

Middle Georgia State University
Institutional Review Board
Guidelines
Last Revised: July 2022

Primary Investigators Responsibilities

The Primary Investigator(s) is the individual or individuals responsible for insuring that the proposed project adheres to all federal, state, and institutional laws and policies. For assistance or samples of any of the documents noted herein please contact the IRB chair.

General considerations

Middle Georgia State University assures, in writing, the United States Office for Human Research Protections (OHRP) that the institution complies with the Department of Health and Human Services (DHHS) regulations for the protection of research participants. In its written agreement with OHRP, Middle Georgia State University (MGA) agrees that research activities involving human participants, regardless of sponsorship, will be reviewed by the IRB when one or more of the following apply:

- The research* is sponsored by MGA, **or**
- The research is conducted by or under the direction of any employee or agent of MGA in connection with his or her institutional responsibilities **or**
- The research is conducted by or under the direction of any employee or agent of MGA using any property or facility of this institution, **or**
- The research involves the use of MGA records, or uses non-public information to identify or contact human research participants or prospective participants, **or**
- The research will be conducted on the grounds of MGA or uses as subjects MGA students, faculty, or staff in their respective roles, **or**
- Data collection which will result in an article, master's thesis, doctoral dissertation, poster session, abstract, or any other publication, presentation, or any dissemination of the collected data.

*For the purposes of this document "research" is defined as a systematic investigation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. In practical terms, the Middle Georgia State University IRB defines research as systematic investigation intended to produce data that will or may be published or presented with the intention of contributing to the greater body of knowledge in the field of interest. Please contact the chair of the IRB if you are unsure if your activity would be considered research.

Filing an application for review

The required forms have been designed to provide the Middle Georgia State University IRB with the information necessary to expeditiously evaluate your project. Complete each item carefully and follow the instructions below. These forms must be approved prior to beginning any sponsored or non-sponsored research in which there is research involving human participants. The request for approval must be submitted to the Chair of the IRB committee. In addition, any questions regarding completion of the form or the process should be directed to the IRB chair, as well.

Summary of levels of review

Full Review Projects requiring the review of the full IRB at a convened meeting

Expedited Review Projects that involve no more than minimal risk and therefore can be reviewed without a convened meeting of the IRB.

Exempt Review Projects that are exempt from review by the full IRB and only require review by the IRB Chair and one IRB voting member.

Level of Review Decision Charts

Timeline for approval

Full Review

Proposals which require Full review will receive a response within three weeks of submission.

Expedited and Exempt Review

Proposals which meet the requirements for Expedited or Exempt review will receive a response within three days of submission.

Completing the IRB Form

1. Project Title

The project title should relate directly to and briefly describe the research. If funding is being sought for the research and a grant proposal is associated, the title must match verbatim the language used in the funding proposal.

2. Source of Funding

All funding sources (on or off-campus) awarded or being sought must be listed. If funding is not being sought, report "Un-funded" or "None." Do not leave this section blank.

3. Dates of Proposed Research

Provide the beginning and ending dates of the proposed research. Where applicable, dates must match the grant period. Proposals are not reviewed retroactively and when dates precede submission to the IRB, the proposal will be returned to the Principal Investigator without review, and, thus, without IRB approval. Please allow a few weeks for the IRB review process when choosing your start dates.

4. Describe the Scientific Purpose of the Investigation

Indicate, in non-technical terms, the scientific reason for conducting this research.

5. Describe the Research Methodology

In non-technical language, describe in detail what will be done with or to the research participant(s). Describe or list research instruments to be administered. List all phases of the research plan, including pilot testing and follow-up. Typically this is one page in length or more.

6. Potential Benefits

List any benefit(s), whether direct benefits to the participants, or benefits of this research to the field of study. Be certain to include long-term and short-term potential benefits.

7. Potential Risks

Risk includes, but is not limited to, physical harm to a participant. The risk of economic, social, and/or psychological harm must also be considered. If the risks of harm to a participant are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations, then state no anticipated risk. If, however, the project involves more than minimal risk, specify what that risk is and the procedures for protecting participants.

8. Describe how participants will be recruited

How many participants are you seeking, what is their age, and from where will you obtain them?

Recruiting minors

Special Requirements - 45 CFR 46 Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research

Compensation

9. Describe why it is necessary that the Primary Investigator(s) and/or Supervisor know the identity of the participants

Many projects can be conducted with participants providing data anonymously. A full or expedited review is deemed necessary when the identity of the participants will be known by the Primary Investigator and/or the Supervisor. Provide a description of why it is necessary to have this information and how this information will be kept safe.

10. Describe how data collected for this project will be securely stored and when and how it will be destroyed

Data Security and Destruction All data must be stored and destroyed in compliance with mandated data governance policies.

11. Describe the Informed Consent Process

12. Signatures page

The original signature(s) of the Principal Investigator(s) and Faculty Supervisor (if any) are required to be sent in hard copy form to the Chair of the IRB.

After IRB Review

Adverse Events

An adverse event is an undesirable and unintended, although not necessarily unexpected, result involving risks to research participants or others.

Changes in Protocol

When protocol changes are proposed, a change in risk associated with the research occurs, and/or adverse events, unanticipated problems, or complaints about the research are reported, the Principal Investigator is responsible for contacting the IRB.

Re-Approval – Continuing Review

Projects are re-reviewed when the use of human participants is expected to continue beyond the original IRB approval period.