# Middle Georgia State University
# Institutional Review Board
# Standard Operating Procedures Manual

Last Revised:
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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.

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

### Meeting Schedule

IRB meetings are scheduled as needed for protocols requiring full board review. Otherwise, the board meets once at the beginning of the year (to review policies and training credentials of the board) and at the end of the year (to summarize activity for the year and plans going forward).

### Meeting Procedures

Agendas are prepared two weeks before each IRB meeting. Proposals which require Full review must be submitted on or before the 15th of the month in order for the proposal to be on the agenda for consideration during the next month's meeting, excluding December and May. Principal Investigators will be informed of the status of their proposal by the last workday of the month in which it was reviewed.

### Attendance at IRB Meetings

Because each member of the IRB serves a particular role (see *Structure* below), attendance at meetings is imperative. A member who misses three consecutive meetings, or who misses half or more of the meetings in a year, forfeits his/her membership on the IRB.

### Meeting Quorum

An IRB meeting can be called to order only when a quorum exists. A quorum is defined as a majority of members. The quorum may not consist entirely of men or women, and must have one scientist and one non-scientist.

### Principal Investigator's Participation during IRB Meetings

A Principal Investigator or Co-Investigator may not participate in the review and approval process whether a member of the IRB or not. A Principal Investigator or Co-investigator who is a member of the IRB must recuse himself/herself from the meeting. Additionally, any IRB member who believes there is any conflict of interest, given his/her relationship with the Principal Investigator or Co-Investigator, is expected to recuse himself/herself from the meeting.

Principal Investigator or Co-Investigator may be invited by the IRB to provide information requested. The Principal Investigator or Co-Investigators will be asked to leave the meeting during the discussion and voting phase of the review and approval process. Such action will be noted in the minutes of the IRB meeting.

# The Board

## *Structure*

The responsibility for compliance with Federal, State, and Institutional regulations concerning activities involving human participants rests with the President of Middle Georgia State University. The President has delegated this authority to the IRB.

The IRB consists of:

1. Members
    a. Faculty and staff members of the IRB are appointed by the President on the recommendation of the IRB and Executive Committee.
    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 current IRB members and appointed by the President to serve as voting members of the board. These members may not be affiliated with the Institution and are not part of the immediate family of someone who is.
    d. The IRB membership shall include (note that a single member may satisfy more than one of these):
        i. At least two members whose primary concerns are non-scientific
        ii. At least one member who is able to represent the interest of children, pregnant women, persons with disabilities, and other vulnerable groups of people.
        iii. At least one scientist
        iv. At least one member who is from the field of education
2. Director of Institutional Research or Presidential appointee
    a. One Presidential appointee, commonly the Director of Institutional Research, will serve as a voting member of the committee and will represent any concerns of the University with regards to the conductance human research.

## *Job Descriptions*

### Chair

The Chair shall be responsible to the President for the general supervision of the activities of the IRB. The Chair provides leadership and promotes an environment conducive to scholarly research and activities that protect human participants who take part in research. The Chair shall serve for a one-year term. The duties of the Chair are as follows:

1. Preside at all meetings of the IRB.
2. Call special meetings of the IRB.
3. Maintain accurate records of all protocols, including relevant discussions, correspondence, modifications and final actions.
4. Maintain and distribute forms and manuals including those posted on the university website.

5. Conduct reviews of all protocols submitted to the IRB proposing use of human participants in research.*
6. Advise and counsel Principal Investigators*
7. Make decisions on emergency conditions as they relate to the IRB's protection of human participants in compliance with Federal regulations.
8. Keep the IRB informed of developing problems in the area of human research on any current or pending project.
9. Perform functions delegated to an official of the IRB in accordance with institution, State and Federal regulations.

* The Chair may designate the Chair Elect or an experienced IRB member to manage the intake and review of exempt and/or expedited protocols.

### Chair Elect

The Chair elect will assume the responsibility of Chair for the September meeting each Academic year. The Chair Elect will also fulfill the duties of the Chair, as described above, when the Chair is unable to do so. Beyond these duties the primary responsibilities of the Chair Elect are to help with education efforts concerning human subjects and the annual audit.

