IRB

Institutional Review Board

at

AUM

What is the IRB?

The Institutional Review Board is a board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects

45 CFR 46

Why do we have an IRB?

- To ensure that we protect the rights of human research participants.
- To comply with federal regulations.
- To promote research.
- Protect the institution.

Why (continued)

Because there is a long history of researchers behaving badly.

A few examples are:

- **1932 to 1972 The Tuskegee Syphilis Study.** Researchers (U.S. Public Health Dept) withheld treatment for syphilis for 30 years.
- **1956 to 1980 Willowbrook State School**. researchers conduct hepatitis experiments on mentally disabled children at They intentionally infected subjects with the disease and observed its natural progression. The experiments were approved by the New York Department of Health.

- **Jewish Chronic Disease Study.** 1954 to 1965 Elderly patients in a nursing home were injected with live cancer cells to study how compromised immune systems react.
- **Stanley Milgram. 1961** electric shock experiments.
- **Zimbardo Stanford prison experiment.** 1970
- **Conflict of interest.** Industry/large donors/political entities can influence research outcomes. **Fabricating or falsifying data.**

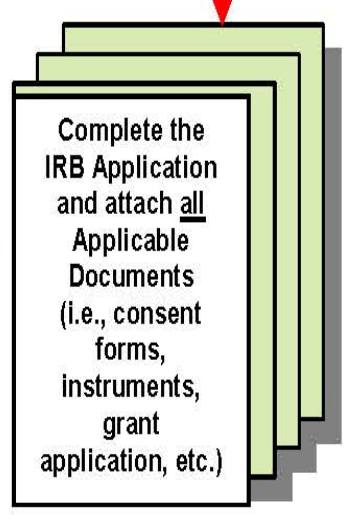
Who is the IRB at AUM?

- Chair: Dr. Glen Ray
- Administrator: Debra Tomblin
- Representation from each college:
  - Education: Dr. Kate Simmons
  - Sciences: Dr. Ray
  - Nursing and Health Sciences: Dr. Courtney Cochran
  - Social Sciences & Liberal Arts: Dr. Theresa Pelfrey
  - Business: Dr. Zach Jordan

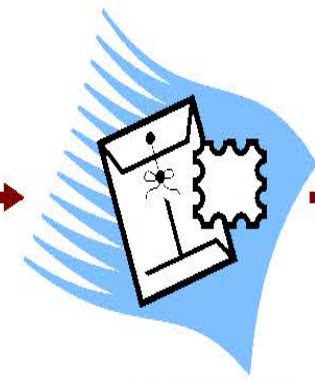
- External Members:
  - Kelley Birchfield
  - Cheryl Moyer

NON-BIOMEDICAL RESEARCH!

IRB – The Application Review Process at AUM



Gather Appropriate Signatures
(PI, faculty advisor, dept. head)

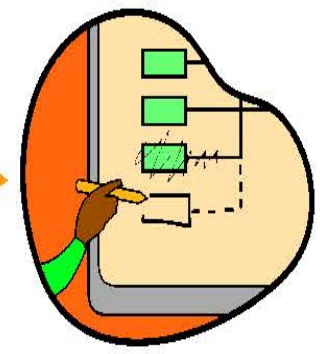


Submit to IRB
Office of Sponsored Programs

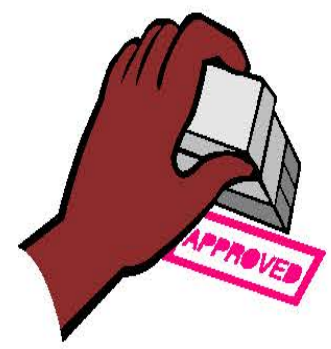
IRB Admin Verifies Receipt
Assigns Protocol Number

IRB Reviews:
Exempt – Adm/Chair
Expedited – Adm/Chair/designated reviewer
Full – committee review and vote

