AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS

RESEARCH PROTOCOL REVIEW FORM
FULL BOARD or EXPEDITED

For Information or help contact **THE OFFICE OF RESEARCH COMPLIANCE (ORC),** 115 Ramsay Hall, Auburn University
Phone: 334-844-5966 **e-mail:** IRBAdmin@auburn.edu **Web A ddress:** http://w ww .auburn.edu/research/vpr/ohs/index.htm

Revised 2.26.2020 **Submit completed form to IRBsubmit@auburn.edu.**

***Complete this form using Adobe Acrobat** Writer **(versions 5.0 and greater).** Hand written copies not accepted.*

1. PROPOSED START DATE of STUDY:_____ **Today's Date:**_____

PROPOSED REVIEW CATEGORY (Check one): ☐ **FULL BOARD** ☐ **EXPEDITED**

SUBMISSION STATUS (Check one): ☐ **NEW** ☐ **REVISIONS (to address IRB Review Comments)**

2. PROJECT TITLE:

3. _____ **PRINCIPAL INVESTIGATOR** | _____ **TITLE** | _____ **DEPT** | _____ **AU E-MAIL**

_____ **MAILING ADDRESS** | _____ **PHONE** | _____ **ALTERNATE E-MAIL**

4. FUNDING SUPPORT: ☐ N/A ☐ Internal ☐ External Agency: _____ ☐ Pending ☐ Received

For federal funding, list agency and grant number (if available). _____

5a. List any contractors, sub-contractors, other entities associated with this project:

_____

b. List any other IRBs associated with this project (including Reviewed, Deferred, Determination, etc.):

_____

PROTOCOL PACKET CHECKLIST

All protocols must include the following items:

- ☐ **Research Protocol Review Form** (All signatures included and all sections completed)
  (Examples of appended documents are found on the OHSR website: http://www.auburn.edu/research/vpr/ohs/sample.htm)
- ☐ **CITI Training Certificates** for all Key Personnel.
- ☐ **Consent Form or Information Letter** and any Releases (audio, video or photo) that the participant will sign.
- ☐ **Appendix A**, "Reference List"
- ☐ **Appendix B** if e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.
- ☐ **Appendix C** if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to attach them in the order in which they are listed in # 13c.
- ☐ **Appendix D** if you will be using a debriefing form or include emergency plans/procedures and medical referral lists (A referral list may be attached to the consent document).
- ☐ **Appendix E** if research is being conducted at sites other than Auburn University or in cooperation with other entities. A **permission 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.
- ☐ **Appendix F** - Written evidence of acceptance by the host country if research is conducted outside the United States.

6. GENERAL RESEARCH PROJECT CHARACTERISTICS

6A. Research Methodology

Please check all descriptors that best apply to the research methodology.

Data Source(s): ☐ New Data ☐ Existing Data

Will recorded data directly or indirectly identify participants?
☐ Yes ☐ No

Data collection will involve the use of:

☐ Educational Tests (cognitive diagnostic, aptitude, etc.)
☐ Interview
☐ Observation
☐ Location or Tracking Measures
☐ Physical / Physiological Measures or Specimens (see Section 6E.)
☐ Surveys / Questionnaires
☐ Internet / Electronic
☐ Audio
☐ Video
☐ Photos
☐ Digital images
☐ Private records or files
☐ Other: _____

6B. Participant Information

Please check all descriptors that apply to the target population.
☐ Males ☐ Females ☐ AU students

Vulnerable Populations
☐ Pregnant Women/Fetuses ☐ Prisoners ☐ Institutionalized
☐ Children and/or Adolescents (under age 18 in AL)

Persons with:
☐ Economic Disadvantages ☐ Physical Disabilities
☐ Educational Disadvantages ☐ Intellectual Disabilities

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

6C. Risks to Participants

Please identify all risks that participants might encounter in this research.

☐ Breach of Confidentiality* ☐ Coercion
☐ Deception ☐ Physical
☐ Psychological ☐ Social
☐ None
☐ Other:

*Note that if the investigator is using or accessing confidential or identifiable data, breach of confidentiality is always a risk.

