

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

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## **Origin of the Institutional Review Board (IRB)**

An Institutional Review Board is a committee mandated by the National Research Act, Public Law 93-348, to be established within each university or other institution that conducts most types of research involving humans. The purpose of the IRB is to review all proposals for human research before the research is conducted to determine whether the research plan has adequately included the ethical dimensions of the project. Federal oversight of the IRB is conducted by the United States Office for Protection from Research Risks (OPRR), within the National Institutes of Health. Institutions not in compliance with the law may lose Federal funding. Because of worldwide opinion after World War II, the Nuremberg Code was promulgated. The first principle of this code states that humans must not be participants in research projects unless they are fully informed of the proposed procedures and voluntarily consent to the procedures. Due to reports of some biomedical research carried on in the United States in the late 1950s and early 1960s, the United States Surgeon General enforced regulations that govern all research sponsored by the Department of Health, Education, and Welfare (now DHHS). In 1974, Congress passed the National Research Act, that together with the Multiple Project Assurance agreements, broadens the regulations by having them apply to all research involving human participants conducted at institutions receiving Federal funding, not just projects that are Federally funded. The original focus of the regulations was on biomedical research, but conformity studies and obedience studies raised questions about invasions of privacy. However, research conducted between 1956 and 1964 involving behavioral effects of drugs in normal social settings caused the interpretation of the regulations and the National Research Act to include social and behavioral research.

## **Primary Investigators Responsibilities**

The Primary Investigator(s) is the individual or individuals responsible for insuring that the proposed project adheres to all federal, state, and institutional laws and policies.

## **General considerations**

Middle Georgia State University assures, in writing, the United States Office for Protection from Research Risks (OPRR) that the institution complies with the Department of Health and Human Services (DHHS) regulations for the protection of research participants. In its written agreement with OPRR, Middle Georgia State University (MGA) agrees that research activities involving human participants, regardless of sponsorship, will be reviewed by the IRB when one or more of the following apply:

- The research\* is sponsored by MGA, **or**
- The research is conducted by or under the direction of any employee or agent of MGA in connection with his or her institutional responsibilities **or**
- The research is conducted by or under the direction of any employee or agent of MGA using any property or facility of this institution, **or**
- The research involves the use of MGA records, or uses non-public information to identify or contact human research participants or prospective participants, **or**
- The research will be conducted on the grounds of MGA or uses as subjects MGA students, faculty, or staff in their respective roles, **or**
- Data collection which will result in an article, masters thesis, doctoral dissertation, poster session, abstract, or any other publication, presentation, or any dissemination of the collected data.

\*For the purposes of this document “research” is defined as a systematic investigation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. In practical terms, the Middle Georgia State University IRB defines research as systematic investigation intended to produce data that will or may be published or presented with the intention of contributing to the greater body of knowledge in the field of interest. Please contact the chair of the IRB if you are unsure if your activity would be considered research.

## **Filing an application for review**

The required forms have been designed to provide the Middle Georgia State University IRB with the information necessary to expeditiously evaluate your project. Complete each item carefully and follow the instructions below. These forms must be approved prior to beginning any sponsored or non-sponsored research in which there is research involving human participants. The request for approval must be submitted to the Chair of the IRB committee. In addition any questions regarding completion of the form or the process should be directed to the IRB chair, as well.

## **Summary of levels of review**

***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.

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.

***Exempt Review*** Projects that are exempt from review by the full IRB and only require review by the IRB Chair and one IRB voting member.

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.

***No Review Required*** Although some protocols do not require IRB review, all faculty, staff, or students collecting data should be familiar with this handbook.

