Middle Georgia State College
Institutional Review Board
Standard Operating Procedures Manual

Last Revised on:

General Information

The President of Middle Georgia State College gives the Middle Georgia State College IRB the authority to disapprove or approve research proposals, to require modifications of protocols to protect the rights, dignity, and well being of human research participants and to assure compliance with all Federal and State regulations.

Introduction

Purpose

This document sets forth the policies and procedures for the Middle Georgia State College Institutional Review Board (hereafter referred to as IRB).

Application

The policies and procedures described herein apply to all research, development, and other activities involving human participants, whether funded or not, for which Middle Georgia State College is responsible. Middle Georgia State College IRB is responsible for overseeing all research conducted by faculty, staff, or students which involves human subjects. In addition Middle Georgia State College IRB is responsible for any research in which Middle Georgia State faculty, staff, and/or students will serve as participants.

General Principles

The IRB accepts as basic principles the ideology expressed in the Nuremberg Code (1947), the Declaration of Helsinki (revised 1975), and the Belmont Report (1979) as well as the following documents:

Title 45 CFR Part 46, OPRR Protection of Human
The Belmont Report
Nuremberg Code
Code of Ethics of the American Anthropological Association (1998)
Ethical Principles of Psychologists and Code of Conduct (2002)
American Sociological Association Code of Ethics (1999)
Code of Ethics of the National Association of Social Workers (2008)
World Health Organization: Operational guidelines for ethics committees that review biomedical research. Geneva, 2000 (TDR/PRD/ETHICS/2000.1).
Office for Human Research Protections (OHR) IRB Guidebook

Copies of or links to these documents are distributed to IRB members and are available for review on the IRB website. In addition, the IRB will ensure that potential or perceived coercion is minimized for all research participants. The IRB will ensure that Principal Investigators are especially sensitive to this issue when dealing with captive and vulnerable populations such as students, minors, and prisoners. Principal Investigators considering doing research which would involve recruiting their own (or their h participants should consult the PI Handbook Appendix D for recommended classroom data collection protocol.

Continuous Improvement Plan

In order to best provide protection of human participants and maintain compliance with all regulatory guidelines, including but not limited to those of the OPRR, State of Georgia, Middle Georgia State College, and the IRB *Standard Operating Procedures Manual* and
Principal Investigator's Manual, the IRB will:

1. Update the IRB *Standard Operating Procedures Manual as* needed and distribute dated revisions to all members.
2. Update the IRB *Principal Investigator's Manual* as needed and distribute dated revisions to all members.
3. Annually (January), the IRB will select at least 2 protocols from the active files to audit. The IRB Chair Elect will direct this review. A written report of the summary of this audit will be presented to the IRB members, with recommendations listed, if any. Success of this program will be shown by the contents and list of recommendations with each report. The procedure will consist of, but not be limited to, reviewing each selected file to verify the completeness of:
    a. the approval process
    b. consent process
    c. adverse event reports
    d. debriefing, if deception is involved
    e. the renewal process
    f. reported revisions
    g. ethical issues
    h. assent procedures when minors are participants.

4. Provide continuing education to IRB members and Principal Investigators via written and oral communications and attendance at workshops and meetings designed to educate members about new or changed OPRR regulations or guidelines.

Meetings

Meeting Location

Reviews of exempt and expedited protocols may be conducted by email or electronic means. Protocols requiring full review may also be conducted by conference call and/or live electronic format, provided that IRB members are able to view, modify, and discuss the protocol in real time. If a live meeting is necessary, the Warner Robins campus will be the preferred location.

b. A Chair shall be elected by the IRB members from among those members who have served on the IRB for at least one year.
c. At least one and preferably two community members are nominated by

above, when the Chair is unable to do so. Beyond these duties the primary responsibilities

4) Data collection which will not result in an article, masters thesis, doctoral dissertation, poster session, abstract, or any other publication, presentation, or any dissemination of the collected data.