1. Develop and assist in the orientation and continuing education of faculty, staff and students with IRB procedures and policies.
2. Perform the annual audit as described above under *Continuous Improvement Plan.*
3. Help maintain accurate records of all protocols, including relevant discussions, correspondence, modifications and final actions.
4. Help maintain and distribute forms and manuals including those posted on the university website

### 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. Review all introductory and regulatory documents relating to the use and protection of human participants.
4. Disqualify themselves from participating in the review of, or voting on any activity in which he/she has a conflict or interest or even the perception of a conflict of interest.
5. Contact the IRB Chair if unable to attend a meeting.
6. Willingly participate in subcommittee activities as time and interests allow.
7. Protect the confidentiality of the records and information provided to him/her.

## *Orientation and Training of New Members*

Each new member of the IRB will be provided orientation and training through the following procedures (signature form in appendices):

1. Completion of assigned readings and signature of member stating their familiarity with the Middle Georgia State University IRB:
    a. *Standard Operating Procedures Manual*
    b. *Principal Investigator's Manual*

2. And either:
   Completion of assigned readings and signature of member stating their familiarity with the materials, which includes, but is not limited to:
    a. Title 45 CFR Part 46, OPRR Protection of Human Subjects
    b. *Code of Ethics of the American Anthropological Association (1998)*
    c. *Ethical Principles of Psychologists and Code of Conduct (2002)*
    d. *American Sociological Association Code of Ethics (1999)*
    e. *Code of Ethics of the National Association of Social Workers (2008)*
    f. *World Health Organization: Operational guidelines for ethics committees that review biomedical research*. Geneva, 2000.1
    g. *Office for Human Research Protections (OHR) IRB Guidebook*

   Or:

   *Completing online training found at: http://phrp.nihtraining.com/users/login.php and submitting completion certificate to the IRB chair.*

# 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** course-assigned 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.

## *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 subject involvement that can be considered for Exempt Review.

1) **No information is recorded in a manner where human subjects can be directly or indirectly identified.**
2) The research will be conducted in an educational setting and involve normal practices.
3) If observation of public behavior is involved the PI or researchers cannot participate in the activity being observed.
4) The collected data are publically available or were previously collected and in existence prior to the current proposal.
5) The research involves examination of a public service program and has been approved by the appropriate agency head.
6) The research involves the tasting and evaluation of wholesome foods.

## *Criteria for 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. If the protocols do not meet the above criteria for Exempt Review, then the project is likely an Expedited Review.

### Expedited Project Examples

1) Research conducted in commonly accepted educational settings involving normal educational practices, use of educational tests, survey procedures, interview procedures
2) observation of public behavior provided that the information obtained is recorded in such a manner that the participants cannot be identified and that any disclosure 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. Proposals which require Full review must be submitted on or before the 15th of the month in order for the proposal to be on the agenda for consideration during the next month's meeting, excluding December and May. (For example, a proposal submitted by the 15th of September would be reviewed in the October meeting). Principal Investigators will be informed of the status of their proposal by the last workday of the month in which it was reviewed.

**If the Principal Investigator can answer YES to any of the following questions for their research protocols, Full Review is required:**

1) Does the protocol involve protected populations (e.g. prisoners, minors, pregnant women etc.)?
2) Are participants receiving or does your project involve any kind of compensation (some examples: money, gift cards, course credit, release time, extra credit points or any academic credit)?
3) Are any other institutions, other than MGA, involved in this research?
4) Is there any risk beyond what participants would experience if they were not to participate in this project?
5) Is deception used in any way as part of this project?
6) Will the data collected be used in any way after the completion of this proposed work, other than scholarly research presentations or publication?

# 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. The reviewer ballot can be used for the reviewer's preliminary, as well as final, comments. Each reviewer must complete and submit a ballot for each project reviewed by the date indicated on the first page of the proposal packet.
5. Members are expected to attend each monthly meeting. Projects to be reviewed at a convened meeting will be forwarded to each member at least one week before the meeting. Members are expected to review and be prepared to discuss any and all items on the agenda for that monthly meeting. Ballots for items discussed at the meeting must be marked and returned by the close of that meeting.

## *Definitions*

### Research:

For the purposes of this document "research" is defined as a systematic investigation, including research, development, testing and evaluation, 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 at a professional conference with intention of contributing to the greater body of knowledge in the field of interest.

### Risk:

Risk is defined as exposure to harm or injury (e.g. physical, psychological, social, or economic) through participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

### Minimal Risk:

When "the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests" (45 CFR 46.102[i]).

## 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 that the data being collected is recorded by the researcher in such a manner that participants cannot be identified, are normally approved as exempt from the full IRB. The decision that a protocol meets all of the criteria for Exempt review rests solely with the IRB Chair.