## **Determining your project's appropriate review level**

### ***Projects not requiring IRB review***

Data collection which **does not require IRB review includes** course-assigned data collection and course directed simulations of human research that are part of a current session class at Middle Georgia State University taught by Middle Georgia State University faculty. Protocols not requiring review will meet the guidelines for what is not considered 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 University is required to generate reports as part of its regular operations.
- 4) Data collection which will not result in an article, masters thesis, doctoral dissertation, poster session, abstract, or any other publication, presentation, or other dissemination of the collected data. \*

\*Faculty or staff wishing to conduct surveys of the entire student body that do not otherwise meet the definition of human participants 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 Associate Vice President for Institutional Research.

### ***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, who is randomly selected from IRB voting members. Exemption is predicated upon how human participants 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 participants 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 Principal Investigator cannot participate in the activity being observed.
- 4) The collected data are publicly 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 your project is likely an Expedited Review. Before selecting the “Expedited Review” option on the IRB Form consider the following questions. **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 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?

### **Expedited Project Examples**

- 1) Research conducted in commonly accepted educational settings involving normal educational practices, use of educational tests, survey procedures, and/or 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/or 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***

**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 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?

\*Protocols submitted by MGA 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 MGA faculty member.

### ***Assessment of risks and benefits***

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 anticipated risks will be minimized to the extent possible
- 3) identifying the probable benefits to be derived from the research
- 4) determining whether 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, when appropriate, determining that adequate provisions are in place for monitoring the data collected. In addition, the IRB will determine the adequacy of the provisions designed to 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

## **Completing the IRB Form**

### ***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 Middle Georgia State University students recruited from courses**

If students will be recruited from Middle Georgia State University courses, provide the course number(s) and instructor(s). In addition, contact the appropriate academic unit(s) concerning any specific policies regarding the use of students in their classes. To minimize the perception of coercion, the Board strongly discourages Principal Investigators from recruiting students from their (or their supervisor's) courses to participate in their research. Furthermore the Board recommends closely following an established set of procedures to try and insure the minimization of coercion (see Appendix C). Please note that the use of course credit, release time, extra credit points or any academic credit for participation is a form of compensation and therefore requires a Full Review.

### **If recruiting minors**

If potential participants are younger than age 18, be specific about their age (do not only list grade level). If potential participants are older than 18, you may indicate 18+, unless a specific age category is sought.

### **If using a form of compensation**

All proposed compensation must be listed. Be specific as to type and amount of compensation. The use of course credit, release time, extra credit points or any academic credit for participation is a form of compensation and therefore requires a Full Review.

## ***9. Describe why it is necessary that the Primary Investigator(s) and/or Supervisor know the identity of the participants***

Many projects can be conducted with participants providing data anonymously. A full or expedited review is deemed necessary when the identity of the participants will be known by the Primary Investigator and/or the Supervisor. Provide a description of why it is necessary to have this information and how this information will be kept safe.

## ***10. Describe how data collected for this project will be securely stored and when and how it will be destroyed***

### **Data storage**

All data, electronic or physical, should be stored behind two locks whenever it is not being used. This could include a locked office, and a locked file cabinet. It also includes a locked office and a password protected computer file.

### **Data destruction**

This approved proposal allows for the Principal Investigator and/or Supervisor to securely store the data for up to three years. Further retention of the data requires Principal Investigator request in writing to the Middle Georgia State University 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.

## **Informed Consent**

Faculty wishing to perform research on human participants are required to obtain signed consent from those participants by means of an informed consent document. One of the main ethical responsibilities of a Principal Investigator is to ensure that potential participants have been provided with all the information they might reasonably need to know about the research project before they begin participating.

Regardless of how innocuous the nature of the project may seem, potential participants have the right to:

- 1) **Disclosure** of all relevant information about the research,
- 2) their **comprehension** of the information, and
- 3) their **voluntary** agreement, free of coercion and undue influence

Informed consent is a process that involves providing participants a description of the planned procedure in language appropriate to their level of understanding and which requests their voluntary participation in accordance with applicable regulations. Note that OPRR requires that written informed consent documents have an expiration date affixed by the Middle Georgia State University IRB at the time of approval. The IRB may make a determination to waive the requirement for the Principal Investigator to obtain a signed consent form for some or all participants as outlined in applicable regulations. In cases where the IRB determines that written documentation of consent may be waived and that consent may be obtained orally, a written version of the process to be delivered orally to the participant must still be included in the protocol.