Surveys of the entire student body / MGSC community: Faculty or staff wishing to conduct surveys of the entire student body that do not otherwise meet the definition of human subjects research (i.e. the survey questions/results are specific to Middle Georgia State College and do not contribute to generalizable knowledge) are asked to submit a brief description of the planned survey to the IRB chair and to coordinate survey procedures with the office of the Vice President for Institutional Research (VPIR). The IRB chair will review the description and forward the survey request to the VPIR if the survey requires no further action by the IRB.

Criteria for IRB Exempt Review

Certain research proposals may involve activities that may exempt the proposal from Full Board Review. Exempt Review means that the protocols are reviewed by the IRB Chair and one other voting member, randomly selected from IRB review. Exemption is predicated upon how human subjects are involved. Below are the categories of human

of the participants' responses outside the research could not reasonably place the participants at risk of criminal or civil liability nor be damaging to the participants' financial standing, employability, or reputation

3) Research and demonstration projects that are designed to study, evaluate, or examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or, possible changes in methods or levels of payment for benefits or services under those programs.
4) Use of educational tests, surveys and interviews in which the participants are elected or appointed public officials or candidates for public office or when Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
5) Collection of hair and nail clippings, deciduous teeth, or permanent teeth that need extraction.
6) Collection of excreta, sweat, or uncannulated saliva.
7) Collection and recording of data from participants 18 years or older using noninvasive procedures routinely employed in clinical practice (i.e., weighing, testing of sensory acuity, thermography, electrocardiography, electroencephalography).
8) Voice recordings made for research purposes such as investigations of speech defects.
9) Moderate exercise by healthy participants.
10) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development where the Principal Investigator does not manipulate participants' behavior and the research will not involve stress to participants

Criteria for Full Review

Projects require review by the full IRB at a convened meeting unless they meet the criteria for expedited review or exemption. Protocols that necessitate review at a convened meeting must be received in the IRB office before the first workday of the month.

Research protocols involving the following require Full Review:

1) Protocol involves protected populations (e.g. prisoners, minors, pregnant women etc.).
2) Participants are receiving compensation.
3)

The Review Process

The IRB reviews protocols in four basic ways: 1) with full Board review; 2) by expedited review; 3) by exemption; and, 4) by identifying a protocol as having indefinite plans for the use of human participants. These are described below in detail.

Reviewer Responsibilities

Expectations

1. Members are expected to review all protocols assigned to them.
2. The reviewers are encouraged to contact the IRB Chair if further information is needed.
3. Special attention should be taken to identify ethical issues.
4. comments. Each reviewer must complete and submit a ballot for each project reviewed by the date indicated on the first page of

Expedited Review

Most research projects that involve no more than minimal risk qualify for expedited review. This type of review necessitates that the Chair, and three other voting members delegated by the Chair, review the project. When one or more of these IRB members cannot agree to approve a protocol, the protocol is referred to the full IRB for consideration at the next convened meeting. The decision that a protocol meets all of the criteria for Expedited review rests solely with the IRB Chair.

1. If the protocol is eligible for Expedited Review as assessed by the Chair of the IRB, then the materials will be electronically sent to three other voting members.
2. All evaluating members will complete a Ballot stating their approval and any recommendation notes
3. If one or more evaluating members do not approve of the protocol then it will be reviewed by the full board at the next scheduled meeting.
4. Primary Investigators will be informed of the status of their proposal **within 15 workdays** from the date the completed application and all materials were received.

Exempt Review

Research protocols exempt from full IRB review are reviewed by the IRB Chair and one other voting member, randomly selected. If the Chair and the IRB member cannot agree to approve a protocol, the protocol is referred to the full IRB for consideration at the next convened meeting. The kinds of projects that are exempt include the use of existing data, documents, and/or records that are publicly available. Also, research projects which present no more than minimal risk and in which the data collection procedures are such that the data being collected is recorded by the researcher in such a manner that particip

Annual Review

1. All Principal Investigators with projects which are ongoing as of September will be sent a Renewal Form in September.
2. All renewals must be received by the first working day in October, otherwise projects will automatically be considered ended.
3. Returned Renewal Forms will be reviewed by the IRB Chair and approved granted that there are no significant changes to the project.
4. Any significant change to the project will be considered by the IRB at its meeting in the month of October.

