

SOP: External Research

1. PURPOSE

To establish standard procedures for reviewing research conducted by external researchers that involves Governors State University's (GSU) faculty, staff, students, or alumni as research participants.

2. DEFINITIONS

- 2.1. **External researcher** - an unaffiliated researcher who has no close formal or informal association with GSU.
- 2.2. **GSU liaison** – a university faculty or staff member who assists the external researcher with recruitment of subjects at GSU. GSU liaisons do not serve as investigators or co-investigators for the external researcher's project.
- 2.3. **IRB** - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

3. SCOPE

This guidance applies to external researchers who are interested in conducting research involving GSU faculty, staff, students, and/or alumni. The guidance applies to external researchers who intend to do any of the following:

- 3.1. Request *assistance* of GSU faculty and/or staff with recruitment of other faculty, staff, students, or alumni by informing or providing prospective subjects with information about research or contact information of investigators; and/or
- 3.2. Request *assistance* of GSU faculty and/or staff with distribution of on-line surveys via campus listservs; and/or
- 3.3. Recruit GSU students, staff, and faculty via fliers/other informational materials distributed on the GSU campus without the help of GSU faculty and/or staff; and/or
- 3.4. Recruit GSU students, staff, and faculty in person via on-campus presentations; and/or
- 3.5. Use GSU facilities to conduct research involving GSU faculty, staff, students, or alumni; and/or Obtain data from institutional records about GSU faculty, staff, students, or alumni.
- 3.6. In addition, this procedure applies to situations when GSU is the primary awardee on a grant funding human subjects research even if all study activities

are conducted by non-GSU researchers without assistance from GSU.

- 3.7. This procedure does NOT apply to:
- 3.7.1. Cooperative research conducted under reliance agreements with collaborating institutions that allows one IRB to conduct the review of all or parts of a research study (see SOP Reliance Agreements);
 - 3.7.2. Research projects for which GSU facilities are rented by external researchers for interactions or interventions with non-GSU subjects;
 - 3.7.3. Research projects for which university faculty's and/or staff's participation is solicited directly through their publicly available emails.

4. GUIDANCE

- 4.1. Research with human subjects conducted by an external researcher must be reviewed by the GSU IRB for appropriateness and compliance. Approval decisions are made on a case-by-case basis. The external researcher must provide a compelling justification for using GSU faculty, staff, students, or alumni as study participants and/or demonstrate some direct benefit to the GSU community.
- 4.2. In addition, permission to conduct research at GSU must be obtained from the appropriate university official relative to the research to be conducted.
- 4.3. For research activities that are subject to this guidance, an external researcher must identify a GSU employee (regular, full-time) willing to serve as the GSU liaison for the duration of the research project. The GSU liaison should be able to answer questions about the project and serve as the campus contact for questions or concerns about the research.

5. PROCEDURES

- 5.1. An external researcher will obtain permission to conduct research at GSU from the appropriate university official relative to the research to be conducted. For example, requests involving data from institutional records must be approved by GSU Office of Institutional Research. For assistance, the researcher will contact the Office of Sponsored Programs and Research.
- 5.2. An external researcher will identify a GSU faculty, researcher, or administrator willing to serve as the GSU liaison for the duration of the research project. For assistance, the researcher will contact the Office of Sponsored Programs and Research.
- 5.3. An external researcher will provide the GSU liaison with a copy of the complete application approved by their home institution's IRB, including: protocol; recruitment and consent documents, if applicable; all documents that subjects will receive or review; proof of training (i.e., CITI training certificate), and evidence of IRB approval or an exemption determination.
- 5.4. The GSU liaison will submit the external researcher's materials to the GSU IRB using the EXTERNAL RESEARCH submission option in Cayuse. For requests involving data from institutional records, a submission option for secondary data research may be used.
- 5.5. The GSU IRB will review the materials and determine if the research is

acceptable and may proceed at GSU. The IRB's decision will be communicated to the GSU liaison.

- 5.6. The GSU IRB reserves the right to request additional information or modifications in the external researcher's application materials.

REGULATIONS

45 CFR 46.114

AUTHOR REFERENCE

St. Mary's University, IRB SOP "External Researcher Guidelines"

University of North Carolina, Asheville, IRB SOP "External Researchers"

University of California, Berkeley, IRB SOP "ENGAGEMENT IN HUMAN SUBJECTS RESEARCH"

Governors State University Policy 53

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.