### ***When is informed consent needed?***

Informed consent (or assent) is a cornerstone of the federal laws intended to protect human research subjects. However, under limited circumstances involving minimal risks to participants, the requirement for obtaining informed consent may be waived. For the purposes of research at Middle Georgia State University, this exception would most likely arise when research involves normal classroom practices. For example, if a researcher wished to collect anonymous data on student performance before and after trying a new teaching technique, the requirement of informed consent of the students in the class could likely be waived. Any decision to not obtain informed consent must be fully justified in the protocol submission to the IRB.

### ***Maintaining records of consent***

The Principal Investigator is responsible for maintaining signed consent documents for a minimum period of three (3) years after completion of the research. If data obtained from this project is still in existence three years after completion of the research project then consent forms must be kept for as long as this data exists. The requirement for maintaining records of informed consent may be waived if the record of consent constitutes the only identifying link between a research subject and research data.

## ***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 whom your document is directed. Avoid technical terms and jargon. Do not assume the participant will understand anything about what your instrument measures or they know the difference between a survey, an inventory, or some other instrument. At the same time, guard against being condescending or pandering.

### **Research participants vs. subjects**

In accordance with the American Psychological Association guidelines, individuals taking part in research should be referred to as "research participants," not "subjects."

### **Using the primary language of the participant who is consenting**

The Informed Consent document must be provided in the participant's primary language. When the consent document are to be provided / presented to participant(s) in a language other than English, provide the IRB with the consent document in that language and include an English translation of them as part of your IRB submission.

### **Legal considerations**

No informed consent, whether oral or written, may include any exculpatory or other self-serving language through which the participant or the representative of the participant (e.g. a parent or guardian who represents a child participant) is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the Primary Investigator, the sponsor, the institution or its agents from liability for your or their negligence that causes personal or property injury to the participant.

## **Adult Informed Consent form requirements**

Provide the participant with a duplicate of the informed consent and retain signed copies of the informed consent. 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 informed consent forms.

- 1) Introduction and Purpose
  - a. Identify yourself by name, specify your connection to Middle Georgia State University, and when applicable, identify your faculty supervisor.
- 2) Procedure
  - a. Provide a statement that the study involves research, and a fair explanation of your research procedures (what you expect the participants to do) and their purposes, including identification of any procedures that are experimental. Note the amount of time (number of sessions, if more than one) the participant can expect to devote to the project.
- 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. State whether or not compensation will be awarded. Specify what compensation is offered. When monetary compensation is offered, indicate the amount. If no compensation is provided state, "there is no direct compensation for participation in this study."
- 5) Voluntary Participation, Withdrawal and Removal
  - a. Indicate that taking part in this procedure is voluntary. Include a statement that the participant is free to withdraw at any time without penalty. Alternatively, where applicable, make it clear if there are any consequences to the participant for discontinuing. Explain any circumstance under which you, as Principal Investigator, might terminate an individual's participation (e.g. those not scoring above 50% will be dropped from this project).
  - b. When questionnaires, surveys, or interviews are involved, note that the participant does not have to answer any question s/he does not wish to answer. Do not attach any conditions to the statement (e.g. "You do not have to answer any questions that make you uncomfortable.") Remember, participation is voluntary, and a participant does not have to be able to provide a reason for not answering a question.
- 6) Confidentiality and access to results
  - a. Explain how the participants' privacy will be protected. It is not adequate to only state "Data collected will be kept confidential to the extent provided by law." You must also indicate the steps you will take to protect the participant's privacy. If identifiers will be replaced with codes, note at what point in the research this will take place and how the linking list, if any, will be kept confidential. Anonymity can be promised when there are no personal identifiers at all or, if there are such identifiers, that they are

not attached to the data or available to the public. Avoid seeking participant's Social Security numbers unless the participants consent and it is necessary (e.g. because financial compensation to participants must be reported to the IRS and, in some cases, have withholdings taken out).

