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

Last Revised on: November 25, 2012

Forms and additional information available online: Middle Georgia State College IRB

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An Institutional Review Board is a committee mandated by the National Research Act, Public Law 93-

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

Projects which do not qualify for Expedited or Exempt review require review by the full IRB at a convened meeting (IRB annual meeting schedule). The status of the project is decided via majority vote by a quorum of the IRB members at the convened meeting. All required materials must be submitted on or before the first workday of the month in order for the materials to be reviewed that month. Applications which are incomplete or received after the first workday of the month will be reviewed at the next convened meeting after that month.

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

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

- 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, electrocardiography).
- 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

Answering yes to ANY of the following means that your project requires Full Review

- 1) Does the protocol involve protected populations (e.g. prisoners, minors, pregnant women etc.)?
- 2) Are participants receiving compensation?
- 3) Are any other institutions, other than Middle Georgia State, 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?

*Protocols submitted by Middle Georgia State faculty enrolled in graduate programs at other institutions may qualify for exempt or expedited review if the involvement of the outside institution is limited to mentorship/training of the Middle Georgia State faculty member.

Assessment of risks and benefits

The IRB assessment of risks and anticipated benefits involves 1)

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protect the privacy of research participants and to maintain the participants' confidentiality with respect to collected and reported/published research data and, when the participants are likely to be members of a vulnerable population, the IRB will also determine that appropriate additional safeguards

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?

If using

Principal Investigator request in writing to the Middle Georgia State IRB to retain the data for longer. It is expected that a date of destruction be provided on this form upon which it is the sole responsibility of the Principal Investigator to destroy the data. **Please note that throwing data in the trash is not destroying the data**. All data including hard copies, audio/video recordings, disks, etc must be shredded or destroyed in some other manner so that the information is undecipherable. All electronic files must be deleted from computer(s) or other storage devices.

11. Describe the Informed Consent Process

Informed consent is the process through which potential research participants are provided with all the information reasonably needed for them to decide whether to participate (see Informed Consent below for a more detailed description). The process additionally provides for obtaining voluntary agreement to participate in the research. A copy of the informed consent process (whether a written form, cover letter, or script of a verbal process) must be attached with this form. Waiver of the informed consent process is limited to research involving the collection or study of existing data, publicly available information, and observation of un-manipulated public behavior where data is recorded in such a manner that identifiers cannot be linked to individuals. The IRB must approve any waiver of 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.

Principal Investigator

Provide the name(s) of the person(s) conducting the research, degree actually held (not being sought), title, department, address and phone number where the principal investigator(s) may be contacted (campus address and day-time phone numbers, where applicable).

Faculty Supervisor (required for all non-faculty Principal Investigators) Provide the name(s) of faculty supervisor(s), degree held, title, department, campus address and phone number, and e-mail address.

Faculty wishing to perform research on

Writing the Informed Consent Form

General

Make every effort to keep the informed consent brief and to the point. In most cases, informed consent should be written in the second person (i.e. you, your), with the exception of the signature portion. The document should also be written so as to be easily comprehended by someone with **less than a high school education**. Some of the same information may be present in multiple sections, but please keep the document as brief and as easily understandable as possible. When duplicate copies are to be used, divide the information portion of the written consent from the signature section with a solid line. When a "tear-off portion" is to be used for the signature section, a dotted line is suggested. Written informed consent forms should be kept to one page whenever possible. Before submitting the consent document to the IRB please be certain to check for spelling, grammatical, and typographical errors. Make certain that the language you use in any research document is understandable and "reader friendly" for the person to

b. Should tape recording of participants be a part of the protocol, inform the potential participants of this as part of the informed consent procedure. Specify whether "audio" or "video" tape will be used, whether personal information, (e.g. name, address, etc.) will be requested during the taping, who will have access to the tapes, what steps will be taken to black out participants' faces and to delete personal information from the tape, and what the disposition of the tapes will be.

7) Contact Information

a. Offer to answer any inquiries concerning the procedures and provide information that a participant can use to reach you later (i.e. your campus or other telephone number and/or campus address).

8) Signature

- a. Identify yourself by name and provide the title of the project on the signature portion of the informed consent form.
- b. Provide places for dated signatures of the participant, the Principal Investigator and, where appropriate, a witness for written informed consent.
- c. Conclude all written informed consents with the following statement or its equivalent:
 - i. I have read the procedure described above. I voluntarily agree to participate in the procedure, and I have received a copy of this description.