IRB sends PI comments



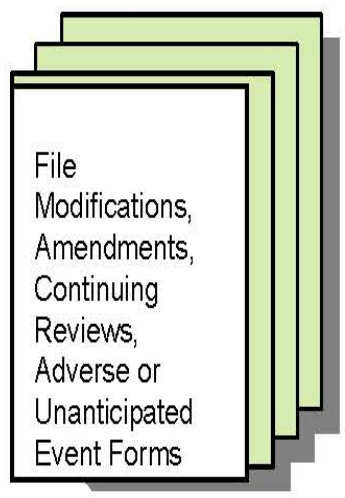
Possibility #1
Revise/Modify/Clarify

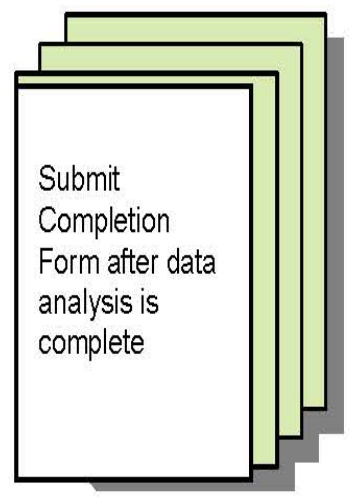


Possibility #2
Exempted or Approved

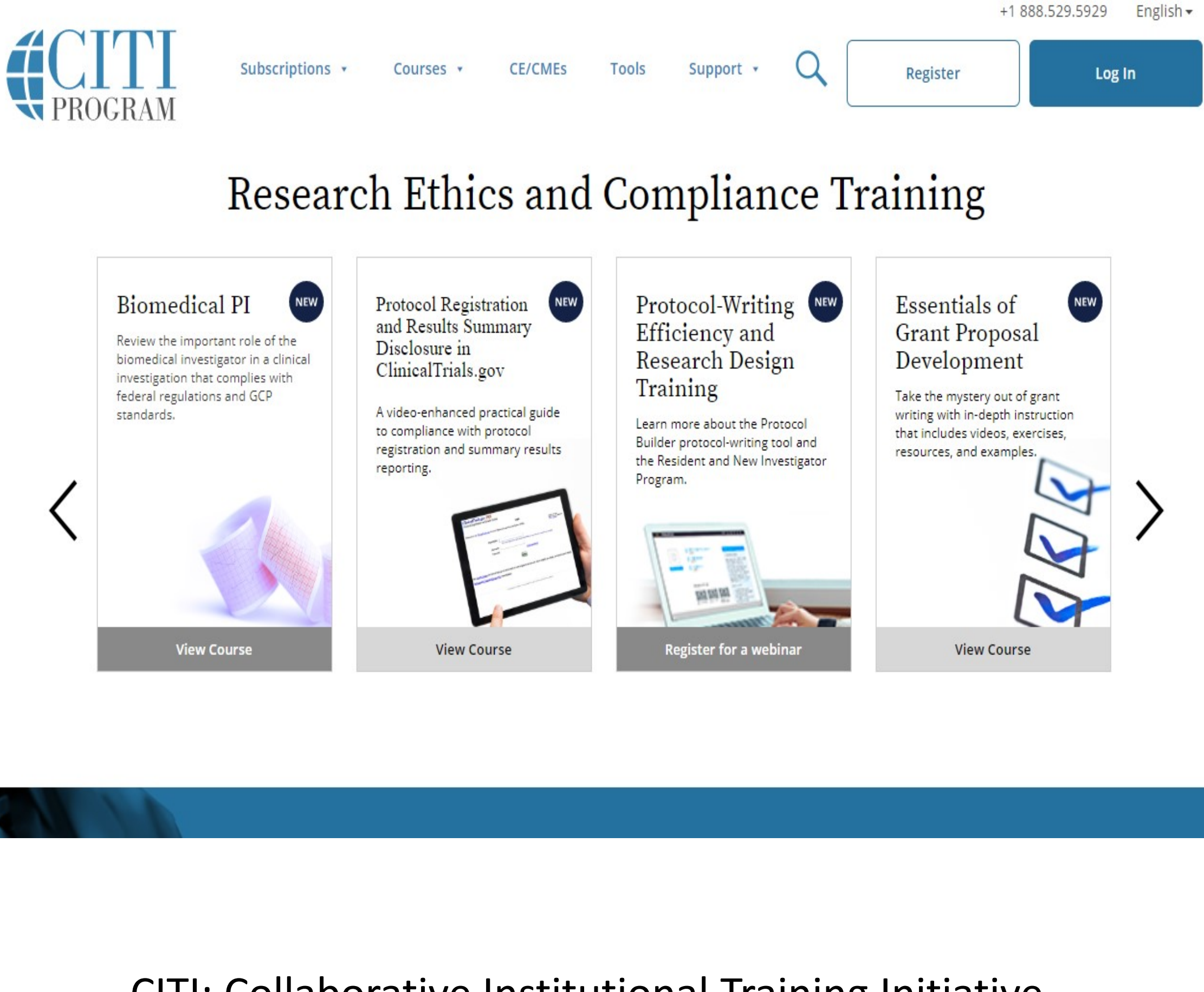
Possibility #3
Disapproved

Conduct Research





Before you submit your IRB research protocol you must complete training in conducting human subjects research.



