Governors State University

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

# SOP: Convened IRB Review

## 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 convened review of research with human subjects.

## 2. GUIDANCE

2.1. In accordance with federal regulations, initial and continuing reviews of research with human subjects must be conducted by the IRB at convened meetings at which a simple majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas, except where expedited review is allowed in accordance with 45 CFR 46.110.

2.2. Review of amendments to previously approved research must be conducted by the IRB at convened meetings, except when changes are minor.

2.3. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

## 3. PROCEDURES

3.1. **Quorum**

3.1.1. The IRB may only review proposed research at a convened meeting at which a simple majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.

3.1.2. Should the IRB meeting lose quorum the meeting is terminated from further votes until the quorum is restored.

3.2. **Conflict of Interest**

3.2.1. No IRB member may participate in the IRB's review of a project in which the member has a conflict of interest. If a conflict exists, the IRB member can provide information requested by the IRB but cannot be present for the discussion and the vote, as detailed in SOP "IRB Member COI".

3.3. **Pre-review**

3.3.1. An IRB analyst is authorized to complete a preliminary review of submitted protocol materials to determine their completeness and accuracy.

3.3.2. The pre-review is guided by a pre-review checklist, and serves as a mechanism to assist with the following:

3.3.2.1. Confirmation that all documents required by the IRB have been submitted by the investigator.

3.3.2.2. Assessment as to whether the protocol was submitted for the appropriate level of review.

3.3.2.3. Identification of potential regulatory and/or administrative issues and concerns that the IRB may wish to consider.

3.3.3. The analyst may contact researchers following the pre-review in an attempt to resolve any outstanding issues before the meeting as time permits and depending upon the nature of the pre-review comments.

3.4. **Primary Reviewers**

3.4.1. Primary reviewer(s) are assigned according to their scientific expertise and/or research experience relevant to the study. A minimum of two primary reviewers are assigned to initial reviews, and a minimum of one reviewer is assigned to continuing reviews and amendments. Assignment of the primary reviewer(s) is performed by the IRB analyst in consultation with the IRB Chair.

3.4.2. Primary reviewers are notified of their assignment via email from Cayuse. Within Cayuse, the reviewers are provided with the complete submission, the pre-review comments, and appropriate review guides. The reviewers are required to perform an in-depth review of all submitted documents in advance of convened meetings to be familiar with, and prepared to discuss, the research protocol.

3.4.3. By completing the review guide, the reviewer confirms that they have no conflicting interests and have the appropriate experience to review the research.

3.4.4. The reviewer evaluates whether the criteria for approval at 45 CFR 46.111 (and subparts B, C, and D, when applicable) or 21 CFR 56.111 and other protocol-specific determinations are met for initial reviews, continuing reviews, and for amendments when the changes affect a criterion for approval. The reviewer documents these determinations in writing on the designated review guide.

3.4.5. Evaluation of the requirements for the informed consent process and documentation (or waiver or alteration) is also provided in writing on the appropriate review guide (45 CFR 46.116 or 21 CFR 50.25).

3.4.6. The completed review guides are maintained with the protocol record.

3.4.7. Primary reviewers are most often responsible for presenting their findings, providing an assessment of the merits and safety of the protocol, reviewing the consent process, and recommending specific actions to the IRB. If the primary reviewer cannot attend the meeting, they must provide a checklist with their comments to the IRB Chair or co-Chair to present on their behalf. If present, the primary reviewer should lead the discussion of the protocol at the convened meeting.

3.4.8. After discussion and review of the primary reviewer's findings, the IRB determines whether the protocol application meets the minimum criteria for initial approval, the minimum criteria for continuing approval, or the minimum criteria for approval of an amendment.

3.5. **Actions by the IRB**

3.5.1. "Approved." An approval is granted if the research activities meet the criteria for approval at 45 CFR 46.111 (and subparts B, C, and D, when applicable) or 21 CFR 56.111 and no changes to the research are required by the IRB.

3.5.2. "Deferred," when additional information or clarifications are needed before a final determination can be made.

3.5.3. "Disapproved," when a study is found to be unethical, without scientific or scholarly merit and/or not meeting the criteria for approval. Written notification from the IRB of a decision to disapprove a protocol is accompanied by the IRB's reasons for the decision and an invitation for reply by the Investigator. A protocol may not be disapproved under expedited review procedures.

3.5.4. "Minor Stipulations," when minor corrections in the text of the application or revisions in the recruitment and consent documents are required. Under this scenario, further review of the research by the convened IRB may not be necessary. The IRB may designate the Chair (or other IRB member) to review the written response from the investigator, determine whether the conditions for approval have been met, and, when they are met, approve the research. The date of approval is the date when the Chair (or designee) determines the conditions for approval have been met.

3.6. **Documentation**

3.6.1. Discussions and actions taken by the IRB are documented in the minutes.

3.7. **Approval Period**

3.7.1. Research approved by the full board at a convened IRB meeting is limited to an approval period of no more than 365 days.

3.8. **Notification of IRB Review**

3.8.1. The IRB analyst notifies the investigator of the IRB's determination within seven (7) business days of the convened board meeting.

**REGULATIONS**

21 CFR 56.108(a), 21 CFR 56.109
45 CFR 46.111
OHRP Guidance on Continuing Review of Research, OHRP, DHHS, November 10, 2010
OHRP Guidance on IRB Approval of Research with Conditions, OHRP, DHHS, November 10, 2010
OHRP Guidance on Written IRB Procedures OHRP, DHHS, July 1, 2011
OHRP Frequently Asked Questions: IRB Procedures

**REFERENCES**

Adapted from the University of Illinois of Chicago IRB SOP "Review of Research by Convened 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.

**APPROVALS**

OSPR Director
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IRB Chair
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Provost
_____

Legal Counsel
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