IRB Protocol Submission Instructions

- All members of the research team and faculty/department personnel signing the protocol must **complete CITI (Collaborative Institutional Training Initiative) training prior to submission**.

Instructions for CITI:

  - The on-line, self-paced researcher training can be found at: http://www.citiprogram.org/
  - **To prevent non-AUM researchers from utilizing AUM's program there are several screening requirements: 1) institutional ID # is required. This is your student or faculty/staff ID. 2) also, required is registration with your aum.edu e-mail address. Failure to register using these identifiers will result in being rejected from the system. Periodic screening takes place and non-affiliated users are removed. Contact dtomblin@aum.edu with questions.**
  - Select "New Users Register Here"
  - Select "The Protection of Human Research Subjects"
  - Select "Participating Institutions" and find "Auburn University at Montgomery" in the drop down menu
  - Create your username and password
- Institutional ID # is your AUM "S" number (nine digit student or faculty/staff #). Please enter this number without the "S". If you do not know your "S" number, you can find it here: https://mars.aum.edu/secure/enrollmentservices/idlookup/
  - Enter your name and AUM email address
  - Click on "Submit"
  - Complete the Course Registration Information
  - And start (and complete the CITI training). Completion reports are automatically sent to the AUM IRB Administrator.

Instructions for IRB Submission:

- The IRB Protocol Review Form can be found on AUM.net (SharePoint) site and aum.edu website. It is in a Word.doc format with expandable text fields.
- The IRB Protocol Review Form must be typed (not handwritten).
- Forms must have the appropriate signatures (Assurances).
- Determination for type of review (exempt, expedited, full board) will be made by the IRB.

- Include the appropriate informed consent document and/or assent document. The informed consent form is a crucial element in conforming to the Department of Health and Human Services' regulations on human subjects research. (Those

regulations can be found in the Code of Federal Regulations, 45 CFR 46.) These guidelines are important both legally and ethically, so researchers should make every effort to stay in compliance. IRB groups like the one at AUM advocate ethical, responsible human subjects research and endeavor to assist researchers in their attempts to develop and conduct HHS-compliant studies of human populations.

- Include **all** instruments that will be used for data collection (surveys, interview questions, health history questionnaires, etc.)

Specific Instructions for completing the IRB protocol

General instructions: be as specific and thorough as possible. Use complete sentences. Check the document for thoroughness, omissions, and typos. It is recommended that you write answers to questions in a *word.doc* first so that you can use spell check and then cut and paste into the protocol form.

Location of Research (#9):

Provide the specific location/s where data collection will take place. Also give location where data analysis will take place.

Background (#10):

Briefly discuss the relevant literature and research findings that led to the development of this project. Please cite relevant sources and include a "reference list" as Appendix A. Inclusion of a reference list (literature review) is an indicator that background work has been conducted that will result in meaningful scientific results. The study design and scientific quality of each study be evaluated to determine if participants' time and efforts are being unduly infringed upon.

Purpose & Significance (#12):

Be specific. The purpose should include a hypothesis for the study.

Compensation and Cost for Subjects (#12.e):

Researchers much describe any incentives, compensation or reimbursement provided to research subjects. Such compensation may take the form of reimbursement for expenses associated with research participation such as travel expenses, lost wages, parking costs etc. At times, it may also be appropriate to offer incentives for participation. In all instances, the IRB must be certain the compensation or reimbursement offered is not so large as to be coercive. The form of compensation and the timing of offering the compensation also become part of the review process. When children are the research subjects, IRB members have to consider who receives compensation.

The researcher must explain any costs associated with participation in the research and expenses that may occur as a result of research participation. If the subject's medical expenses are covered by health insurance, it is important to indicate who is responsible for any study expenses, especially if the research is not covered by the health insurance or the insurance company refuses to pay. Plans for compensation and treatment in the event of any injury that results from participation must also be addressed.

Participants (#13)

Researchers must provide information on how and when participants are to be identified and approached for recruitment. Explain all methods for recruiting subjects (advertisements, World Wide Web sites, medical records, databases, newsletters, referrals, etc.). In addition, it is important to consider who will approach potential research subjects, when subjects will be contacted, where they will be approached, and the amount of time provided for potential subjects to consider participation. All recruitment materials and practices must be reviewed and approved by IRB. The IRB must be assured that the recruitment process promotes voluntary participation and is not coercive.

Project Design and Methods (#13)

Project Overview (#13.a):

Describe all procedures involved in research. Include the following information: "How is the participation to be treated? What procedures will they undergo for the purposes of research?" Differentiate those procedures that are performed for research purposes from those that are performed for routine care or evaluation. Researchers must include information on the actual studies, including timing, the setting, and the qualifications of those conducting the procedures or evaluations. Procedures for monitoring the subject during the research must be evaluated. When questionaries' and behavioral or psychological assessments are included as part of the research evaluation, copies of all assessment instruments must be attached to the protocol. The IRB members will review what would happen to the study results. If there are flow charts or schemas, it is important that they be consistent with the text of the protocol and the informed consent document.

