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

**EXEMPT REVIEW APPLICATION**

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** **IRBsubmit@auburn.edu** **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. **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.
**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. **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. **Project Key Personnel –** Identify all key personnel who will be involved with the conduct of the research and describe their role in the project. Role may include design, recruitment, consent process, data collection, data analysis, and reporting. ([To determine key personnel, see decision tree](https://grants.nih.gov/policy/clinical-trials/ct-decision-tree.pdf)**).** *Exempt determinations are made by individual institutions; reliance on other institutions for exempt determination is not feasible. Non-AU personnel conducting exempt research activities must obtain approval from the IRB at their home institution.*

Key personnel are required to maintain human subjects training through [CITI](https://cws.auburn.edu/OVPR/pm/compliance/irb/training). Only for EXEMPT level research is documentation of completed CITI training NO LONGER REQUIRED to be included in the submission packet. NOTE however, **the IRB will perform random audits of CITI training records to confirm** reported training courses and expiration dates. Course title and expiration dates are shown on training certificates.

**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.AU Affiliated?[ ] Yes[ ] No If no, name of home institution:Click or tap here to enter text.Plan for IRB approval for non-AU affiliated personnel?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) and revise the Exempt Application form.

If YES, choose course(s) the researcher has completed: Choose a course Expiration Date
 Choose a course Expiration Date

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If YES, choose course(s) the researcher has completed: Choose a course Expiration Date
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If YES, choose course(s) the researcher has completed: Choose a course Expiration Date
 Choose a course Expiration Date

1. **Funding Source –** Is this project funded by the investigator(s)? Yes [ ]  No [ ]
Is this project funded by AU? Yes [ ]  No [ ]  If YES, identify source Click or tap here to enter text.
Is this project funded by an external sponsor? Yes [ ]  No [ ]  If YES, provide name of sponsor, type of sponsor (governmental, non-profit, corporate, other), and an identification number for the award.
Name:Click or tap here to enter text.Type:Click or tap here to enter text.Grant #:Click or tap here to enter text.
2. List other AU IRB-approved research projects and/or IRB approvals from other institutions that are associated with this project. Describe the association between this project and the listed project(s):
Click or tap here to enter text.

**2. Project Summary**

 **a. Does the study *TARGET* any special populations?** Answer YES or NO to all.

 Minors (under 18 years of age) 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 [ ]

 **b. Does the research pose more than minimal risk to participants?**  Yes [ ]  No [ ]
 *If YES, to question 2.b, then the research activity is NOT eligible for EXEMPT review.*

 *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the
 research is not greater in and of themselves than those ordinarily encountered in daily life or during
 the performance of routine physical or psychological examinations or test. 42 CFR 46.102(i)*

**c. Does the study involve any of the following?** *If YES to any of the questions in item 2.c, then the*

 *research activity is NOT eligible for EXEMPT review.*

 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 [ ]

**d**. **Does the study include deception? Requires limited review by the IRB\*** Yes [ ]  No [ ]

**3.** **MARK the category or categories below that describe the proposed research. Note the IRB Reviewer**

 **will make the final determination of the eligible category or categories.**

 [ ]  **1.** Research conducted in established or commonly accepted educational settings, involving normal
 educational practices. The research is not likely to adversely impact students’ opportunity to learn
 or assessment of educators providing instruction. 104(d)(1)

 [ ]  **2.** Research only includes interactions involving educational tests, surveys, interviews, public
 observation if at least ONE of the following criteria. (The research includes data collection only;
 may include visual or auditory recording; may NOT include intervention and only includes
 interactions). **Mark the applicable sub-category below (I, ii, or iii). 104(d)(2)** [ ]  **(i)** Recorded information cannot readily identify the participant (directly or indirectly/ linked);
 **OR
 -** surveys and interviews: no children;
 **-** educational tests or observation of public behavior: can only include children when investigators
 do not participate in activities being observed.

 [ ]  **(ii)** Any disclosures of responses outside would not reasonably place participant at risk; **OR**

 [ ]  **(iii)** Information is recorded with identifiers or code linked to identifiers and IRB conducts limited
 review; no children. **Requires limited review by the IRB.\*** [ ]  **3.** Research involving Benign Behavioral Interventions (BBI)\*\* through verbal, written responses
 including data entry or audiovisual recording from adult subjects who prospectively agree and
 ONE of the following criteria is met. (This research does not include children and does not
 include medical interventions. Research cannot have deception unless the participant
 prospectively agrees that they will be unaware of or misled regarding the nature and purpose of
 the research) **Mark the applicable sub-category below (A, B, or C).** 104(d)(3)(i)
[ ]  **(A)** Recorded information cannot readily identify the subject (directly or indirectly/ linked); **OR** [ ]  **(B)** Any disclosure of responses outside of the research would not reasonably place subject at risk;
 **OR** [ ]  **(C)** Information is recorded with identifies and cannot have deception unless participants
 prospectively agrees. **Requires limited review by the IRB.\*** [ ]  **4.** Secondary research for which consent is not required: use of identifiable information or
 identifiable bio-specimen that have been or will be collected for some other ‘primary’ or ‘initial’
 activity, if one of the following criteria is met. Allows retrospective and prospective secondary
 use. **Mark the applicable sub-category below (i, ii, iii, or iv).** 104 (d)(4)[ ]  **(i)** Bio-specimens or information are publicly available;
[ ]  **(ii)** Information recorded so subject cannot readily be identified, directly or indirectly/linked;
 investigator does not contact subjects and will not re-identify the subjects; **OR**