CITI: Collaborative Institutional Training Initiative.
Online training program for researchers.

https://about.citiprogram.org/en/homepage/

Cover Page

AUM Research Protocol Review Form

Institutional Review Board for Research Involving Human Subjects

Office of Sponsored Programs (OSP), 334.244-3250

For IRB use only:
Date received in OSP: _____ PROTOCOL #_____
Date assigned IRB review: _____ Reviewed by: _____ Date of IRB approval: _____
Type of review: Expedited, Full Board, Exempt Interval for Continuing Review:

ONLY TYPEWRITTEN FORMS WILL BE ACCEPTED

1. Proposed dates of study: from _____ to _____
2. Project Title: _____
3. Principal Investigator: _____
4. Title: _____ Dept: _____ Phone: _____ Email:_____
5. Source of Funding/Project Support: ☐ Internal ☐ External (list) ☐
6. Status of Funding/project support: ☐ received ☐ approved ☐ pending ☐ n/a
7. General research characteristics:

A. Research Methodology	B. Participant Information
Please identify the descriptors that best apply to the research methodology. Data collection will be: ☐ Prospective* ☐ Retrospective* ☐ both Data will be recorded so that participants can be directly or indirectly identified: ☐ Yes ☐ No Data collection will involve the use of: ☐ Educational Tests (cognitive, diagnostic, aptitude, achievement) ☐ Surveys/Questionnaires ☐ Private Records/Files ☐ Interview/Observations ☐ Audiotaping ☐ Videotaping ☐ Physical/Physiologic Measurements or Specimens ☐ Other (explain Q.12a)	Check all descriptors that apply to the participant population: ☐ Males ☐ Females Vulnerable Populations: ☐ Pregnant Women ☐ Age 17 & under ☐ Prisoners ☐ Elderly ☐ Economically Challenged ☐ Physically Challenged ☐ Mentally Challenged Do you plan to recruit AUM Students? ☐ Yes ☐ No Do you plan to remunerate participants? ☐ Yes ☐ No
C. Research Content Area	**D. Risks to Participants**
Identify (list) 3 or 4 keywords to identify this research project. _____	Please identify all risks that may reasonably be expected as a result of participating in this research: ☐ Breach of Confidentiality ☐ Deception ☐ Social ☐ Psychological ☐ Coercion ☐ Physical

Research Team

8. **INVESTIGATORS:**

Identify each individual involved with the conduct of this project and describe his or her roles and responsibilities related to this project.

Principal Investigator (PI): the PI must have completed IRB-approved human research protections training through CITI. IRB staff must verify training before approval is granted. The CITI training site is available through the following link www.citiprogram.org ☐ CITI completion report **attached**			
Name:		Email:	
Department:		Phone:	
☐ Faculty	☐ Staff	☐ Graduate Student	☐ Undergraduate Student
Role/Responsibility:			

Investigator: must have completed IRB-approved human research protections training through CITI. IRB staff must verify training before approval is granted. The CITI training site is available through the following link www.citiprogram.org ☐ CITI completion report attached			
Name:		Email:	
Department:		Phone:	
☐ Faculty	☐ Staff	☐ Graduate Student	☐ Undergraduate Student
Role/Responsibility:			

Researcher: must have completed IRB-approved human research protections training through CITI. IRB staff must verify training before approval is granted. The CITI training site is available through the following link www.citiprogram.org ☐ CITI completion report attached			
Name:		Email:	
Department:		Phone:	
☐ Faculty	☐ Staff	☐ Graduate Student	☐ Undergraduate Student
Role/Responsibility:			

Research: must have completed IRB-approved human research protections training through CITI. IRB staff must verify training before approval is granted. The CITI training site is available through the following link www.citiprogram.org ☐ CITI completion report attached			
Name:		Email:	
Department:		Phone:	
☐ Faculty	☐ Staff	☐ Graduate Student	☐ Undergraduate Student
Role/Responsibility:			

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9. **LOCATION OF RESEARCH: List all locations where data collection will take place and analyzed. Be as specific as possible.** _____

10. **BACKGROUND: Briefly discuss the relevant literature and research findings that lead to the development of this project. Please cite relevant sources and include a "Reference List" as Appendix B.** _____

11. **PURPOSE & SIGNIFICANCE:**
    a. **Clearly state the objectives, goals, or aims of this project.** _____

    b. **How will the results of this project be used? (e.g., presentation? Publication? Thesis? Dissertation?)** _____