9) Additional consent requirements

- a. When appropriate, one or more of the following additional elements of information should also be provided to each participant in the informed consent:
 - i. A statement that the particular procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;
 - ii. Any costs to the participant that may result from taking part in the research:
 - iii. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
 - iv. A statement that significant new findings developed during the course of the research, that may relate to the participant's willingness to continue, will be provided to the participant; and
 - v. The approximate number of participants involved in the study.

Parental Informed Consent

Provide the participant's parent(s)/guardian(s) with a duplicate of the informed consent document and retain signed copies. While the precise layout of the informed consent document will vary with the nature of the study the following elements (1-8 below) are required for all consent forms.

1) Introduction and Purpose

a. Identify yourself by name, specify your connection to Middle Georgia State College, and when applicable, identify your faculty supervisor.

2) Procedure

- a. Provide a statement that the study involves research and explain what the child will be asked to do. Indicate who will administer the procedure(s) (e.g. you, the teacher, your supervisor, a colleague). Make note of the approximate amount of time your procedure will take (number of days, minutes, etc.).
- b. When the procedure is to take place during school hours, make note of the activity the child will miss in order to take part in the study. Inform the parent(s) or guardian(s) if the child will be removed from academic classes and, if so, whether or not the child will be allowed to make up any missed work. Indicate if this procedure is part of the ordinarily scheduled instruction by the teacher.
- c. If you will be approaching an intact class or group for participation, indicate what those without permission will be doing while the research procedure is taking place.
- d. When questionnaires, surveys, or interviews are involved, state that the child does not have to answer any question that s/he does not wish to answer. Do not attach conditions to this statement.

3) Potential Risk or Discomfort

a. Include a description of anticipated risk or discomfort. If none is anticipated, make a statement to that effect.

4) Potential benefits and Compensation

- a. Include a description of direct benefits to participants. If none is anticipated, make a statement to that effect.
- b. Note benefits that may result for a child taking part in the study, including knowledge gained. Describe any appropriate alternative procedures that might be advantageous for the participant. If no direct benefits are anticipated, make a statement to that effect. (e.g. there is no direct benefit or anticipated risk to/for participants).
- c. Indicate whether compensation will be awarded. When monetary compensation is offered, state the amount. If another form of compensation will be offered, be specific (e.g. sticker, pencil). Avoid vague statements such as "Children will receive a small prize for participation." When children will be rewarded for returning the informed consent form, include provisions for non-participation in the signature portion similar to the following: I voluntarily agree to allow my child, [e j | ln f | our participate inm___

- c. Conclude all Parental/Guardian informed consent with the following statement or its equivalent
 - i. I have read the procedure described above and I voluntarily agree to allow my child, [ejknføu"pcog], to participate in Dr. [name] 's (brief description here) study, and I have received a copy of this description.
- 9) Additional consent requirements
 - a. When appropriate, one or more of the following additional elements of information should also be provided to each participant in the informed consent:
 - i. A statement that the particular procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;
 - ii. Any costs to the participant that may result from taking part in the research:
 - iii. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
 - iv. A statement that significant new findings developed during the course of the research, that may relate to the participant's willingness to continue, will be provided to the participant; and
 - v. The approximate number of participants involved in the study.

Assent for Minors

Assent is an individual's voluntary, affirmative agreement to participate in research. A minor participant's failure to object cannot be construed as assent. Assent of minor participants is required in addition to written consent of their parent(s). A verbal assent script is required as part of the IRB submission whenever minor participants are involved (ages 7-17). Assent scripts should be brief, to the point, and at a language level appropriate to the participant. The following information, along with examples available in the Appendix, may assist you in preparing this document.

- 1) Identify yourself and your connection to Middle Georgia State College
- 2) Explain what you are asking the child to do. Include a statement that the child can stop at any time and, where when applicable, that s/he does not have to answer any questions and participation or nonparticipation will not affect his/her grades.
- 3) Conclude with a question, about the child's willingness to participate, to which the child can respond either positively or negatively.

Debriefing after deception

Whenever deception is involved as part of the research or information is withheld from a participant before or during the research, this information must be disclosed to the participant at the close of the research either verbally or in writing. A copy of this

Timeline for approval

Full Review

Proposals which require Full review must be submitted on or before the first workday of the month in order for the proposal to be on the agenda for consideration that month. Proposals received after the first workday of the month will be considered at the next convened meeting following the month the proposal was submitted. Principal Investigators will be informed of the status of their proposal by the last workday of the month.

