination of IRB approval.

REFERENCES

45 CFR 46.108
GSU IRB SOP "Noncompliance"
GSU IRB SOP "Reportable Events"

Sources that have been consulted: Medical Colleges of Wisconsin, Office of Research SOP "REQUIREMENTS FOR REPORTING TO THE IRB"

CONTACT INFORMATION

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DISCLAIMER

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Institutional Official calls for review. Requests for exception to any portion of this SOP must be presented in writing to the Institutional Official.