Governors State University

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

SOP: Continuing Review

1. **PURPOSE**
   1.1. This guidance outlines the requirements of the Governors State University (GovState) Institutional Review Board (IRB) for continuing review of research.

2. **GUIDANCE**
   2.1. The IRB conducts continuing review of research at intervals appropriate to the degree of risk, not less than once per year as required by Federal regulations.
   2.2. The IRB decides the frequency of continuing review for each research project necessary to ensure the continued protection of the rights and welfare of research subjects. Reviews conducted more frequently than once per year may be appropriate when the risks to subjects warrant more frequent reassessment.
   2.3. The IRB considers factors such as the following when deciding on an appropriate interval for continuing review:
      2.3.1. The nature of any risks posed by the research project;
      2.3.2. The degree of uncertainty regarding the risks involved;
      2.3.3. The vulnerability of the subject population;
      2.3.4. The experience of the investigators in conducting research;
      2.3.5. The IRB's previous experience with the investigators (e.g., compliance history, previous problems with the investigator obtaining informed consent, or prior complaints from subjects about the investigator);
      2.3.6. The projected rate of enrollment; and
      2.3.7. Whether the research project involves novel interventions.
   2.4. Unless the IRB determines otherwise, continuing review of research is not required for exempt research, research requiring limited review, research eligible for expedited review, and research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
      2.4.1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
      2.4.2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
   2.5. When considering whether to renew a study, the IRB applies the same criteria used to grant initial approval, as defined in 45 CFR 46.111. During continuing review, the IRB determines whether the study can be renewed at the same risk/benefit ratio, or if new information has changed that determination. As an outcome of continuing review, the IRB may require that the research be modified to meet the criteria for

approval. Additionally, the IRB may need to impose new precautions or revise those it had previously imposed on the research protocol.

2.6. The IRB reviews the currently approved recruitment and consent documents to ensure that the information is still accurate and complete. The IRB considers investigator and institutional issues and research progress.

2.7. The IRB reassesses the approval period for each continuing review application. The length of the approval period is documented in Cayuse and, if applicable, the minutes of the convened board meeting.

2.8. Any significant new findings that may relate to the participants' willingness to continue participation should be included and submitted with the continuing review application.

2.9. An application requesting modifications to a research protocol may be submitted along with a continuing review application. The modification shall not be implemented by an investigator unless and until it is reviewed and approved by the IRB.

2.10. IRB continuing review approval is not granted until all requested changes to previously approved documents are completed by the investigator and reviewed and approved by the GovState IRB.

3. **PROCEDURES**

3.1. Continuing review applications are available within the IRB electronic submission system Cayuse.

3.2. Cayuse sends two automatic notifications about the expiration of IRB approval.

3.3. Investigators are required to submit a continuing review application to the IRB immediately after receiving the first notification to ensure the IRB reviews and reapproves the study before it expires.

3.4. The continuing review application must include a copy of the current IRB date-stamped informed consent documents as well as a clean copy for stamping of the new approval and expiration dates once granted by the IRB.

3.5. The continuing review of studies requiring convened GovState IRB review follows the procedures outlined in the IRB SOP "Convened IRB Review."

3.6. The continuing review of expedited studies that have been determined to require continuing review follows the procedures outlined in the IRB SOP "Expedited Review of Research."

3.7. The continuing review of cooperative research follows the procedures outlined in the IRB SOP "Cooperative Research."

3.8. The effective date of the first continuing review approval is no later than one year after the effective date of initial IRB approval.

3.9. The IRB does not maintain a fixed anniversary date for the expiration of annual IRB approvals. The effective date of the second and subsequent continuing review approvals is the date of the convened meeting when the IRB conducts continuing review and approves the study without conditions, the date on which the IRB chairperson (or any other individual(s) designated by the IRB) has reviewed and accepted as satisfactory any revised protocol or informed consent documents or any

other responsive materials required by the IRB from the investigator as part of conditional approval, or the date when the study is re-approved by the expedited process.

3.10. There is no grace period extending the conduct of the research beyond the expiration date of IRB approval.

3.11. If a study is not reviewed before the expiration date, the IRB notifies the study principal investigator to cease all research activities and submit the study for continuing review as soon as possible.

3.12. The investigator may resume research activities once continuing review and approval by the IRB have occurred.

3.13. Prolonged lapses in IRB approval (e.g., studies that have been expired for more than 60 days) result in a notice of administrative closure. If no action is taken by the investigator, the protocol will be closed within 30 days after sending the notice.

3.14. An administrative closure of expired research may affect the investigator's future submissions to the IRB.

REFERENCES

45 CFR 46.104, 45 CFR 46.109, 45 CFR 46.110, 45 CFR 46.111, 45 CFR 46.114
OHRP Continuing Review Guidance (2010)
Approval of Research with Conditions: OHRP Guidance (2010)
GovState IRB SOP "Convened IRB Review"
GovState IRB SOP "Expedited Review of Research"
GovState IRB SOP "Cooperative Research"

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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.