Describe all procedures and methods used to address the purpose: (#13.b):

In the procedure subsection, the researcher should describe exactly how the study will be executed, from the moment the participant/s and researcher come into contact to the moment their contact was terminated. Consequently, this section represents a step-by-step account of what both the researcher and the participant will do during the study. This section should include any instructions or stimulus conditions presented to the participants and the responses that will be required of them, as well as any control techniques that will be used (such as randomization or counterbalancing). In other

words, explain exactly what both you and the participants will do and how you will do it. It is also recommended to use a timetable to further illustrate sequence of events.

List all Instruments used in data collection (#13.c)

This will include surveys, questionnaires, educational tests, data collections sheets, outline of interviews, scripts, audio and or video methods, etc. Please include a copy of all data collection instruments that will be used in this project.

List AND describe these instruments. Why are they necessary? How will they be used?

Data Analysis and Statistical Analysis (#13.d):

Data Analysis should refer to Purpose & Significance section. The hypothesis stated should be tested by realistic and reliable analytical methods.

Research protocols must contain well-conceived and appropriate sections on interpretation of data and statistics. The interpretation of data should summarize the proposal design, the reasoning for the design, and plans for analysis of results. This section should provide enough evidence to convince a reviewer that the proposed design has a reasonable chance of achieving the principal objectives of the research. IRB members should determine that the sample size and statistical power or precision associated with the sample size are adequate. In addition, there must be a sound method of data and statistical analysis, with adequate satisfaction factors and treatment allocation plans for the study design. When appropriate, IRB members must be adequately informed about plans to monitor the data, including the description of early stopping rules if necessary.

Risks and Discomforts (#14)

RISKS:

Researchers are charged with the responsibility of identifying and stating the potential risks, discomforts, hazards, or inconveniences of a research protocol. This includes the probability, magnitude, and duration of the risks. Researchers must identify the physical pain or discomfort as well at the psychological, emotional, or sociological harm, including invasion of privacy, loss of confidentiality, harassment, and lessening of an individual's dignity. Inconveniences such as loss of time or pay are also included in this category. Risk to a community or a group of individuals must also be considered. The IRB will consider the potential risks as well as the precautions that will be taken to avoid or minimize potential risks.

Precautions (#15):

List and describe all precautions that will be taken to eliminate or reduce the risks listed above in #14. This may include the use of a comprehensive Informed Consent document, or removal of personal identifiers, or the use of Information Letter instead of

Informed Consent, anonymous response mechanism, use of referral to counseling professionals, training of all research team members in specific safety procedures, etc.

Benefits (#17):

Potential benefits can apply directly to the subject or to the advancement of scientific knowledge. The IRB will consider the magnitude and probability of direct benefit to a subject to be certain the research protocol does not over-state the benefits or potentially raise false expectations in participants. It is important for the IRB to evaluate the risk/benefit ratio and to understand the rationale for believing the risk/benefit ratio is acceptable. There are cases where there may be no benefits to participants.

VULNERABLE POPULATIONS:

The IRB must give special consideration to risks and benefits for research involving children and other vulnerable populations such as the mentally impaired and prisoners.

Protection of Data (#17):

Privacy and Confidentiality

Researchers must explain the possibility of a research protocol's invading the privacy of a research subject or breaching confidentiality. These possibilities present a risk of harm to the subject. Researchers must consider the type and sensitivity of the information sought, how the information will be recorded, precautions taken to protect confidentiality, and who has access to the research records. Precautions can and should be taken, depending on the nature of the research.

Informed Consent/Assent

The Consent Document

Researchers must include (with the protocol) an Informed Consent document (as necessary). The required elements of the Consent are:

1. Consent/assent form checklist
2. Statement that the study involves research
3. Purpose of research stated in lay language
4. Reason subject is asked to participate
5. Expected duration of study
6. Study design described in lay language (number of groups, randomization, use of placebo)
7. Study procedures or treatments
8. Description of drug or device (if applicable); state whether it is investigational
9. Compensation or reimbursement
10. Number of subjects

11. Potential risks or discomfort to the subject
12. Potential direct benefits or benefits to society
13. Alternatives available (indicate if none)
14. Statement that participation is voluntary and subject may withdraw
15. Additional costs associated with participation-who will pay for what
16. How confidentiality will be protected; who has access to the data
    If applicable:
17. Anticipated circumstances under which a subject's participation may be terminated
18. Consequences of withdrawal
19. If greater than minimal risk, statement included regarding compensation in event of injury.

The Informed Consent must be written in language appropriate for the subjects. Generally, an 8th grade reading level is required for adults.
The IRB will review the informed consent and determine whether each element is present, absent, or not applicable. IRB members are encouraged to "mark up" a copy of the proposed consent with any additions, deletions, comments, suggestions, or rewording necessary. A marked-up version of the informed consent, which combines all comments, is forwarded to the investigator after the meeting along with any other questions and concerns raised regarding the protocol application.

Assent from Children

For protocols that involve children, the researcher must provide the document (as an attachment). the IRB is required to determine whether assent is required and, if so, determine an appropriate mechanism to obtain and document assent. Many institutions require separate documentation, whereas others require a child's co-signature on the parental permission form.

Amdur and Bankert: IRB Handbook