6D. Corresponding Approval/Oversight

- **Do you need IBC Approval for this study?**
  ☐ **Yes** ☐ **No**

  If yes, BUA #_____ **Expiration date**_____

- **Do you need** Radiation Safety (RSC) **Approval for this study?**
  ☐ **Yes** ☐ **No**

  If yes, RSC **#**_____ **Expiration date** _____

- **Does this study involve the Auburn University MRI Center?**
  ☐ **Yes** ☐ **No**

  Which MRI(s) will be used for this project? (Check all that apply)
  ☐ **3T** ☐ **7T**

  Does any portion of this project require review by the MRI Safety Advisory Council?
  ☐ **Yes** ☐ **No**

  Signature of MRI Center Representative: _____
  Required for all projects involving the AU MRI Center

  Appropriate MRI Center Representatives:
  Dr. Thomas S. Denney, Director AU MRI Center
  Dr. Ron Beyers, MR Safety Officer

7. PROJECT ASSURANCES

A. PRINCIPAL INVESTIGATOR'S ASSSURANCES

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 ofResearch Compliance
    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 Research Compliance 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 ORC, 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 Research Compliance 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.

My signature indicates that I have read, understand and agree to conduct this research project in accordance with the assurances listed above.

Printed name of Principal Investigator	**Principal Investigator's Signature**	**Date**

B. FACULTY ADVISOR/SPONSOR'S ASSURANCES

1. I have read the protocol submitted for this project for content, clarity, and methodology.
2. By my signature as faculty advisor/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.
3. I agree to meet with the investigator on a regular basis to monitor study progress. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
4. I assure that the investigator will promptly report significant incidents and/or adverse events and/or effects to the ORC in writing within 5 working days of the occurrence.
5. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the ORC by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of renewals, modifications or the final report, I will assume that responsibility.

Printed name of Faculty Advisor / Sponsor	**Faculty Advisor's Signature**	**Date**

C. DEPARTMENT HEAD'S ASSSURANCE

By my signature as department head, I certify that I will cooperate with the administration in the application and enforcement of all Auburn University policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department.

Printed name of Department Head	**Department Head's Signature**	**Date**

8. **PROJECT OVERVIEW: Prepare an abstract that includes:**
(**350** word maximum, in language understandable to someone who is not familiar with your area of study**):**

   a) **A summary of relevant research findings leading to this research proposal:**
   (*Cite sources; include a "Reference List" as* ***Appendix A.)***
   b) **A brief description of the methodology, including design, population, and variables of interest**

9. **PURPOSE.**
   a. **Clearly state the purpose of this project and all research questions, or aims.**

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

10. **KEY PERSONNEL.** Describe responsibilities. Include information on research training or certifications related to this project. **CITI is required. Be as specific as possible.** (Include additional personnel in an attachment.) *All key personnel must* ***attach CITI certificates of completion.***

Principal Investigator _____ **Title:** _____ **E-mail address** _____

Dept / Affiliation: _____

Roles / Responsibilities:

Individual: _____ **Title:** _____ **E-mail address** _____

Dept / Affiliation: _____

Roles / Responsibilities:

Individual: _____ **Title:** _____ **E-mail address** _____

Dept / Affiliation: _____

Roles / Responsibilities:

Individual: _____ **Title:** _____ **E-mail address** _____

Dept / Affiliation: _____

Roles / Responsibilities:

Individual: _____ **Title:** _____ **E-mail address** _____

Dept / Affiliation: _____

Roles / Responsibilities:

Individual: _____ **Title:** _____ **E-mail address** _____

Dept / Affiliation: _____

Roles / Responsibilities:

11. **LOCATION OF RESEARCH. List all locations where data collection will take place.** (School systems, organizations, businesses, buildings and room numbers, servers for web surveys, etc.) **Be as specific as possible. Attach permission letters in Appendix E.**
(See sample letters at http://www.auburn.edu/research/vpr/ohs/sample.htm)

12. PARTICIPANTS.

a. Describe the participant population you have chosen for this project including inclusion or exclusion criteria for participant selection.