- 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 University, 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,

[*child's name*], to participate in \_\_\_\_\_. or I do not wish for my child, [*child's name*], to participate in.

- 5) Voluntary Participation, Withdrawal and Removal
  - a. Specify that the parent(s)/guardian(s) (as well as the child) has/have the right to withdraw permission for the child's participation or for the use of the child's data at any time, without any penalty or prejudice. Do not place conditions on the right to withdraw (e.g. Your child may stop if s/he becomes frustrated). Make clear any consequences for the participant's withdrawing. Explain any circumstance under which you, as Principal Investigator, might terminate the individual's participation (e.g. Children who do not score above 70% on the pretest will not be included in the experimental session).
  - b. Where applicable, include a statement that participation or nonparticipation in this study will not affect the child's grade in any class or status in his/her program.
- 6) Confidentiality and access to results
  - a. Explain how the child's identity will be protected (anonymous response, coding, etc.) and, if applicable, make a positive statement regarding confidentiality (e.g. include a statement that individual student scores will be kept confidential to the extent provided by law through a numerical coding system and that only group scores will be published). State whether or not data will be shared. If so, indicate specifically what data will be shared, whether group or individual, and with whom (e.g. parent, teacher, school board).
  - b. If tape recording of the participants is a part of the process, include this information as part of the parental/guardian informed consent procedure. Specify whether you will audio- or videotape, how identity will be protected, who will have access to the tapes 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 a signature line labeled Parent/Guardian and a place for the date and a second signature line labeled 2<sup>nd</sup> Parent/Witness with a place for the date. This is to accommodate parents with court appointed joint custody. Because it is not your responsibility to become knowledgeable as to which children require joint permission, if a consent form is returned with only one parental signature, you may assume this child's parents do not fall into that category. Federal regulations require the signature of both parents under the following:
    - i. when research involves greater than minimal risk with no prospect of direct benefit to individual participants, but is likely to yield

- generalizable knowledge about the participant's disorder or condition
  - ii. when research, otherwise not approvable, presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
  - 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, [*child's name*], 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 University
- 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.

## **Extenuating Circumstances**

### ***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 statement must be attached to the protocol.

### ***Advertising for participants***

If participants will be obtained through advertisements, attach a copy of the ad as part of your protocol submission.

### ***Certificate of Confidentiality***

When data are being collected about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences), Principal Investigators must apply for a Certificate of Confidentiality. Under Federal law, researchers can obtain an Advance Grant of Confidentiality that will provide protections against a subpoena for research data [Public Health Service Act 301(d)]. Protection will be granted sparingly and only when the research is of such a sensitive nature, that protection is judged necessary to achieve the research objectives. For additional information see Appendix D.

## **After IRB Review**

### ***Timeline for approval***

#### **Full Review**

Proposals which require Full review must be submitted on or before the 15<sup>th</sup> 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 15<sup>th</sup> 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.

#### **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.

### ***Adverse Events***

An adverse event is an undesirable and unintended, although not necessarily unexpected, result involving risks to research participants or others. OPRR requires investigators to report adverse events promptly (within 5 working days) and in writing to the IRB Chair. The Principal Investigator must provide a description of the adverse event and state whether or not changes are needed in the protocol and the informed consent process, and whether or not research participants must be notified regarding the event. These revisions must be reviewed by the full Board. If the events are deemed to place participants at increased risk, the Chair may request resubmission of the protocol for full Board review. In a circumstance in which the Board perceives that the research participant(s) may be placed at immediate significant risk, the IRB has the authority to suspend or terminate approval of a protocol, requiring at a minimum the immediate cessation of data collection from research participants. Any such action shall include a statement of the reasons for the IRB action, and the Chair will contact the appropriate University officials.