12. **PARTICIPANTS:**
    a. **Describe the participant population you have chosen for this project.** _____

    What is the minimum number of participants you need to validate the study? _____
    What is the maximum number of participants you will include in the study? _____

    b. **Describe the criteria established for participant selection. (If the participants can be classified as a "vulnerable" population, please describe additional safeguards that you will use to assure the ethical treatment of these individuals.)** _____

    c. **Describe all procedures you will use to recruit participants. Please include a copy of all flyers, advertisements, and scripts and label as Appendix C.**
    _____

    d. **Describe how you will determine group assignments (e.g., random assignment, independent characteristics, etc.)** _____

Page 4

e. Describe the type and amount and method of compensation for participants. ____

13. PROJECT DESIGN AND METHODS:
Describe the procedures you will plan to use in order to address the aims of this study. (NOTE: use language that would be understandable to a layperson. Without a complete description of all procedures, the AUM IRB will not be able to review the protocol.

a. Project overview (Briefly describe the scientific design.) ____

b. Describe all procedures and methods used to address the purpose. ____

c. List all instruments used in data collection. (e.g., surveys, questionnaires, educational tests, data collection 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 and label as *Appendix C*. ____

d. Data Analysis: Explain how the data will be analyzed. ____

14. RISKS AND DISCOMFORTS:
List and describe all of the reasonable risks that participants might encounter if they decide to participate in this research. If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use and label as *Appendix D*. ____

15. PRECAUTIONS:
Describe all precautions you have taken to eliminate or reduce risks that were listed in #14. ____

16. BENEFITS:

a. List all realistic benefits participants can expect by participating in this study. ____

b. List all realistic benefits for the general population that may be generated from this study. ____

17. PROTECTION OF DATA:

a. Will data be collected as anonymous? ☐ Yes ☐ No

b. Will data be collected as confidential? ☐ Yes ☐ No

c. If data is collected as confidential, how will the participants' data be coded or linked to identifying information? ____

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d. Justify your need to code participants' data with identifying information. ____

e. Where will code lists be stored? ____

f. Will data collected as "confidential" be recorded and analyzed as "anonymous"? ☐ Yes ☐ No

g. Describe how the data will be stored (e.g. hard copy, audio recording, electronic data, etc), where the data will be stored, and how the location where data is stored will be secured in you absence. ____

h. Who will have access to participants' data? ____

i. When is the latest date that the data will be retained? ____

j. How will the data (hard copies, electronic and other) be destroyed? ____

Assurances

Principal Investigator's Assurance

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance for this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the AUM IRB. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with AUM IRB policies regarding the collection and analysis of the research data. I have completed CITI training.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities & are in compliance with AUM IRB policies regarding the collection & analysis of the research data.
4. I agree to comply with all AUM IRB policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:

a. Conducting the project by qualified personnel according to the approved protocol
b. Implementing no changes in the approved protocol or consent form without prior approval from the Office of Sponsored Programs (OSP) (except in an emergency, if necessary to safeguard the well-being of human subjects)
c. Obtaining the legally effective informed consent from each participant or his or her legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form.
d. Promptly reporting significant adverse events and/or effects to the OSP in writing within 5 working days of the occurrence.

5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise OSP, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the AUM IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to OSP before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the AUM IRB.
8. I will prepare and submit a final report upon completion of this research project.

Principal Investigator (Please type or print)	Principal Investigator Signature	Date

Faculty Sponsor's Assurance

1. By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol. This requirement includes CITI training.
2. I certify that the project will be performed by qualified personnel according to the approved protocol using conventional or experimental methodology.
3. I agree to meet with the investigator on a regular basis to monitor study progress.
4. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
5. I assure that the investigator will promptly report significant adverse events and/or effects to the OSP in writing within 5 working days of the occurrence. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the OSP by letter of such arrangements.
6. I have read the protocol submitted for this project for content, clarity, and methodology

Faculty Sponsor (Please type or print)	Faculty Sponsor Signature	Date

Department Head's Assurance

By my signature as department head, I certify that every member of my department involved with the conduct of this research project will abide by all AUM policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants.

Department Head (Please type or print)	Department Head Signature	Date

End of document

Checklist

PROTOCOL REVIEW CHECKLIST (for researcher to fill out)
All protocols must include at least items 1-5.
Items 6-10 as applicable.

