**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:**

|  |  |
| --- | --- |
| 1. **Research Methodology**
 | 1. **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** |
| 1. **Research Content Area**
 | 1. **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[ ]  Other (explain) |

***\*(Prospective*** *data collection involves new or original data.* ***\*Retrospective*** *data involves the use of existing data. )*

1. **INVESTIGATORS:**

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

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| **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](http://www.citiprogram.org) [ ] CITI completion report **attached** |
| Name:       | Email:       |
| Department:       | Phone:       |
| [ ] Faculty [ ] Staff [ ] Graduate Student [ ] Undergraduate Student |
| **Role/Responsibility**:       |

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|  **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](http://www.citiprogram.org) [ ] CITI completion report attached |
| Name:       | Email:       |
| Department:       | Phone:       |
| [ ] Faculty [ ] Staff [ ] Graduate Student [ ] Undergraduate Student |
| **Role/Responsibility**:       |

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| **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](http://www.citiprogram.org) [ ] CITI completion report attached |
| Name:       | Email:       |
| Department:       | Phone:       |
| [ ] Faculty [ ] Staff [ ] Graduate Student [ ] Undergraduate Student |
| **Role/Responsibility**:       |

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| --- |
| **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](http://www.citiprogram.org) [ ] CITI completion report attached |
| Name:       | Email:       |
| Department:       | Phone:       |
| [ ] Faculty [ ] Staff [ ] Graduate Student [ ] Undergraduate Student |
| **Role/Responsibility**:       |

1. **LOCATION OF RESEARCH: List all locations where data collection will take place and analyzed. Be as specific as possible.**
2. **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.**
3. **PURPOSE & SIGNIFICANCE:**
	1. **Clearly state the objectives, goals, or aims of this project.**
	2. **How will the results of this project be used? (e.g., presentation? Publication? Thesis? Dissertation?)**
4. **PARTICIPANTS:**
	1. **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?**

* 1. **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.)**
	2. **Describe all procedures you will use to recruit participants. Please include a copy of all flyers, advertisements, and scripts and label as Appendix C.**

* 1. **Describe how you will determine group assignments (e.g., random assignment, independent characteristics, etc.)**
	2. **Describe the type and amount and method of compensation for participants.**
1. **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.**

* 1. **Project overview (Briefly describe the scientific design.)**
	2. **Describe all procedures and methods used to address the purpose.**
	3. **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*.**
	4. **Data Analysis: Explain how the data will be analyzed.**
1. **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*.**

1. **PRECAUTIONS:**

**Describe all precautions you have taken to eliminate or reduce risks that were listed in #14.**

1. **BENEFITS:**
	1. **List all realistic benefits participants can expect by participating in this study.**
	2. **List all realistic benefits for the general population that may be generated from this study.**
2. **PROTECTION OF DATA:**
	1. **Will data be collected as anonymous?** [ ]  Yes [ ]  No
	2. **Will data be collected as confidential?** [ ]  Yes [ ]  No
	3. **If data is collected as confidential, how will the participants’ data be coded or linked to identifying information?**
	4. **Justify your need to code participants’ data with identifying information.**
	5. **Where will code lists be stored?**
	6. **Will data collected as “confidential” be recorded and analyzed as “anonymous”?** [ ]  Yes [ ]  No
	7. **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.**
	8. **Who will have access to participants’ data?**
	9. **When is the latest date that the data will be retained?**
	10. **How will the data (hard copies, electronic and other) be destroyed?**

**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.**

**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:
	1. Conducting the project by qualified personnel according to the approved protocol
	2. 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)
	3. 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.
	4. 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.

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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

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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.

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