Governors State University

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

SOP Expedited Review of Research

1. PURPOSE

1.1. The purpose of this guidance is to clarify the Governors State University ("GSU" or the "University") Institutional Research Board ("IRB") requirements for expedited review of human subjects research.

2. GUIDANCE

2.1. Minimal risk research in which activities involving human subjects are limited to one or more of the federally defined categories can be reviewed by the expedited process, as allowed by 45 CFR 46.110.

2.2. Initial review, amendments to previously approved research, post-approval reporting, and closure reports may be reviewed by the expedited process when they meet the criteria specified by federal regulations.

2.3. The expedited reviewer(s) may exercise all of the authorities of the IRB except that they may not disapprove the research. If the reviewer(s) find(s) that the research should not be approved, the research must be referred to the convened IRB for a final determination.

2.4. If a research protocol meets the requirement of minimal risk, but includes activities outside of the expedited review categories, then the protocol must be reviewed by the convened IRB. The convened IRB may opt to make the determination that the research does not involves more than minimal risk and, therefore, may be reviewed under expedited category 9 in the future. This determination can only be made by the convened IRB at the time of initial or a subsequent continuing review.

2.5. Expedited review procedure may not be used where identification of subjects and/or their responses would reasonably place them at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, insurability, educational advancement, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to the invasion of privacy and breach of confidentiality are no greater than minimal.

2.6. Amendments to research previously approved by the convened review or expedited review are also eligible for the expedited review process when the proposed changes are minor, involve no greater than minimal risk, and the research continues to meet the expedited review criteria.

2.7. Studies approved at the expedited level do not require continuing review (45 CFR 46.109(f)(1)(i)), unless the reviewer makes a determination that a continuing review is required.

2.8. Expedited approvals are valid for five (5) years. After five years, the researcher must submit a continuing review or close the study. If no continuing review or closure report is received, the study will be closed administratively.
2.9. Closure reports for expedited studies are required.

3. PROCEDURES

3.1. Expedited reviews are conducted on a rolling basis.
3.2. Expedited reviews are conducted by the IRB Chair or an experienced IRB member.
3.3. IRB members are informed through the agenda for the convened IRB meeting of initial reviews, amendments of previously approved research, post-approval reporting, and final reports reviewed by the expedited process.
3.4. Applications for expedited review are submitted through Cayuse.
3.5. An IRB analyst performs a pre-review of an expedited application. The pre-review is guided by a pre-review checklist, and serves as a mechanism to assist with the following:
  3.5.1. Confirmation that all documents required by the IRB have been submitted by the investigator.
  3.5.2. Assessment as to whether the protocol was submitted for the appropriate level of review.
  3.5.3. Identification of potential regulatory and/or administrative issues and concerns that the IRB may wish to consider.
3.6. The analyst assigns the proposal to the IRB Chair or an experienced IRB member. If warranted, a second reviewer or *ad hoc* consultant may be assigned.
3.7. The analyst in consultation with the IRB Chair may also directly refer the proposal to the convened IRB when the preliminary evaluation indicates that the eligibility criteria for expedited review are not met.
3.8. Conversely, when reviewing a proposal submitted for convened review, the analyst in consultation with the IRB Chair may decide the proposal meets the criteria for expedited review and reassign it to this level of review.
3.9. With scenarios 4.6 and 4.7, the investigator is notified of the IRB's decision through administrative communication by the analyst.
3.10. The reviewer is notified of their assignment to an expedited submission via an email from Cayuse. Within Cayuse, the reviewer is provided with the complete submission, the completed pre-review, and appropriate review guide. The reviewer is expected to perform an in-depth review of the complete set of documents submitted by the investigator via Cayuse. Their review includes all materials submitted in conjunction with the IRB application and any additional materials obtained from the investigator during the pre-review process.
3.11. By completing the review guide, the reviewer confirms that they have no conflicting interests and have the appropriate experience to review the research.
3.12. 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 and for amendments when the changes affect a criterion for approval. The reviewer documents these determinations in writing on the designated review guide.

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

3.14. The completed review guide serves as documentation of the expedited review process and is maintained with the protocol record.

3.15. The IRB reviewer indicates one of following actions:

3.15.1. Approve. The research has met the criteria for approval at 45 CFR 46.111 (and subparts B, C, and D, when applicable) or 21 CFR 56.111.

3.15.2. "Differed" when additional information or clarifications are needed before a final determination can be made.

3.15.3. "Minor stipulations" when minor corrections in the text of the application or revisions in the recruitment and consent documents are required.

3.15.4. "Return" when CITI training is missing or incorrect, or when the investigator failed to address the IRB's findings.

3.15.5. Proposed activity does not meet the definition of research or research involving human subjects.

3.15.6. Proposed research does not engage GSU.

3.15.7. Refer to the convened IRB for review. Either the proposal does not meet the requirements for minimal risk, the expedited review categories, or minor change to previously approved research; the IRB reviewer(s) has concerns regarding the protocol and would like a convened review; or the IRB reviewer feels the research is not approvable. When the proposal is referred to the convened IRB for review, the researcher is notified about the reason for referral, the date of the convened IRB meeting if known, and any recommendations for revisions, clarifications, or additional information prior to convened IRB review.

3.16. The reviewer's decision is sent to the researcher through Cayuse.

3.17. Investigators are provided 90 days to respond to the IRB's findings. If no response is received, the application will be administratively closed for non-response.

3.18. If the study is not completed and closed within five (5) years following the approval, the investigator will receive a reminder to submit a continuing review or close the study. If no continuing review or closure report is received, the study will be closed administratively.

REGULATIONS

45 CFR 46 (sections 109, 110,111, 116)
21 CFR 50.25, 21 CFR 56.111
Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure (1998))

AUTHOR REFERENCES

Adopted from University of Illinois Chicago IRB's SOP "Expedited Review of 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.

APPROVALS

OSPR Director

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IRB Chair

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Provost

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Legal Counsel

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