Expedited and Exempt Review

Proposals which meet the requirements for Expedited or Exempt review will be initially evaluated by the Chair of the IRB and then disseminated to the appropriate IRB members. 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.

previously approved protocols (i.e. number of participants, venue of the data collection, etc.) must be reviewed by the IRB Chair. Other proposed modifications will be reviewed us

centrality scale for gender (Sellers et. al, 1998), and Ambivalent Sexism Inventory (Glick & Fiske, 1996).

6. What are the potential benefits of this research (either directly to the participants, or to the body of knowledge being researched):

Although there are no direct benefits to the participants, the knowledge gained from this study could be useful to campuses across the United States, and will expand the psychological literature on the subject of sexual coercion.

7. What are the anticipated risks (risks include, physical, psychological, or economic harm; be certain to describe the steps taken to protect participants from these risks).

Although this is a very low risk procedure, it is not without some potential risk. It is possible that having to watch visual depictions of nonphysical sexual coercion will be uncomfortable for some, especially for those who may have personal experience with sexual coercion. This could result in psychological distress. This risk is heightened because we cannot tell participants in advance that they will be viewing images of sexual coercion because doing so would taint their perceptions of the videos. In addition, having to make judgments regarding the perpetration and victimization of sexual coercion may make some participants uncomfortable.

We will take steps to ensure the psychological well-being of the participants. At no point during the study will participants reveal their personal sexual history. In addition, although the participants will not be told in advance that sexual coercion is specifically being studied, they will be told that this is a study of sensitive matters of inter-gender sexual relations, including positive and negative depictions. This should alert any participant sensitive to the subject matter of our study, while maintaining experimental control. It is necessary to omit the word "coercion" because it could bias the participants to view vignettes as more coercive than they would have otherwise. Furthermore, use of the word "coercive" could elicit a social desirability effect in which the participants rate the unwanted pressure as higher in an effort to appear sensitive to the issue of sexual coercion. Although the subject matter is undeniably sensitive, these vignettes will not depict any physical contact or sexual activity. They will be confined to the verbal interaction leading up to a sexual encounter. Additionally, at any time during the study

11. Describe the informed consent process:

All participants will read and sign the informed consent document upon their arrival at the designated testing site, prior to their participation in any study measure. After the participants have concluded participation, or decided to withdraw from the study, they will be given a verbal and written debriefing statement. See attached informed consent document

References

Glick, P. & Fiske, S. T. (1996). The Ambivalent Sexism Inventory: Differentiating

Appendix B: Example Consent Form

The following is a sample consent form for a fictional educational study using student subjects:

Middle Georgia State College Department of Natural Sciences and Engineering Informed Consent for Participation in a Research Study

Title of Study: A Novel Electronic Device for the Study of Biology

Principal Investigator: John S. Doe, Ph.D.

I. Introduction and Purpose

You are invited to participate in an educational research study. The purpose of this study is to determine the effect of using a new electronic device on your performance in BIOL 9999. Specifically, we are interested to learn if your use of the device increases your grasp of the material in this course and how much of the material you remember at a later date. About 50-60 BIOL 9999 students will be asked to participate in this study. Participation will require you to use the device in according to directions given by Dr. John Doe. You will then be asked to complete a survey with questions about your use of the device. Your performance on regular class exams will also be studied to determine to usefulness of the device. In addition, Dr. Doe may contact you with further questions and to get your feedback on the findings of the study. Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand before you decide if you will participate. If you do decide to participate, you will receive a copy of this informed consent document for your records.

IV. Potential Benefits

You will not be compensated for participation, and there are no guaranteed benefits to you for participating in this study. Using the device may h 0mprove your understanding of the material. Also, by participating in this research, you are contributing to improving the education of future biology students at Middle Georgia State.

V. Voluntary Participation, Withdrawal and Removal

Participation in this research is voluntary. You have the right not to be in this study and sti 0l be enrolled in B IOL 9999. If yodecide to be in the study, you have the right to drop out at any time. You will not be subject to any penalty for withdrawing from the study,

