Middle Georgia State University
Institutional Review Board
Standard Operating Procedures Manual

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General Information

The President of Middle Georgia State University gives the Middle Georgia State University 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 University 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 University is responsible. Middle Georgia State University IRB is responsible for overseeing all research conducted by faculty, staff, or students which involves human subjects. In addition Middle Georgia State University 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 Subjects
- 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 supervisor's) employees or students as research participants should consult the PI Handbook Appendix D for recommended classroom data collection protocol.

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 face-to-face meeting is necessary, the Warner Robins campus will be the preferred location.

Meeting Schedule

Recorder

1. Take and distribute minutes of IRB meetings that record the attendance and actions of the IRB.
2. Help maintain records of all IRB deliberations and actions during electronic, video-conferencing and in person meetings.
3. Develop and assists in the orientation and continuing education of faculty, staff and students with IRB procedures and policies.

Members

The university will provide orientation and training opportunities at the local and/or national levels in IRB matters. The duties of the IRB members are as follows:

1. Attend all meetings.
2. Review materials before each meeting.
3. R >>BhRd4llnicy4iini-2(.-Tj 2.58t0.004 pr)c, mi:2.55 0Tc -0.3.

Categories of Review

The IRB assessment of risks and anticipated benefits involves:

1. identifying the risks associated with the research, as distinguished from the risks the participants would encounter even if not participating in research
2. determining that the risks will be minimized to the extent possible
3. identifying the probable benefits to be derived from the research
4. determining that the risks are reasonable in relation to the benefits to research participants, if any, and the importance of the knowledge to be gained
5. assuring that potential participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits
6. determining intervals of periodic review, and, where appropriate, determining that adequate provisions are in place for monitoring the data collected. In addition, the IRB will determine the adequacy of the provisions to protect the privacy of research participants and to maintain the confidentiality of the data, and when the participants are likely to be members of a vulnerable population, determine that appropriate additional safeguards are in place to protect the rights and welfare of these research participants.

Projects not requiring IRB review:

Data collection which does not require IRB review include courseassigned data collection and course directed simulations of human research that are part of a current session class at Middle Georgia State taught by Middle Georgia State University faculty. Exempt proposals will meet the guidelines for what is considered NOT Research, listed below:

1) Simulations of human experimentation
2) Data collection for educational purposes in which no data will be reported outside of the classroom and all data is properly destroyed by the end of the academic term (reporting and discussion of data within the class during a single term is acceptable).
3) Data collection for the purpose of reporting to state or national accrediting bodies or other agencies to which Middle Georgia State is required to generate reports as part of its regular operations.
4) Data collection which will not result in an article, Master's thesis, Doctoral dissertation, poster session, abstract, or any other publication, presentation, or any dissemination of the collected data.

Surveys of the entire student body / Middle Georgia State University 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 University 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.

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)

The Review Process

IRB Procedures

1. When a new protocol is received, a project identification number is assigned. This project number indicates the year and sequential number of the protocol (e.g. 2010.1001, 2010.1002, etc.).

2. The project number, protocol title, Principal Investigator's name, and other relevant information are entered into the IRB database.

3. The protocol is screened by the IRB Chair or designee to verify that the IRB form is complete and the informed consent process is thoroughly described. Other information, if any, including, for instance, the copy of methodology, copy of questionnaires/surveys/instruments, debriefing statement, and/or advertisements are also screened to verify they are complete or satisfy regulatory requirements.

4. Protocol which are incomplete or do not satisfy regulatory requirements are returned to the Principal Investigator by the Chair with notes regarding inadequacies.

5. Protocols which are complete are sent out to IRB members for review and/or placed on the agenda for the next IRB meeting.

6. Recommendations made by the Board are recorded in the computer database and in the project file.

7. Appropriate memoranda are sent informing the Principal Investigator of the action by the Board along with a dated, IRB-approved informed consent document(s), when applicable.

Full Board Review

New protocols require full board review unless they meet the criteria for exemption or expedited review. New protocols for full board review are those that are first time submissions or resubmissions of expired protocols where the Principal Investigator wishes to re-activate the study. New protocols may be submitted at any time. New protocols must conform to the format and must contain the information outlined in the IRB Principal Investigator's Manual. The approval period for a protocol will be determined by the Board, but can be no longer than 12 months from the date of review, and is based on the information available to the IRB reviewers and the perceived risk to the participant as determined by the Board.

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

3. If either the Chair or evaluating member 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.

Annual Review

1. All Principal Investigators with projects which are still collecting data one year from approval must submit a renewal form on or before each anniversary date.
2. Returned Renewal Forms will be reviewed by the IRB Chair and approved granted that there are no significant changes to the project.
3. Any significant change to the project will be considered by the IRB.

Minor Changes

Changes that do not increase the risk for previously approved projects are minor changes to a protocol. These may involve changes to the number of participants, venue of the data collection, etc). Minor changes need the approval of the Chair.

1. Principal investigators must keep the IRB informed of all changes to protocols, including but not limited to, alteration of consent forms, additions to questionnaires or surveys, or other changes which impact the treatment of human subjects.
2. Principal Investigators should complete a Renewal Form and provide any altered documentation and/or a description of changes in protocol to the Chair of the IRB. The Chair of the IRB will review the alterations and determine whether review is necessary.

Major Changes

Major changes are those that increase risk to participants.

1. Projects with major changes must re-submit in the same manner as initial review as if it were a new project.

Adverse Events

1. Projects in which an adverse event has been reported must be reviewed by the full committee.
2. Adverse events are undesirable and unintended, although not necessarily unexpected incidents involving risks to participants or others. The OPRR requires Principal Investigators to report adverse events promptly and in writing to the Chair. This report must be submitted within five working days and provide a description of the adverse event, state whether or not changes are needed in the protocol and the informed consent process, and indicate whether or not participants must be notified regarding the event. These revisions will be reviewed by the full Board. The Principal Investigator is also

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
Middle Georgia State University
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 initial each section below and sign and date at the bottom of this document.

1. I have read and am familiar with the Middle Georgia State University IRB: Initial: _____
    a. Standard Operating Procedures Manual
    b. Principal Investigator's Manual

2. Select ONE of the following:

    1. I have read and am familiar with the following documents: Initial: _____
        a. Title 45 CFR Part 46, OPRR Protection of HumanP

Approval Memorandum (Exempt Review)

DATE

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

Approval Memorandum (Expedited Review)

DATE

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

SUBJECT: Approval of Project # XXXX
Title: XXXX

I am pleased to inform you that your project has been approved under the Expedited Review protocol of the Middle Georgia State University Institutional Review Board. Your project complies with the IRB guidelines for expedited proposals including "research projects which present no more than minimal risk and therefore can be reviewed without a convened meeting."

If you wish to make any changes to this protocol, you must disclose your plans before you implement them so the IRB 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 letter, 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 current Chair of the IRB.

Sincerely,

Continuing Review Memorandum

DATE

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

SUBJECT: Approval of Project # XXXX
Title: XXXX

Approval for this project by the Middle Georgia State University Review Board is about to expire. To help us keep our records current, please complete the following form and

Re-approval Memorandum

DATE

TO: XXXX
FROM:
XXX, Chair
Middle Georgia State University
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 University Institutional Review Board. 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 Office for Protection from Research Risk. 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.