1. If the protocol is eligible for Exempt Review as assessed by the Chair of the IRB, then the materials will be electronically sent to one other voting member.
2. The Chair and evaluating member will complete a Ballot stating their approval and any recommendation notes.

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 put on notice that if the events submitted are deemed to place participants at increased risk, the Chair may request resubmission of the protocol for full

Board review. In a circumstance where the Board perceives the participant(s) may be placed at immediate significant risk, the IRB has the authority to suspend or terminate a protocol. Any such action shall include a statement of the reasons for the IRB action, and the Chair will contact the appropriate university officials.

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. No action is needed.
    b. Changes are needed in the informed consent.
    c. Current participants must be informed of this new information and risk.
    d. The protocol needs to be revised due to this new information.
    e. The protocol is suspended until more information is made available.
    f. The protocol is terminated
5. When protocol is suspended, new participant recruitment must stop. Interventions under the research protocol must be stopped unless an over-riding concern for the safety or well being of the participants, or other ethical issues, are involved. In such cases, the Principal Investigator must contact the IRB immediately. The suspension will be lifted when and if the protocol is reapproved by the IRB.
6. When a protocol is terminated, no further participants may be recruited into the study and all participants currently enrolled must be notified of the protocol's termination. Participants may not be followed for research observation or data collection after such termination.

## Protocol Violations

1. If a protocol violation occurs or is suspected, the Chair will notify the Principal Investigator in writing of the event in question. IRB approval for the protocol may be withdrawn until the issue is resolved. The Principal Investigator will have 5 working days to respond in writing to the inquiry.
2. If no response is received from the Principal Investigator, a second notice will be sent to the Principal Investigator and the Vice President for Academic Affairs.
3. Once the response is received, the Chair will decide what further action, if necessary, will occur. This could include a recommendation to withdraw IRB approval for the study, reinstatement of the study, review by full Board, or a recommendation to the Vice President for Academic Affairs.
4. If the Chair feels the IRB approval for the study should be withdrawn, this recommendation will be brought to the full Board for final review.

# Actions/Decisions

## *Protocols Approved as Submitted, No Revisions*

Approval memoranda are generated by the Chair at the completion of the review period or, when feasible, the same day as the IRB meeting. Approval memoranda are the first priority of the IRB staff. A copy of the IRB approved informed consent document with the expiration date affixed will be included with the approval memorandum sent to the Principal Investigator.

## *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 to inform the Principal Investigator of the Board's decision and the reasons.

# 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 Human
        b. *Code of Ethics of the American Anthropological Association (1998)*
        c. *Ethical Principles of Psychologists and Code of Conduct (2002)*
        d. *American Sociological Association Code of Ethics (1999)*
        e. *Code of Ethics of the National Association of Social Workers (2008)*
        f. *World Health Organization: Operational guidelines for ethics committees that review biomedical research*. Geneva, 2000.1
        g. *Office for Human Research Protections (OHR) IRB Guidebook*

    2. I have completed the online NIH training and submitted a completion certificate to the IRB chair. (Training website: http://phrp.nihtraining.com/users/login.php) ***Initial:*** _____

By inserting your initials above and signing and dating below, you are certifying that you have reviewed and comprehend the documents listed.

_____

Name and Title (Print)

_____

Signature and Date

**Send this document electronically (and NIH training certificate, if applicable) with initials/signatures to Chair of IRB**

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 (Exempt 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 Exempt Review protocol of the ***Middle Georgia State University*** Institutional Review Board. Your project complies with the IRB guidelines including "Projects that are exempt from review by the full IRB and only require review by the IRB chair and one IRB voting member."

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,

## *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 return to the Chair of the IRB.

Approval for this project will expire on XXXX

Check **ONE** item below that describes the status of your project:

_____ The project is complete. The IRB file on this project may be closed on the expiration date noted above.

_____ Human participants will not be involved in this project after the expiration date noted above.

_____ Extension of the IRB approval is requested for this project. (The Board will determine the IRB approval period appropriate to the degree of risk.)

Check all items that apply for this project:

_____ No change will be made to the approved protocol.

_____ I wish to modify the protocol as described in the attached memorandum.

_____ No adverse effects or unanticipated outcomes occurred during the past year.

_____ The attached memorandum describes the adverse effects and/or unanticipated outcomes that occurred during the past year.

_____ Attached is the documentation of any participants who withdrew from the research or if there were any complaints about the research.

_____ The risks to the participants have not increased during the past year.

_____ The risks to the participants have increased during the past year. The reasons for this change in the risk are described in the attached memorandum.

## *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.