Governors State University

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

SOP: Reportable Events

1. PURPOSE

1.1. The purpose of this guidance is to clarify the Governors State University ("GSU" or the "University") Institutional Review Board's ("IRB") requirements for reportable events.

2. GUIDANCE

2.1. Federal regulations 45 CFR 46.108(a)(4) and 21 CFR 56.108(b) require that institutions have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and regulatory and funding agencies of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB, or suspension or termination of IRB approval.

2.2. To fulfill this requirement, the Institutional Official will ensure that full, accurate, and timely reports are submitted to the appropriate regulatory and funding agencies for 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.

3. PROCEDURES

3.1. The Assistant Director of Research Compliance in conjunction with the IRB Chair will report the following events to the Institutional Official or designee (Director, Office of Sponsored Programs and Research ("OSPR")):

3.1.1. Suspension or termination of previously approved research, regardless of the reason for the suspension or termination.

3.1.2. Serious or continuing noncompliance as determined by the IRB.

3.1.3. Unanticipated problems involving risks to subjects or others as determined by the IRB.

3.2. The contents of the report to the Institutional Official (or designee) must include:

3.2.1. Title of the research project and grant proposal in which the problem occurred.

3.2.2. Name of the principal investigator on the protocol.

3.2.3. Cayuse protocol ID number.

3.2.4. Detailed description of the problem.

3.2.5. IRB's findings.
3.2.6. Actions the IRB is taking or plans to take to address the problem.
3.2.7. Basis for the actions.
3.2.8. Any further investigation or actions recommended to be taken if applicable.

3.3. Within fifteen (15) business days of the final review by the IRB, the Institutional Official or designee (Director, Office of Sponsored Programs and Research) is responsible for submitting a formal report for the events identified in this policy to the following:
3.3.1. External Recipients:
3.3.1.1. Office for Human Research Protections (OHRP) when the study is subject to U.S. Department of Health and Human Services (DHHS) regulations.
3.3.1.2. Other federal agencies when the research is subject to those agencies and the agency requires reporting separate from that to OHRP
3.3.1.3. Commercial sponsors or funders of the research when required by sponsors or funders.
3.3.2. Internal Recipients:
3.3.2.1. General Counsel and Ethics Officer.
3.3.2.2. Principal Investigator's division/department chair.

3.4. Institutional Official A copy of the formal report will be kept in the OSPR/IRB's records for the duration specified by the University policies.

REGULATIONS
45 CFR 46.103(b)(5) and §113
21 CFR 56.108(b) and §113

REFERENCES
Adapted from The Children's Hospital of Philadelphia SOP "Reporting to Regulatory Agencies & Sponsors Regarding Human Subjects Research."

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.