### ***Changes in Protocol***

When protocol changes are proposed, a change in risk associated with the research occurs, and/or adverse events, unanticipated problems, or complaints about the research are reported, the Principal Investigator is responsible for contacting the IRB. A written description of proposed changes to the protocol, informed consent process and/or research instruments must be submitted to the Board for review and approval prior to implementation. Only in the rare circumstance when it is necessary to eliminate apparent immediate hazards to the research participants, as noted in Federal regulations, is a researcher permitted to modify an approved protocol without the prior review and approval of the IRB. In this case, the IRB must be informed within 5 days of the change following its implementation. The change will be reviewed to determine that it is

consistent with protection of human participants. Minor modifications proposed for 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 using the same process used for the review of the original protocol as described above.

### ***Re-Approval***

Projects are re-reviewed when the use of human participants is expected to continue beyond the original IRB approval period. All protocols approved by the IRB are subject to continuing review at intervals appropriate to the degree of risk, but not less than once in the 12 months following approval. If the Principal Investigator does not receive a form for continuing review within one month before the expiration of the current IRB approval, a request for a form should be made by contacting the Chair of the IRB. If the IRB approval of a protocol expires before it is re-reviewed, the protocol will be suspended. While suspended, new participant accruals must stop. Interventions under the research protocol must be halted except when over-riding concerns for the safety or well-being of the participants, or other ethical issues, are involved. In such cases, the investigator must contact the IRB immediately. The suspension will be lifted when and if the protocol is re-approved by the IRB. It is the Principal Investigator's responsibility to apply for renewal before the expiration date of IRB approval. If the IRB has not re-approved the protocol before the expiration date, approval expires and data collection must cease. The Principal Investigator will receive written notification of the IRB's review and decision for continuing a research protocol when the review process is complete.

## **Appendices**

## **Appendix A: Sample IRB Protocol Submission (Full Review)**

*The following sample study form was derived from a study performed at Colgate University, Hamilton, NY. The study from was published on the website of Colgate University Institutional Review Board. The cover/signature page has been omitted from this sample*

1. Project Title: The world between yes and no: Gender effects on the perception of sexual coercion

2. Source of Funding (if any): No source of funding

3. Dates of proposed project (cannot be retroactive):

From: \_\_xx/xx/xxxx\_\_\_\_\_ To: \_\_ xx/xx/xxxx\_\_\_\_\_

4. Describe the Scientific Purpose of the Investigation:

Sexual coercion continues to be a problem in American society, especially on university campuses. Despite research demonstrating that non-physical forms of sexual coercion are far more prevalent than physical forms (*citation*), empirical investigation has centered on physical coercion (rape or attempted rape), specifically instances of men physically coercing women. The current study seeks to contribute to the body of literature on sexual coercion by exploring differences in gender perception of non-physical sexual coercion. In addition, this study will address is the coercion of men by women, which anecdotal evidence suggests is prevalent enough to merit research.

5. Describe the research methodology in non-technical language (the IRB needs to know what will be done with or to all research participants):

The participants will be in one of four conditions: female participants viewing male perpetrators, female participants viewing female perpetrators, male participants viewing male perpetrators and male participants viewing female perpetrators. Participants in each condition will view six filmed vignettes on a computer, ranging in intensity of nonphysical sexual coercion from clearly consensual to clearly coercive. There will be no physical contact of any kind between the actors in the vignettes. After viewing each vignette, the participants will be asked to rate how sexually engaged each actor was in the situation and how much unwanted pressure those characters were feeling to have sex on a 1-7 likert scale (see attached). Participants will also be asked how certain they are of their assessment. Participants will have been pre-screened with the following measures: Gender Norms Scale (Thompson & Pleck, 1986), and the adaptation of the Race



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 participants will be allowed to skip questions or to discontinue participation without providing an explanation and still receive course credit. The study will also include a comment section after the last question in order to provide each participant with an outlet for any commentary or distress that may be generated by the study. Finally, the debriefing statement will include the contact information for the psychological counseling center on campus that can aid participants if they were made uncomfortable by the subject matter of the study or if they feel they could benefit from personal attention in the matter. These steps should prevent any negative psychological impacts of

the study on the participants, but also allow access to professional intervention in the event of any adverse effects.

