Middle Georgia State University
Institutional Review Board
Principal Investigator's Handbook

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Origin of the Institutional Review Board (IRB)

An Institutional Review Board is a committee mandated by the National Research Act, Public Law 93348, to be established within each university or other institution that conducts most types of research involving humans. The purpose of the IRB is to review all proposals for human research before the research is conducted to determine whether the research path has adequately included the ethical dimensions of the project. Federal oversight of the IRB is conducted by the United States Office for Protection from Research Risks (OPRR), within the National Institutes of Health. Institutions not in compliance with the law may lose Federal funding. Because of worldwide opinion after World War II, the Nuremberg Code was promulgated. The first principle of this code states that humans must not be participants in research projects unless they are fully informed of the proposed procedures and voluntarily consent to the procedures. Due to reports of some biomedical research carried on in the United States in the late 1950s and early 1960s, the United States Surgeon General enforced regulations that govern all research sponsored by the Department of Health, Education, and Welfare (now DHHS). In 1974, Congress passed the National Research Act, that together with the Multiple Project Assurance agreements, broadens the regulations by having them apply to all research involving human participants conducted at institutions receiving Federal funding, not just projects that are Federally funded. The original focus of the regulations was on biomedical research, but conformity studies and obedience studies raised questions about invasions of privacy. However, research conducted between 1956 and 1964 involving behavioral effects of drugs in normal social settings caused the interpretation of the regulations and the National Research Act to include social and behavioral research.

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.

General considerations

Middle Georgia State University assures, in writing, the United States Office for Protection from Research Risks (OPRR) that the institution does comply with the Department of Health and Human Services (DHHS) regulations for the protection of research participants. In its written agreement with OPRR, 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
- 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 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.