1. ☐ IRB Protocol Form is complete

2. ☐ IRB Protocols Assurances page has all necessary signatures

3. ☐ Verification of CITI Training for all researchers: indicated on page 2 and completion reports attached.

4. ☐ **Appendix A:** Informed Consent Form/s

5. ☐ **Appendix B:** Reference List (Literature Review)

6. ☐ **Appendix C:** if flyers, advertisements, generalized announcements or scripts are used for data collection.

7. ☐ **Appendix C:** if data collection sheets, surveys, tests, or other recording instruments will be used for data collection. Be sure to mark each of the data collection instruments as they are identified in section #13 , part c.

8. ☐ **Appendix D**: if debriefing form is used.

9. ☐ If research is being conducted at sites other than AUM or in cooperation with other entities, a letter from the site/program director must be included indicating their cooperation or involvement in the project. NOTE: if the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of IRB approval from each entity is required prior to initiating the project. **Include in Appendix A**.

10. ☐ Written evidence of acceptance by the host country if research is conducted outside of the United States (approval by host country IRB). **Include in Appendix A.**

Attachments

Appendix A: Informed Consent Forms, Assent Forms, etc

Appendix B: Reference List (Lit Review)

Appendix C: Flyers, advertisements, recruitment materials.

Appendix D: Debriefing form

Others:

- Permission Letters
- CITI training completion report/s

Auburn University at Montgomery

(*Department*)

INFORMED CONSENT

Concerning Participation in a Research Study

(*Title of Study*)

Research Purpose & Procedures:

We hope to learn (*state what the study is designed to investigate*). You were selected as a possible participant because (*state why the respondent was selected*). If you decide to participate, (*I/we*), (*name and title of the investigators and associates*), will (*describe procedures to be followed, including purposes, how long they will take, location, and their frequency*).

Risks or Discomforts/Potential Benefits:

- *Explain or describe any discomforts and inconveniences that reasonably can be expected and estimate the total time required of the subject.*
- *Describe risks identified in the protocol and precautions taken to reduce risks.*
- *If there is a possibility of additional cost to the subject because of participation, describe.*
- *If extra credit is involved, state amount.*
- *Describe benefits that reasonably can be expected.*
- *If any benefits are described, add:* We cannot promise you that you will receive any or all of these benefits.

Alternative Procedures:

(*Describe appropriate alternative procedures that might be advantageous to the respondent, if any. You must disclose the nature of any treatment that is being withheld*).

Provisions for Confidentiality:

Any information obtained in connection with this study that can be identified with you will remain confidential. (*state persons or agencies to whom the information will be furnished and the purposes of the disclosure*). (*If the subject will receive compensation, describe the amount or nature.* The information that will be published will be data that is in group (aggregate) form so that individuals cannot be identified.

Management of Research-related Injury:

If medical treatment for physical injuries is available, state the extent of treatment that will be provided and where it will be carried out. In the case of a social/behavioral research project include appropriate referrals (ex: for psychological counseling.)

Contacts for Additional Information:

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, *(name, email, phone number)*. If you have any questions about your rights as a volunteer in this research, contact Debra Tomblin, Research Compliance Manager, AUM, 334-244-3250, dtomblin@aum.edu.

Voluntary Participation & the Right to Discontinue Participation without Penalty:

If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without penalty. If you decide later to withdraw from the study, you may also withdraw any information that has been collected about you. Your decision whether to participate will not prejudice your future relations with Auburn University at Montgomery (*and name of cooperating institution or agency, if any*). The researcher may discontinue the study at any point.

We will give you a copy of this consent form to take with you.

YOU ARE MAKING A DECISION WHETHER TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TOPARTICIPATE, HAVING READ THE INFORMATION PROVIDED ABOVE.

Participant's signature & Date

_____ _____

Investigator's signature

_____

Contact the IRB:

Debbie Tomblin, IRB Administrator

dtomblin@aum.edu

244-3250

Library Tower, Room 917

http://www.aum.edu/sponsored-programs/institutional-review-board

AUM → Faculty & Staff → Research & Grants → Institutional Review Board

Historical Documents

- The Nuremberg Code, 1947

  Legal responsibilities: **http://www.hhs.gov/ohrp/archive/nurcode.html**

- The Declaration of Helsinki, 1964

  Ethical responsibilities (written by physicians)

  http://www.wma.net/en/30publications/10policies/b3/index.html

- The Belmont Report, 1979

  Separation of research from practice (written by physicians)

  http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

- Henry Beecher Article, 1966

  http://www.hhs.gov/ohrp/archive/documents/BeecherArticle.pdf