**AUBURN UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM (HRPP)**

**CEDED REVIEW APPLICATION
(For use in expedited and convened research studies when AU is a study site and will rely on an External IRB)**

For assistance, contact: **The Office of Research Compliance (ORC)**

Phone: **334-844-5966** E-Mail: **IRBAdmin@auburn.edu** Web Address: [**http://www.auburn.edu/research/vpr/ohs**](http://www.auburn.edu/research/vpr/ohs)

 **Submit completed form and supporting materials as one PDF to** [**IRB Submission Page**](https://auburn-650430.workflowcloud.com/forms/58a0c1d0-4826-4b79-a1ec-15b359f81c8f)**.

1. Project Identification Today’s Date:** Click or tap to enter a date.

 **Anticipated start date of the project:**Click or tap to enter a date.**Anticipated duration of project:**Choose an item.

1. **Project Title:** Click or tap here to enter text.
2. **AU Principal Investigator (PI):** Click or tap here to enter text.Degree(s): Click or tap here to enter text.Rank/Title: Choose Rank/Title Department/School: Choose Department/School

Role/responsibilities in this project:Click or tap here to enter text.

Preferred Phone Number:Click or tap here to enter text. AU Email: Click or tap here to enter text.
**AU Faculty Advisor Principal Investigator (if applicable):** Click or tap here to enter text.Rank/Title:Choose Rank/Title Department/School:Choose Department/SchoolRole/responsibilities in this project:Click or tap here to enter text.

Preferred Phone Number:Click or tap here to enter text. AU Email: Click or tap here to enter text. **AU Department Head:** Click or tap here to enter text.Department/School:Choose Department/SchoolPreferred Phone Number:Click or tap here to enter text.AU Email: Click or tap here to enter text.

Role/responsibilities in this project: Click or tap here to enter text.

1. **AU Key Personnel:** [(link to decision tree)](https://cws.auburn.edu/OVPR/pm/compliance/irb/guidance) (Add additional key personnel by copy and paste this item)

Name: Click or tap here to enter text. Degree(s):Click or tap here to enter text.Rank/Title:Choose Rank/Title Department/School: Choose Department/SchoolRole/responsibilities in this project: Click or tap here to enter text.

- Do you have any known competing financial interests, personal relationships, or other interests that
 could have influence or appear to have influence on the work conducted in this project? [ ]  Yes [ ]  No
- If yes, briefly describe the potential or real conflict of interest:Click or tap here to enter text.- Completed required CITI training? [ ]  Yes [ ]  No If NO, complete the appropriate [CITI basic course](https://cws.auburn.edu/OVPR/pm/compliance/irb/training)
- If YES, choose course(s) the researcher has completed: Choose a course Expiration Date

1. **Reliance Information** (note the AU IRB does not enter into agreements for EXEMPT level research)

Reviewing IRB Protocol Number: Click or tap here to enter text.

Reviewing IRB (IRB that will be relied on): Click or tap here to enter text.

Plan for Reliance (drop down that include IAA, SMART IRB, and OTHER): Click or tap here to enter text.

If IIA, copy of the reliance agreement included: [ ] Yes[ ] No

Lead Site: Click or tap here to enter text. Lead PI: Click or tap here to enter text.

Funding Source: Click or tap here to enter text.

Funding Source Type (governmental, corporate, etc.): Click or tap here to enter text.
AU OSP Number: Click or tap here to enter text.

If an IAA is the plan for reliance, only when a copy of the final version of the IAA (which includes all requested information and signatures of both Institutions’ Signatory Officials) is received and reviewed by the IRB Reviewer will IRB approval of the reliance agreement by issued. No research activities may occur until IRB approval is issued. **Select YES to acknowledge this process.** [ ]  **YES**

**2. Project Summary**

1. **Purpose:** Click or tap here to enter text.
2. **Scope of Work** (Describe the research activities of AU key personnel)**:** Click or tap here to enter text.
3. **Does the study *TARGET* any special populations?** Answer YES or NO to all.

 Minors (under 18 years of age) Yes [ ]  No [ ]

 Auburn University Students Yes [ ]  No [ ]

 Pregnant women, fetuses, or any products of conception Yes [ ]  No [ ]

 Prisoners or wards (unless incidental, not allowed for Exempt research) Yes [ ]  No [ ]

 Temporarily or permanently impaired Yes [ ]  No [ ]

1. **Does the study involve any of the following?**

 Procedures subject to FDA regulations (drugs, devices, etc.) Yes [ ]  No [ ]

 Use of school records of identifiable students or information from
 instructors about specific students. Yes [ ]  No [ ]

 Protected health or medical information when there is a direct or indirect
 link which could identify the participant. Yes [ ]  No [ ]

 Collection of sensitive aspects of the participant’s own behavior,

 such as illegal conduct, drug use, sexual behavior or alcohol use. Yes [ ]  No [ ]

1. **Study Materials:** If available, submit a copy of all template study materials, as applicable for the AU site,
2. **Provisions to maintain confidentiality of data, including collection, transmission to/from AU, and storage at AU.:** Click or tap here to enter text.

**3. Assurances**

1. **Principal Investigator’s Assurances:**
	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 care 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 polices 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 Research Compliance
		3. Obtaining the legally effective in 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
		4. Promptly reporting significant adverse events and/or effects to the Office of Research Compliance in writing within 5 working days on 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 IRB of the project.

**Signature of Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of AU Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_**

1. **Department Head’s Assurance:**
	1. By my signature as department head, I certify 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.

**Signature of AU Department Head: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of AU Department Head: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**4. Attachments** List all attachments included with the submission. (CITI documentation; external IRB
 materials, etc.)Click or tap here to enter text.