AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS

RESEARCH PROTOCOL REVIEW FORM

For information or help completing this form, contact: **THE OFFICE OF HUMAN SUBJECTS RESEARCH**, 307 Samford Hall,
Phone: 334-844-5966 **e-mail:** hsubjec@auburn.edu **Web Address:** http://www.auburn.edu/research/vpr/ohs/index.htm

Complete this form using Adobe Acrobat Writer (versions 5.0 and greater).

1. **PROPOSED DATES OF STUDY:** **FROM:** _____ **TO:** _____

REVIEW TYPE (Check one): ☐ **FULL BOARD** ☐ **EXPEDITED** ☐ **EXEMPT**

2. **PROJECT TITLE:** _____

3. _____ _____ _____ _____ _____
PRINCIPAL INVESTIGATOR **TITLE** **DEPT** **PHONE** **E-MAIL**

_____ _____
ADDRESS FOR CORRESPONDENCE **FAX**

4. **SOURCE OF FUNDING SUPPORT:** ☐ Not Applicable ☐ Internal ☐ External (External Agency): _____

5. **STATUS OF FUNDING SUPPORT:** ☐ Not Applicable ☐ Approved ☐ Pending ☐ Received

6. **GENERAL RESEARCH PROJECT CHARACTERISTICS**

A. Research Content Area

Please check all descriptors that best apply to this proposed research project.

- ☐ Anthropology
- ☐ Anthropometry
- ☐ Biological Sciences
- ☐ Behavioral Sciences
- ☐ Education
- ☐ English
- ☐ History
- ☐ Journalism
- ☐ Medical
- ☐ Physiology
- ☐ Other (Please list:)_____

Please list 3 or 4 keywords to identify this research project: _____

_____

_____

B. Research Methodology

Please check all 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 / Observation
- ☐ Audiotaping and / or Videotaping
- ☐ Physical / Physiologic Measurements or Specimens

C. Participant Information

Please check all descriptors that apply to the participant population.

- ☐ Males
- ☐ Females

Vulnerable Populations

- ☐ Pregnant Women
- ☐ Children
- ☐ Prisoners
- ☐ Adolescents
- ☐ Elderly
- ☐ Physically Challenged
- ☐ Economically Challenged
- ☐ Mentally Challenged

Do you plan to recruit Auburn University Students? ☐ Yes ☐ No

Do you plan to compensate your participants? ☐ Yes ☐ No

D. Risks to Participants

Please identify all risks that may reasonably be expected as a result of participating in this research.

- ☐ Breach of Confidentiality
- ☐ Coercion
- ☐ Deception
- ☐ Physical
- ☐ Psychological
- ☐ Social
- ☐ None
- ☐ Other (please list):

_____

_____

For OHSR Office Use Only

DATE RECEIVED IN OHSR: _____ **by** _____ **PROTOCOL #** _____

DATE OF OHSR CONTENT REVIEW: _____ **by** _____ **DATE ASSIGNED IRB REVIEW:** _____ **by** _____

DATE OF IRB REVIEW: _____ **by** _____ **DATE IRB APPROVAL:** _____ **by** _____

INTERVAL FOR CONTINUING REVIEW: _____

7. PROJECT ASSURANCES

PROJECT TITLE: _____

_____

A. PRINCIPAL INVESTIGATOR'S ASSSURANCE

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 this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Auburn University IRB.
3. 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 Auburn University policies regarding the collection and analysis of the research data.
4. I agree to comply with all Auburn 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 Human Subjects Research (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 their 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 Office of Human Subjects Research 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 OHSR, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the Auburn University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the Office of Human Subjects Research before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the Auburn University IRB.
8. I will prepare and submit a final report upon completion of this research project.

Principal Investigator (Please Print)	Principal Investigator's Signature	Date

B. FACULTY SPONSOR'S ASSSURANCE

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.
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 OHSR in writing within 5 working days of the occurrence.
6. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the OHSR by letter of such arrangements.
7. I have read the protocol submitted for this project for content, clarity, and methodology.

Faculty Sponsor (Please Print)	Faculty Sponsor's Signature	Date

C. DEPARTMENT HEAD'S ASSSURANCE

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 Auburn University 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 Print)	Department Head's Signature	Date

8. **PROJECT ABSTRACT: Prepare an abstract (400-word maximum) that includes: I.) A summary of relevant research findings leading to this research proposal; II.) A concise purpose statement; III.) A brief description of the methodology; IV.) Expected and/or possible outcomes, and V.) A statement regarding the potential significance of this research project. *Please cite relevant sources and include a "Reference List" as Appendix A.***

9. **PURPOSE & SIGNIFICANCE.**
   a. **Clearly state all of the objectives, goals, or aims of this project.**

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

10. KEY PERSONNEL INVOLVED WITH DATA COLLECTION. Identify each individual involved with the conduct of this project and describe his or her roles and responsibilities related to this project. Be as specific as possible.

Individual: _____ **Title:** _____ **Dept/ Affiliation:** _____
Roles / Responsibilities:

Individual: _____ **Title:** _____ **Dept/ Affiliation:** _____
Roles / Responsibilities:

Individual: _____ **Title:** _____ **Dept/ Affiliation:** _____
Roles / Responsibilities:

Individual: _____ **Title:** _____ **Dept/ Affiliation:** _____
Roles / Responsibilities:

Individual: _____ **Title:** _____ **Dept/ Affiliation:** _____
Roles / Responsibilities:

11. LOCATION OF RESEARCH. List all locations where data collection will take place. Be as specific as possible.

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 B.***

What is the maximum number of potential participants you plan to recruit? _____

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

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

13. **PROJECT DESIGN & 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 Auburn University IRB will not be able to review protocol. If additional space is needed for #13, part b, save the information as a .pdf file and insert after page 6 of this form.)**

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 & 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** ***If "YES", go to part "g".***

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?**

d. **Justify your need to code participants' data or link the 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 cassette, electronic data, etc.), where the data will be stored, and how the location where data is stored will be secured in your 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 be destroyed? (NOTE: Data recorded and analyzed as "anonymous" may be retained indefinitely.)**

PROTOCOL REVIEW CHECKLIST

All protocols must include the following items:

☐ **1.** Research Protocol Review Form (All signatures included and all sections completed)

☐ **2.** Consent Form or Information Letter (examples are found on the OHSR website)

☐ **3.** Appendix A "Reference List"

☐ **4.** Appendix B if flyers, advertisements, generalized announcements or scripts are used to recruit participants.

☐ **5.** 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.

☐ **6.** Appendix D if a debriefing form will be used.

☐ **7.** If research is being conducted at sites other than Auburn University 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.

☐ **8.** Written evidence of acceptance by the host country if research is conducted outside the United States.