In terms of anonymity, the informed consent document and the debriefing survey will not be linked to participants' pre-screening or study data in any way to preserve confidentiality of responses. Although the prescreening data will need to be matched to the study responses, both of those items will be coded numerically so that a participant's name is not used for identification purposes.

8. Describe how participants will be recruited (must include total number and age of all participants to be recruited and any compensation participants will be provided):

This study will be open to everyone in the Psychology 150 class and the general Colgate population. This study will be advertised to students enrolled in Psychology 150 as an opportunity to participate in research for course credit. All students that sign up to participate from Psychology 150 will have completed the prescreening measures prior to the study date. All other participants will complete the measures immediately after the study measures. Participants from Psychology 150 will have their participation in the experiment validated for course credit by having a researcher sign her/his card. All other participants will have their names entered into a raffle to win an iPod shuffle as compensation for their efforts.

9. Describe why it is necessary that the Primary Investigator(s) and/or Supervisor know the identity of the participants (**not required for Exempt Reviews**):

Research participants will be drawn from Psychology XXXX classes, and so it is unavoidable that researchers will know that some of the students in these courses are study participants.

10. Describe how data collected for this project will be securely stored and how and when it will be destroyed:

All data and forms associated with this study will be stored in a locked file cabinet that is only accessible to the primary investigators. During the study administration participants will be located in a private corridor, alone in an enclosed room with a closed door to avoid any threats to confidentiality while responding during study. The above precautions should ensure participant confidentiality. All original data will be destroyed three years following the completion of 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 hostile and benevolent sexism. *Journal of Personality and Social Psychology, 70*, 491-512.

Sellers, R. M., Smith, M.A., Shelton, J. N., Rowley, S.A. J., & Chavous, T. M. (1998). Multidimensional Model of Racial Identity: A reconceptualization of African American racial identity. *Personality and Social Psychology Review, 2*, 18-39.

Thompson, E. H., & Pleck, J. H. (1986). The structure of male role norms. *American Behavioral Scientist, 29*, 531-543.

## Attachments

Informed consent document, debriefing form, and all scales and dependent measures.

## ***Appendix B: Example Consent Form***

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

**Middle Georgia State University  
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.

### **II. Procedure**

If you decide to participate, you will be loaned a device to use as you do learning activities in BIOL 9999 lab during the spring semester of 2010. The device will present quiz questions in an interactive manner, as you work with specimens and models in the laboratory setting. The device will give you feedback about your responses, and adjust the questions based on your performance. Your answers to the questions will be recorded by the device and then collected by Dr. Doe. You will be asked to complete a written survey regarding your use of the device at the mid-term and again at the end of the semester. The devices will be handed out at the beginning of each laboratory session, and collected at the end of the session. At the end of the semester, your device-based quiz responses and your lecture exams will be analyzed to determine any educational benefit of using the device.

### **III. Potential Risk or Discomfort**

Participation in this study presents no risk to you other than the normal risks of daily life.

#### **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 help improve 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 University.