[ ]  **(iii)** Collection and analysis involving investigators use of identifiable health information when use
 is regulated by HIPAA “health care operations” or “research” or “public health activities and
 purposes” (does not include bio-specimens (only PHI and requires federal guidance on how to
 apply); **OR** [ ]  **(iv)** Research information collected by or on behalf of federal government using government
 generated or collected information obtained for non-research activities.
[ ]  **5.** Research and demonstration projects which are supported by a federal agency/department AND
 designed to study and which are designed to study, evaluate, or otherwise examine: (i)public
 benefit or service programs; (ii) procedures for obtaining benefits or services under those
 programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv)
 possible changes in methods or levels of payment for benefits or service under those programs.
 (must be posted on a federal web site). 104.5(d)(5) (must be posted on a federal web site)

[ ]  **6.** Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods
 without additives and consumed or (ii) if a food is consumed that contains a food ingredient at or
 below the level and for a use found to be safe, or agricultural chemical or environmental
 contaminant at or below the level found to be safe, by the Food and Drug Administration or
 approved by the Environmental Protection Agency or the Food Safety and Inspection Service of
 the U.S. Department of Agriculture. The research does not involve prisoners as participants.
 104(d)(6)

***\*****Limited IRB review – the IRB Chair or designated IRB reviewer reviews the protocol to ensure adequate provisions are in place to protect privacy and confidentiality.*

*\*\*Category 3 – Benign Behavioral Interventions (BBI) must be brief in duration, painless/harmless, not physically invasive, not likely to have a significant adverse lasting impact on participants, and it is unlikely participants will find the interventions offensive or embarrassing.*

*\*\*\* Exemption categories 7 and 8 require broad consent. The AU IRB has determined the regulatory requirements for legally effective broad consent are not feasible within the current institutional infrastructure. EXEMPT categories 7 and 8 will not be implemented at this time.*

**4. Describe the proposed research including who does what, when, where, how, and for how long, etc.**

**a**. Purpose

 Click or tap here to enter text.

**b**. Participant population, including the number of participants and the rationale for determining the

number of participants to recruit and enroll.

 Click or tap here to enter text.

**c.** Recruitment process. Address whether recruitment includes communications/interactions between

study staff and potential participants either in person or online. *Submit a copy of all recruitment materials.*

 Click or tap here to enter text.

**d.** Consent process including how information is presented to participants, etc.
 Click or tap here to enter text.

**e**. Research procedures and methodology
 Click or tap here to enter text.

1. Anticipated time per study exercise/activity and total time if participants complete all study activities.
 Click or tap here to enter text.
2. Location of the research activities.
Click or tap here to enter text.
3. Costs to and compensation for participants? If participants will be compensated describe the amount, type, and process to distribute.
 Click or tap here to enter text.
4. Non-AU locations, site, institutions. *Submit a copy of agreements/IRB approvals.*

 Click or tap here to enter text.

1. Additional relevant information.

 Click or tap here to enter text.

**5. Waivers
Check applicable waivers and describe how the project meets the criteria for the waiver.**

 [ ]  Waiver of Consent (Including existing de-identified data)

 [ ]  Waiver of Documentation of Consent (Use of Information Letter, rather than consent
 form requiring signatures)

 [ ]  Waiver of Parental Permission (in Alabama, 18 years-olds may be considered adults

 for research purposes)

1. Provide the rationale for the waiver request.
Click or tap here to enter text.

**6. Describe the process to select participants/data/specimens. If applicable, include gender, race, and
 ethnicity of the participant population.**

Click or tap here to enter text.

**7. Describe why none of the research procedures would cause a participant either physical or
 psychological discomfort or be perceived as discomfort above and beyond what the person would
 experience in daily life (minimal risk).** Click or tap here to enter text.

**8. Describe the provisions to maintain confidentiality of data, including collection, transmission, and
 storage. Identify platforms used to collect and store study data.**  *For EXEMPT research, the AU IRB*

 *recommends AU BOX or using an AU issued and encrypted device. If a data collection form will be used, submit a*

 *copy.*

 Click or tap here to enter text.

1. If applicable, submit a copy of the data management plan or data use agreement.

**9. Describe the provisions included in the research to project the privacy interests of participants
 (e.g., others will not overhear conversations with potential participants, individuals will not be**

 **publicly identified or embarrassed).** Click or tap here to enter text.

**10. Additional Information and/or attachments.**

 *In the space below, provide any additional information you believe may help the IRB review of the
 proposed research. If attachments are included, list the attachments below.*

 *Attachments may include recruitment materials, consent documents, site permissions, IRB approvals from other
 institutions, data use agreements, data collection form, CITI training documentation, etc.* Click or tap here to enter text.

**Required Signatures** *(If a student PI is identified in item 1.a, the EXEMPT application must be re-signed and updated at every revision by the student PI and faculty advisor. The signature of the department head is required only on the initial submission of the EXEMPT application, regardless of PI. Staff and faculty PI submissions require the PI signature on all version, the department head signature on the original submission)* **Signature of Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Faculty Advisor (If applicable):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Dept. Head: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Version Date:** Click or tap to enter a date.