Auburn University Human Research Protection Program

EXEMPTION REVIEW APPLICATION

For information or help completing this form, contact: **THE OFFICE OF RESEARCH COMPLIANCE**
Phone: 334-844-5966 **Email:**IRBAdmin@auburn.edu

Submit completed application and supporting material as one attachment to IRBsubmit@auburn.edu.

1. PROJECT IDENTIFICATION **Today'sDate** _____

a. Project Title _____

_____

b. Principal Investigator_____Degree(s)_____
Rank/Title_____Department/School_____
Phone Number_____AU Email _____

Faculty Principal Investigator (required if PI isa student) _____
Title_____Department/School_____
Phone Number_____AU Email _____

Dept Head_____Department/School_____
Phone Number_____AU Email _____

c. Project Personnel – Identify all individuals who will be involved with the conduct of the research and include their role on the project. Role may include design, recruitment, consent process, data collection, data analysis, and reporting. Attach a table if needed for additional personnel.

Personnel Name_____Degree (s) _____
Rank/Title_____Department/School_____
Role_____
AU affiliated? ☐ YES ☐ NO If no, name of home institution _____
Plan for IRB approval for non-AU affiliated personnel? _____

Personnel Name_____Degree (s) _____
Rank/Title_____Department/School_____
Role_____
AU affiliated? ☐ YES ☐ NO If no, name of home institution _____
Plan for IRB approval for non-AU affiliated personnel? _____

Personnel Name_____Degree (s) _____
Rank/Title_____Department/School_____
Role_____
AU affiliated? ☐ YES ☐ NO If no, name of home institution _____
Plan for IRB approval for non-AU affiliated personnel? _____

d. Training – Have all Key Personnel completed CITI human subjects training (including elective modules related to this research) within the last 3 years? YES ☐ NO ☐

Allow Space for the

AU IRB Stamp

e. Funding source – Is this project funded by the investigator(s)? ☐ YES ☐ NO
Is this project funded by AU? ☐ YES ☐ NO If YES, identify source _____
Is this project funded by an external sponsor? ☐ YES ☐ No If YES, provide the name of the sponsor, type of sponsor (governmental, non-profit, corporate, other), and an identification number for theaward.
Name_____Type_____Grant # _____

f. List other AU IRB-approved research studies and/or IRB approvals from other institutions that are associated with this project.

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2. Mark the category or categories below that describe the proposedresearch:

☐ 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 (directlyorindirectly/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 placesubject at risk; **OR**

☐ **(C)** Information is recorded with identifiers and cannot have deception unless participant 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) Biospecimens or information are publically available;

☐ (ii) Information recorded so subject cannot readily be identified, directlyorindirectly/linked; investigator does not contact subjects and will not re-identify thesubjects;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 biospecimens (only PHI and requires federal guidance on how to apply); OR

☐ (iv) Research information collected by or on behalf of federal government usinggovernment generated or collected information obtained for non-researchactivities.

☐ 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 services under those programs. (must be posted on a federal web site). 104(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 are 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)

New exemption categories 7 and 8: Both categories 7 and 8 require Broad Consent. **(**Broad consent is a new type of informed consent provided under the Revised Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal, or for materials that are collected for non-research purposes, such as materials that are left over from routine clinical diagnosis or treatments. Broad consent does not apply to research that collects information or biospecimens from individuals through direct interaction or intervention specifically for the purpose of the research.) **The Auburn University IRB has determined that as currently interpreted, Broad Consent is not feasible at Auburn and these 2 categories WILL NOT BE IMPLEMENTED at this time.**

Limited IRB review* **– the IRB Chairs 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.**

3. PROJECT SUMMARY

a. Does the study target any special populations? (Mark applicable)

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

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are 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?

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
Deception of participants	☐ YES ☐ NO

4. Briefly describe the proposed research, including purpose, participant population, recruitment process, consent process, research procedures and methodology.

5. Waivers

Check any waivers that apply and describe how the project meets the criteria for the waiver. Provide the rationale for the waiver request.

- ☐ **Waiver of Consent (Including existing de-identified data)**
- ☐ **Waiver of Documentation of Consent (Use of Information Letter)**
- ☐ **Waiver of Parental Permission**

All retrospective information will be de-identified.

6. Describe how participants/data/specimens will be selected. If applicable, include gender, race, and ethnicity of the participant population.

7. Does the research involve deception? ☐ YES ☐ NO If YES, please provide the rationale for deception and describe the debriefing process.

8. 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.

9. Describe the provisions to maintain confidentiality of data, including collection, transmission, and storage.

10. 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).

11. Will the research involve interacting (communication or direct involvement) with participants?
☐ **YES** ☐ **NO If YES, describe the consent process and information to be presented to subjects. This includes identifying that the activities involve research; that participation is voluntary; describing the procedures to be performed; and the PI name and contact information.**

12. 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, etc.

Principal Investigator's Signature_____ **Date** _____

If PI is a student,
Faculty Principal Investigator's Signature _____ **Date** _____

Department Head's Signature_____ **Date** _____