Governors State
U N I V E R S I T Y

SOP: IRB Procedure Development and Approval

1. PURPOSE
This document sets forth the considerations and procedures for the development, review, approval, and dissemination of new and revised Institutional Review Board (IRB) standard operating procedures (SOPs).

2. GUIDANCE
3.1.   As required by federal regulations and institutional policies and in order to maintain a high quality of review of oversight of research, the IRB maintains written SOPs for the major functions of the IRB.

3.2.   In developing SOPs, the IRB ensures that the SOPs are consistent with applicable federal and state regulations, the terms of the GSU's Federalwide Assurance (FWA), the GSU Policy for Protection of Human Research Subjects (Policy 53), and the most current standards of research compliance and industry best practices. The IRB further assures that SOPs provide sufficient step-by-step description with key operational details so that an independent observer can understand how the IRB operates and conducts its major functions.

3.3.   For the avoidance of doubt, in the event there is a conflict between the terms of a SOP and applicable federal and state law, the terms of FWA or Policy 53, applicable federal and state law, the terms of FWA or Policy 53 shall control over the SOP.

3. PROCEDURES
4.1.   Development

4.1.1.   The Provost has delegated authority to the Director of the Office of Sponsored Programs and Research (OSPR) to develop, implement, and revise policies and procedures for the IRB. The Director of OSPR, with advice from the Assistant Director of Research Compliance, the IRB and/or investigators, determines when a new or revised SOP needs to be established. In most cases, the OSPR Assistant Director of Research Compliance drafts new or revised SOPs. The Assistant Director is expected to consult with other GSU offices and well as industry groups and individuals in developing SOPs, and in interpreting regulations and regulatory guidance.

4.1.2.   New SOPs are written using the SOP TEMPLATE. Variations in structure and content are permissible when appropriate for the content or for ensuring clarity.

4.2.   Review and Approval

4.2.1.   All new and revised SOPs must be reviewed initially and recommended for

further action by:
    a.   Director of OSPR
    b.   IRB chair
    c.   IRB membership
    d.   Provost
    e.   Legal counsel

4.2.2.   The Director of OSPR conducts initial screening of new and revised SOPs. Then SOPs are reviewed by the IRB Chair and forwarded to the IRB membership. In most cases, IRB review and voting on new or revised SOPs occurs at convened meetings of the IRB when there is a quorum present. In some cases, votes are collected via email. If the majority of IRB members vote to approve the new or revised SOP, the SOP is sent to the Provost for final administrative approval. Legal counsel reviews the final version for consistency with university policies and applicable law before the SOP is posted on the IRB website.

4.2.3.   Approval is documented by dated signatures of the parties listed above on the last page of the printed SOP. The IRB chair or the designated IRB member will sign on behalf of the IRB.

4.3. Implementation and Distribution

4.3.1.   SOPs are considered to be implemented when they are posted on the IRB website.

4.3.2.   In some circumstances, a SOP may instead be implemented by posting it to the secure internal GSU shared server. This implementation route is used only for a few SOPs that describe internal IRB processes not tied to regulatory requirements. *Example: the SOP on shredding.*

4.3.3.   SOPs are formally distributed to researchers by being posted on the IRB website. Implementation and distribution is formally communicated to all audiences via a targeted announcement or in-person during administrative meetings and other campus-wide events when necessary.

4.4. Revisions

4.4.1.   Revisions of existing SOPs follow the same process as described above for new SOPs. SOPs are revised as needed.

4.5. Management

4.5.1.   IRB SOP Template and SOPs are maintained by the OSPR Assistant Director for Research Compliance.

4.5.2.   The implemented documents are stored as electronic documents on the OSPR-IRB shared drive.

4.5.3.   SOP management information is created, maintained, and revised for each document. It includes: document ID #, date of implementation, version number, type of document, change notes, etc. The management information is maintained in the document itself (e.g., footer).

4.6. Retirement of SOPs

4.6.1.   SOPs are retired for many possible reasons, such as regulatory changes that eliminate the need for the SOP. The OSPR Director in consultation with the IRB Chair and the Assistant Director of Research Compliance is responsible for making the decision to retire a SOP.

4.6.2. The retirement process consists of:

4.6.3. Removing the SOP from the IRB website (or server);

4.6.4. Moving the SOP into the "Archived" section of the OSPR-IRB shared drive; and

4.6.5. Updating the document management information in Notes on SOP development.

5. RESPONSIBILITIES

5.1. **Institutional Official** is responsible for reviewing and approving all SOPs prior to implementation.

5.2. **Legal Counsel** is responsible for reviewing all SOPs after their administrative approval and before they can be implemented.

5.3. **Director of OSPR is** responsible for reviewing all SOPs for consistency and compliance with applicable regulations and institutional policies, obtaining Institutional Official approval; communicating with the university community about SOPs; overseeing the management of SOPs; following implemented SOPs.

5.4. **Assistant Director for Research Compliance** is responsible for drafting new and revised documents; obtaining consultation and feedback; arranging the review process; uploading SOPs on the IRB website; maintaining Notes on SOP development, promoting and ensuring consistency in interpretation and implementation of SOPs, following implemented SOPs.

5.5. **IRB Chair and members** are responsible for reviewing and approving SOPs, and following implemented SOPs.

REGULATIONS

45 CFR 46.108(3), 21 CFR 56.108(a) and (b)

OHRP "Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018)"

AUTHOR REFERENCE

Governors State University Policy 53

University of Washington Human Subjects Division - "Policies and Procedures"

Wayne State University IRB - "Policy and Procedure Development and Approval"

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. Requests for exception to any portion of this SOP must be presented in writing to the Institutional Official.