Minor Changes

3. Notification of adverse events will be immediately reviewed by the Chair and distributed to all members.
4. After review by the Full Board one of the following must be recommended:
   a.

Protocols Approved Pending Explicit Changes

Memoranda requiring specific revisions necessitating simple concurrence by the Principal Investigator are prepared based on the comments and/or concerns submitted by reviewers during the review period and/or the decision made by the members at the meeting. The Principal Investigator's response is reviewed by the Chair, or designated experienced member, for completeness and, if appropriate, the approval memorandum and approved informed consent document is sent to the Principal Investigator.

Protocols Tabled

A protocol is table by IRB when additional information or substantive protocol modifications or informed consent document revision(s) are required in order to complete the review process.

1. Reviewers must record, on a ballot form, all the issues that must be addressed by the researcher.
2. Reviewers must write "Tabled" in the appropriate box of the meeting ballot and return the ballot to the staff at the meeting.
3. Reviewers must keep the original packet of material (the protocol, informed consent and other related material) for the next meeting.
4. A memorandum stating the issues raised is sent to the Principal Investigator following the meeting.
5. When a response is received from the Principal Investigator, a copy of that response and the memorandum to the Principal Investigator are sent to the members for the next meeting.
6. Tabled protocols will be listed on the agenda for the next meeting, along with the issues raised.

Protocols Unable to be Approved

When the Board feels it is unable to approve a protocol, a memorandum is prepared by the Chair

Documents and Records

Agenda

The agenda for IRB meetings must include at a minimum:

1. approval of the previous meeting minutes
2. report of the Exempt Review projects approved since the last meeting
3. report of the Expedited Review projects approved since the last meeting
4. Full Review Protocols

The agenda and any agenda related materials will be sent electronically at least ten days before the meeting. During every meeting the Chair must report the number of Exempt and Expedited projects reviewed including their title, PI, and synopsis of the project.

Minutes Preparation

Minutes of the IRB meetings must include at a minimum:

1. if a quorum is present
2. if a scientist, non-scientist, and community representative is present for voting
3. A list of Exempt review projects approved since the last meeting which includes the name of the PI, all Co-PIs, and Project Title.
4. A list of Expedited review projects approved since the last meeting which includes the name of the PI, all Co-PIs, and Project Title.
5. The outcome of each Full Review Protocol to include
    a. the name of the PI, all Co-PIs, and Project Title
    b. the outcome of the Ballot (e.g., Approved, Tabled etc.).
    c. a synopsis of the discussion to include discussions of any ethical issues, level of risk as assessed by the IRB, and issues involving consent/assent.

Records

1. The minutes and agendas for each meeting will be stored on the IRB local area network and archived into folders by academic year.
2. Individual project electronic copies will be stored on the IRB local area network and archived into folders by academic year, and project ID number. Each file shall contain the IRB Form, Consent Form, and any other project materials (e.g., questionnaires, surveys, etc.).
3. Original consent forms stamped for approval will be scanned and stored in the folder as well. Original hardcopies will be shredded.

APPENDICES

Assurance of Review
For
Middle Georgia State College
Institutional Review Board

It is necessary for all individuals who serve on the IRB to review the listed material and document by signature its comprehension. Please date and initial this electronic copy and email it to Chair of the IRB.

