Governors State University

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

SOP Exempt Research

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 making exempt determinations for human subjects research.

2. GUIDANCE

2.1. Minimal risk research in which activities involving human subjects are limited to one or more of the categories defined in the Code of Federal Regulations 45 CFR 46.104 may qualify for exemption from some of the requirements of 45 CFR 46.

2.2. Studies that qualify for exemption are still considered human subjects research and must adhere to principles of sound research design and ethics. Examples of these principles can be found in the Belmont Report as well as in guidance documents from professional societies and scientific organizations.

2.3. Participants' rights and welfare must be protected in a manner appropriate for research that poses minimal risk. Investigators should obtain informed consent from each subject and institute measures to protect subjects' privacy and confidentiality, as appropriate.

2.4. Investigators do not have the authority under federal guidance and GSU policy to independently determine that their research involving human subjects is exempt. The research must be submitted to the IRB for review prior to initiation.

2.5. The research may not begin until the Principal Investigator (PI) has received a notification from the IRB that the research qualifies for exemption.

2.6. Substantive changes in the study that has been granted an exemption must be submitted to the IRB through a modification to the approved protocol.

2.7. Changes to an exempt study that significantly alter the approved research design, instruments, subject population, and/or recruitment and consent procedures as determined by the IRB may require a new IRB application.

2.8. Exempt determinations are valid for seven (7) years. Exempt studies that continue beyond seven (7) years must be re-submitted for review as a new IRB application. This provision does not apply to ClassEx protocols that must be renewed every three (3) years.

2.9. Closure reports for exempt studies are recommended, but not required. Administrative check-ins for exempt studies will be conducted every three years and studies that have been completed will be closed.

3. General Applicability of Exempt Categories

3.1. Subpart *B of the code of federal regulations 45 CFR 46 (pregnant women, fetuses, and neonates).* Each of the exemptions defined in 45 CFR 46.104 may be applied to research subject to subpart B if the conditions of the exemption are met.

3.2. Subpart *C of the code of federal regulations 45 CFR 46 (prisoners).* Exemptions defined in 45 CFR 46.104 do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

3.3. Subpart *D of the code of federal regulations 45 CFR 46 (children).* The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of 45 CFR 46.104 may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of 45 CFR 46.104 may only apply to research regulated by subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

4. Special Considerations

4.1. GSU IRB does not grant exemptions to studies that:

4.1.1. Collect data through a combination of interventions/manipulations and interactions, unless those studies meet the criteria for exempt category 3;

4.1.2. Collect biospecimens in conjunction with collection of survey, interview, or observational data;

4.1.3. Collect identifiable data from academic or medical records in conjunction with collection of survey/interview/observational data.

4.2. GSU IRB does not apply categories 2.iii, 3(i)C, 7, and 8 that require "limited review." Studies that meet the criteria of these categories are reviewed at the expedited level.

4.3. GSU IRB does not apply category 4.iii, unless the research takes place at a covered entity and that entity first determines through their IRB procedures that the exemption applies, and second, GSU agrees that the exemption applies and/or formally enters into an IRB Authorization Agreement (IAA) with the CE.

4.4. Exemption category 6 is the only category that may pertain to FDA-regulated research [21 CFR 56.104].

5. **Additional considerations**

5.1. When GSU investigators are collaborating with another institution on a study that meets the criteria for exemption, each institution will obtain its own exempt determination.

5.2. When the project involves external investigators not affiliated with a Federalwide Assurance holding institution, those investigators must complete and sign an Individual Investigator Agreement for Exempt Research Studies.

6. PROCEDURES

6.1. Exempt reviews are conducted on a rolling basis.

6.2. Exempt applications can be reviewed by the IRB Chair, IRB member designated by the Chair, or IRB analyst/Assistant Director.

6.3. Exempt applications are submitted through Cayuse.

6.4. Exempt applications are pre-reviewed by an IRB analyst. The pre-review is guided by a pre-review checklist, and serves as a mechanism to assist with the following:

6.4.1. Confirmation that all documents required by the IRB have been submitted by the investigator.
6.4.2. Assessment as to whether the application was submitted for the appropriate level of review.
6.4.3. Identification of potential regulatory and/or administrative issues and concerns that the IRB should consider.

6.5. The analyst may review the application or assign it for review to the IRB Chair or an IRB member.

6.6. In making the determination, the reviewer considers whether:
6.6.1. The research meets the definition of research involving human subjects, the definition of minimal risk, and one or more of the criteria for exemption.
6.6.2. Any of the special and additional considerations as applicable.

6.7. The reviewer makes one of the following determinations:
6.7.1. Exemption is granted.
6.7.2. "Deferred," when additional information or clarifications are needed before a final determination can be made.
6.7.3. "Minor stipulations," when minor corrections in the text of the application or revisions in the recruitment and consent documents are required.
6.7.4. "Return," when CITI training is missing or incorrect, or when the investigator failed to address the IRB's findings.
6.7.5. Proposed activity does not meet the definition of research or research involving human subjects.
6.7.6. Proposed research does not meet the criteria for exemption and must be reviewed by the IRB under expedited or convened review processes.
6.7.7. Proposed research does not engage GSU.

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

6.9. Researchers have 90 days to respond to the IRB's findings. If no response is received, the application will be administratively closed for non-response.

6.10. If the study is not completed and closed within seven (7) years following the approval, the investigator will receive a reminder to close the study or resubmit it as a new application.

REGULATIONS

45 CFR 46.104, 21 CFR 56.104

AUTHOR REFERENCES

Adapted from the University of Illinois Chicago IRB SOP "Exempt Review of Research"

CONTACT INFORMATION

Office of the Sponsored Programs and Research
Governors State University
1 University Parkway
University Park, IL 60484
708.235.2846

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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