☐ **Check here if using existing data, describe the population from whom data was collected, & include the # of data files.**

b. **Describe, step-by-step, in layman's terms, all procedures you will use to recruit participants.** *Include in* ***Appendix B*** *a copy of all e-mails, flyers, advertisements, recruiting scripts, invitations, etc., that will be used to invite people to participate. (See sample documents at http://www.auburn.edu/research/vpr/ohs/sample.htm.)*

c. What is the minimum number of participants you need to validate the study? _____

How many participants do you expect to recruit? _____

Is there a limit on the number of participants you will include in the study? ☐ **No** ☐ **Yes – the # is** _____

d. Describe the type, amount and method of compensation and/or incentives for participants.

(If no compensation will be given, check here: ☐)

Select the type of compensation: ☐ Monetary ☐ Incentives

☐ Raffle or Drawing incentive (Include the chances of winning.)
☐ Extra Credit (State the value)
☐ Other

Description:

13. PROJECT DESIGN & METHODS.

a. Describe, step-by-step, all procedures and methods that will be used to consent participants. If a waiver is being requested, check each waiver you are requesting, describe how the project meets the criteria for the waiver.

- ☐ **Waiver of Consent (including using existing data)**
- ☐ **Waiver of Documentation of Consent (use of Information Letter)**
- ☐ **Waiver of Parental Permission (for college students)**

b. Describe the research design and methods you will use to address your purpose. Include a clear description of when, where and how you will collect all data for this project. Include specific information about the participants' time and effort commitment. (*NOTE: Use language that would be understandable to someone who is not familiar with your area of study. Without a complete description of all procedures, the Auburn University IRB will not be able to review this protocol.* ***If additional space is needed for this section, save the information as a .PDF file and insert after page 7 of this form.***)

13. **PROJECT DESIGN & METHODS.** *Continued*

c. **List all data collection instruments used in this project, in the order they appear in Appendix C.**
(e.g., surveys and questionnaires **in the format that will be presented to participants**, educational tests, data collection sheets, interview questions, audio/video taping methods etc.)

d. **Data analysis: Explain how the data will be analyzed.**

14. **RISKS & DISCOMFORTS: List and describe all of the risks that participants might encounter 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 in Appendix D.*** *(Examples of possible risks are in section #6D on page 2)*

15. **PRECAUTIONS.** Identify and describe all precautions you have taken to eliminate or reduce risks as listed in #14. 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. ***Provide a copy of any emergency plans/procedures and medical referral lists in Appendix D. (Samples can be found online at http://www.auburn.edu/research/vpr/ohs/sample.htm#precautions)***

If using the Internet or other electronic means to collect data, what confidentiality or security precautions are in place to protect (or not collect) identifiable data? Include protections used during both the collection and transfer of data.

16. **BENEFITS.**

a. List all realistic direct benefits participants can expect by participating in this specific study.
(Do not include "compensation" listed in #12d.) Check here if there are no direct benefits to participants. ☐

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

17. **PROTECTION OF DATA.**

a. Data are collected:

☐ **Anonymously with no direct or indirect coding, link, or awareness of who participated in the study (Skip to e)**

☐ **Confidentially, but without a link of participant's data to any identifying information (collected as "confidential" but recorded and analyzed as "anonymous") (Skip to e)**

☐ **Confidentially with collection and protection of linkages to identifiable information**

b. If data are collected with identifiers or as coded or linked to identifying information, describe the identifiers collected and how they are linked to the participant's data.

c. Justify your need to code participants' data or link the data with identifying information.

d. Describe how and where identifying data and/or code lists will be stored. (Building, room number?) **Describe how the location where data is stored will be secured in your absence. For electronic data, describe security. If applicable, state specifically where any IRB-approved and participant-signed consent documents will be kept on campus for 3 years after the study ends.**

e. Describe how and where the data will be stored (e.g., hard copy, audio cassette, electronic data, etc.)**, and how the location where data is stored is separated from identifying data and will be secured in your absence. For electronic data, describe security**

f. Who will have access to participants' data?
(*The faculty advisor should have full access and be able to produce the data in the case of a federal or institutional audit*.)

g. When is the latest date that identifying information or links will be retained and how will that information or links be destroyed?
(Check here if only anonymous data will be retained ☐)