Document Reviewed	Date of Review and Comprehension	Type your initials
Title 45 CFR Part 46, OPRR Protection of Human		
Code of Ethics of the American Anthropological Association (1998)		
Ethical Principles of Psychologists and Code of Conduct (2002)		
American Sociological Association Code of Ethics (1999)		
Code of Ethics of the National Association of Social Workers (2008)		
World Health Organization: Operational guidelines for ethics committees that review biomedical research. Geneva, (2000)		

Ballot

Project ID:

Project Title:

PI:

	Protocol Approved as Submitted, No Revisions
	Protocol Approved Pending Explicit Changes (changes listed on attached document)
	Protocol Tabled
	Protocol unable to be approved

Approval Memorandum (consent not required)

TO: XXXX
FROM:
XXX, Chair

Approval Memorandum (consent required)

TO: XXXX
FROM:
XXX, Chair
Middle Georgia State College
Institutional Review Board

SUBJECT: Approval of Project # XXXX
Title: XXXX

I am pleased to advise you that the Middle Georgia State College Institutional Review Board has recommended that approval of this project. The Board concluded that participants would not be placed at more than minimal risk in this research. Given your protocol it is essential that you obtain signed documentation of informed consent from each participant. Attached is the dated, IRB-approved informed consent to be used when recruiting participants for this research. If you wish to make any changes in this protocol, you must disclose your plans before you implement them so that the Board can assess their impact on your project. In addition, you must report to the Board any unexpected complications arising from the project that affect your participants. If the project will not be completed by [Date (1 year from date of submission)] then you must submit a Renewal Form notifying the IRB of the continuation of this project. It is recommended that you keep your unit supervisor informed about the status of this project. If you have any questions regarding this project please contact the Chair of the IRB.

Approval Memorandum (Parent / Guardian)

TO: XXXX
FROM:
XXX, Chair
Middle Georgia State College
Institutional Review Board

SUBJECT: Approval of Project # XXXX
Title: XXXX

I am pleased to advise you that the Middle Georgia State College Institutional Review Board has recommended that approval of this project. The Board concluded that participants would not be placed at more than minimal risk in this research. It is essential that you obtain signed documentation of informed consent from each participant's parent or legal guardian. When it is feasible, you should obtain signatures from both parents. Enclosed is the dated, IRB-approved informed consent to be used when recruiting participants for this research. If you wish to make any changes in this protocol, you must disclose your plans before you implement them so that the Board can assess their impact on your project. In addition, you must report to the Board any unexpected complications arising from the project that affect your participants. If the project will not be completed by [Date (1 year from date of submission)] then you must submit a Renewal Form notifying the IRB of the continuation of this project. It is recommended that you keep your unit supervisor informed about the status of this project. If you have any questions regarding this project please contact the Chair of the IRB.

Continuing Review Memorandum

Re-approval Memorandum

TO: XXXX
FROM:
XXX, Chair
Middle Georgia State College
Institutional Review Board

SUBJECT: Approval of Project # XXXX
Title: XXXX

Your request to continue your research project involving human participants has been reapproved by the Chair of the Middle Georgia State College Institutional Review Board. He has concluded that participants are not placed at more than minimal risk by the research. You are reminded that a change in protocol in this project must be approved by resubmission of the project to the Board. Renewed approval of this project extends for one year from the date of the review, the maximum duration permitted by the Federal

Approval Memorandum (Review at Meeting)
Written Informed Consent Required

TO:

Approval Memorandum (Review at Meeting)
Written Parental Informed Consent Required

TO: XXXX
FROM:
XXX, Chair
Middle Georgia State College
Institutional Review Board

SUBJECT: Approval of Project # XXXX
Title: XXXX

I am pleased to advise you that this project was approved at today's convened meeting of the Middle Georgia State College Institutional Review Board. The Board concluded that participants would not be placed at more than minimal risk in this research. It is essential that you obtain signed documentation of informed consent from each participant's parents or legal guardian. Enclosed is the dated, IRB-approved informed consent to be used when recruiting participants for this research. If you wish to make any changes in this protocol, you must disclose your plans before you implement them so the Board can assess their impact on your project. In addition, you must report to the Board any unexpected complications arising from the project that affect your participants. Approval of this project is for a period of one year from the date of this meeting, the maximum duration permitted by the Federal Office for Protection from Research Risks (OPRR). If the project will not be completed by [Date (1 year from date of submission)] then you must submit a Renewal Form notifying the IRB of the continuation of this project. It is recommended that you keep your unit supervisor informed about the status of this project. If you have any questions regarding this project please contact the Chair of the IRB.