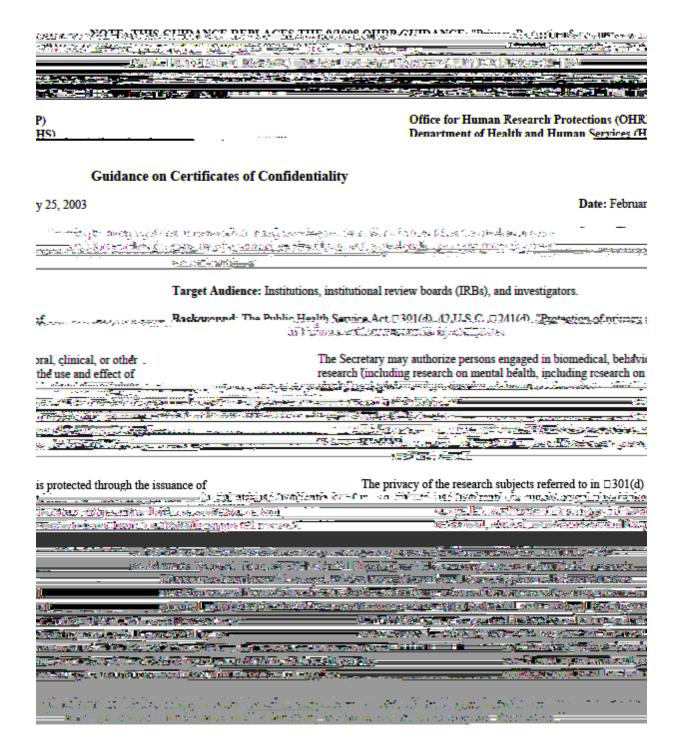
Many research projects conducted by faculty and/or students require the collection of data from Middle Georgia State students, which is commonly collected in the classroom anonymously. Similarly, many research projects conducted by faculty and/or students require the collection of data from Middle Georgia State faculty or staff, which is commonly collected during a regularly scheduled meeting. Both of these instances are examples of "captive audiences" which at the very least might appear to introduce a level of coercion upon participants. The Middle Georgia State College IRB suggests the following protocol for all data collection in which you may have a "captive audience."

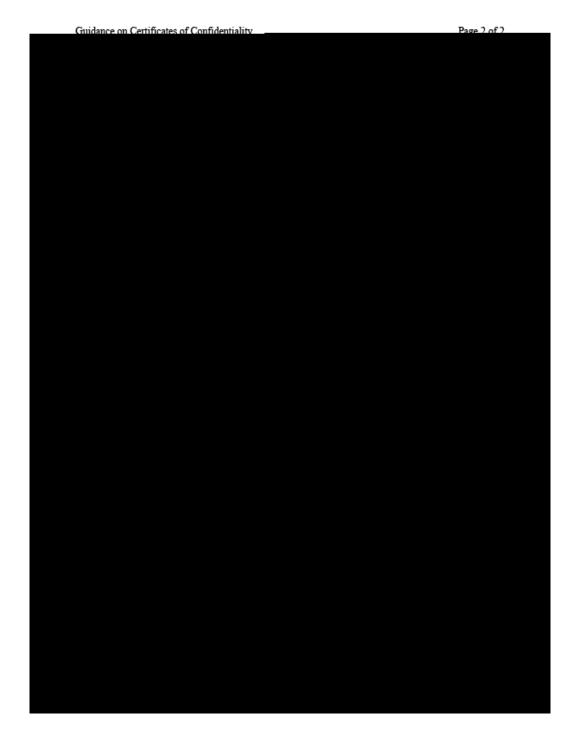
- 1. Provide all documentation to a willing participant (participant assistant)
- 2. All individuals associated with the project and also any person of authority (e.g., supervisor, course instructor etc.) should leave the room.
- 3. The participant assistant should be instructed to provide everyone in the room with the approved protocol materials.
- 4. The participant assistant should read a prepared script, like:
 - a. What has been handed out is a questionnaire about XX that is part of XX research project. If you would like to participate in this project complete XX. If you do not wish to participate please hold on to the forms and when I ask for forms to be returned please just turn in your blank forms.
- 5. After an allotted amount of time the participant assistant should collect the materials and return them to the individual associated with the project.
 - a. If a consent form and anonymous questionnaire or other instrument is used, then the consent form should be collected and returned separately from the questionnaire / instrument(s).
- 6. To be considered for Exempt Review, students, faculty, or staff, should not be provided with any form of compensation including (course credit, extra credit, etc.).

Appendix D: Certificate of Confidentiality

Guidance on Certificates of Confidentiality

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For more information on Certificates of Confidentiality and their limitations, see http://grants.nih.gov/grants/policy/coc/index.htm.

For Certificate of Confidentiality contacts at the National Institutes of Health, see http://grants.nih.gov/grants/policy/coc/contacts.htm.