#### **V. Voluntary Participation, Withdrawal and Removal**

Participation in this research is voluntary. You have the right not to be in this study and still be enrolled in BIOL 9999. If you decide 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, and you will not lose any benefits to which you are otherwise entitled. Dr. Doe will remove you from the study without your permission if you drop BIOL 9999 or stop attending BIOL 9999 during the semester

#### **VI. Confidentiality and access to results:**

Dr. Doe will keep your records private to the extent allowed by law. Your scores on quizzes and exams will not be shared with anyone, and will be kept in a locked office and in a scrambled computer file to which only Dr. Doe will have access. Copies of the written surveys will be kept in a locked file cabinet. You will be identified by a number during analysis and presentation of the data from the study. There will be no way for anyone other than Dr. Doe to know which scores and data belong to you. The original data linked to your name, and copies of all consent forms will be destroyed within five years of the completion of this study. You will be welcome to see the results of the study once they are published, but you will not have access to your individual results, other than those that are a part of regular class exams.

#### **VII. Contact Information**

Call Dr. John Doe at 555-555-555 if you have questions about this study. or email at john.doe@mga.edu. If you have questions or concerns about your rights as a participant in this research study, you may contact Dr. Jane Smith, chair of the Middle Georgia State University Institutional Review Board at 555-555-5555 or email jane.smith@mga.edu.

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

\_\_\_\_\_ printed name of subject \_\_\_\_\_ date

\_\_\_\_\_ signature of subject

\_\_\_\_\_ signature of witness

## ***Appendix C: Suggested anonymous classroom data collection***

Many research projects conducted by faculty and/or students require the collection of data from Middle Georgia State University 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 University 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 University 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

Page 1 of 2

**NOTE: THIS GUIDANCE REPLACES THE 9/1998 OHRP GUIDANCE: "Privacy Protection for Human Research Subjects, Certificates of Confidentiality" [CLICK HERE](#). THIS GUIDANCE HAS BEEN UPDATED IN FORMAT, PROVIDES EMPHASIS ON LIMITATIONS OF THE CERTIFICATES OF CONFIDENTIALITY, AND PROVIDES LINKS TO RELEVANT MATERIALS ON THE NATIONAL INSTITUTES OF HEALTH (NIH) WEBSITE.**

**Office for Human Research Protections (OHRP)  
Department of Health and Human Services (HHS)**

## Guidance on Certificates of Confidentiality

**Date:** February 25, 2003

**Scope:** The purpose of this document is to provide guidance about Certificates of Confidentiality and assistance in locating resources for obtaining a Certificate of Confidentiality to protect the privacy of research subjects.

**Target Audience:** Institutions, institutional review boards (IRBs), and investigators.

**Background:** The Public Health Service Act § 301(d), 42 U.S.C. § 241(d), "Protection of privacy of individuals who are research subjects," states:

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

The privacy of the research subjects referred to in § 301(d) is protected through the issuance of Certificates of Confidentiality. These certificates of Confidentiality provide protection against compelled disclosure of identifying information about subjects enrolled in sensitive biomedical, behavioral, clinical, or other research. This protection is not limited to federally supported research.

**Guidance: OHRP does not issue Certificates of Confidentiality.** Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information from forced or compelled disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in civil, criminal, administrative, legislative, or other proceedings, whether federal, state, or local. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help to minimize risks to subjects by adding an additional level of protection for maintaining confidentiality of private information.

Certificates of Confidentiality protect subjects from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research subjects. Researchers,

<http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm>

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therefore, are not prevented from voluntarily disclosing certain information about research subjects, such as evidence of child abuse or a subject's threatened violence to self or others.

However, if a researcher intends to make such voluntary disclosures, the consent form should clearly indicate this. Furthermore, Certificates of Confidentiality do not prevent other types of intentional or unintentional breaches of confidentiality. As a result, investigators and IRBs must ensure that other appropriate mechanisms and procedures are in place to protect the confidentiality of the identifiable private information to be obtained in the proposed research.

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>.

For information on obtaining a Certificate of Confidentiality for research supported by other HHS agencies, please contact the appropriate program official. *Again, please note that the OHRP does not issue Certificates of Confidentiality.*

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>.