Oklahoma State University Center for Health Sciences
Institutional Review Board
1111 W. 17th St
Tulsa, OK 74107
918-561-1400

Application for Exempt Human Research

Complete this application only if you believe your study qualifies as exempt research based on the categories found at **45 CFR 46.101(b).** The OSU CHS IRB will make the final determination of exempt research projects. The exempt determination must be granted in writing by the OSU-CHS IRB before research can begin on the project. Exempt research must adhere to the same ethical principles governing all research. If the IRB determines the research to be non-exempt, the project must be resubmitted using the "Application for Human Research" form to again proceed through the IRB review process.

Protocol Title		
Principal Investigator "PI"		**Email**

Documents included in this submission	**Version # and/or Date as applicable**	**Check if Submitted**	**Check if NA**
Contact Information Sheet for PI(s)		☐	
If PI is a student, resident, or fellow, also include a Contact Information Sheet for the Faculty Advisor		☐	☐
Recruitment and Advertising materials		☐	☐
Evaluation Instruments (to be completed by subjects) and Surveys		☐	☐
Data Collection Tool		☐	☐
Grant Proposal or Award Document		☐	☐
Other:		☐	☐

Vulnerable Populations

Research involving these vulnerable groups CANNOT be exempt:

- ☐ Children/Minors
- ☐ Mentally impaired
- ☐ Human in vitro fertilization or fetuses
- ☐ Pregnant Women
- ☐ Prisoners

If you checked ANY of the boxes above, your research is NOT EXEMPT according to local IRB policy. Do not complete this application. Complete the "Application for Human Research".

Research Subject to FDA Regulations

Is this research subject to FDA regulations (e.g. drug, device, or biologic)?

☐ No ☐ Yes If yes, do not complete this form. Please contact the IRB Office.

Project Description

Provide detail sufficient for the IRB to determine eligibility for exemption

Anticipated dates to start and complete the study:

Purpose and general description, including experimental design:

Number of study participants:

Study population/specimens/data (e.g., healthy adults age 18-45). Indicate inclusions / exclusions:

Participant recruitment process (include copies of all recruitment materials):

Category of Exemption

Instructions: Please indicate the exemption category (1 through 6) by completing the relevant category section(s) below. Please note that federal regulations do not permit any new categories and only the IRB may determine which research activities qualify for an exempt review. To be exempt, research involving human subjects must involve only activities in one or more of the following categories.

☐ ***Category 1***

Both of the following are true:

☐ Research conducted in established or commonly accepted educational settings

☐ The research involves normal educational practices, Examples include (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Describe the established or commonly accepted educational settings in which this research will be conducted:

Describe the normal educational practices that will be part of this study:

☐ ***Category 2***

Both of the following are true:

☐ The research involves the use of one or more of the following:

- ☐ Educational tests (cognitive, diagnostic, aptitude, achievement)
- ☐ Survey procedures
- ☐ Interview procedures
- ☐ Observation of public behavior

☐ Information obtained is recorded in such a manner that either:

- ☐ Participants CANNOT be identified, directly or through identifiers linked to the participants
- ☐ Both of the following are true:
  - ☐ Participants CAN be identified, directly or through identifiers linked to the participants.
  - ☐ Any disclosure of the participants' responses outside the research could NOT reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

Educational tests, survey procedures, interview procedures and methods of observation of public behavior to be used:

If participants will not be identifiable, directly or through identifiers linked to the participants, how will this be accomplished?

If participants will be identifiable, how will disclosure of the participants' responses outside the research not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation?

☐ ***Category 3***

All of the following are true:

☐ The research is **NOT** exempt under Category 2 above

☐ The research involves the use of one or more of the following:

- ☐ Educational tests (cognitive, diagnostic, aptitude, achievement)
- ☐ Survey procedures
- ☐ Interview procedures
- ☐ Observation of public behavior

☐ Either of the following is true:

- ☐ The participants are elected or appointed public officials or candidates for public office
- ☐ Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

Educational tests, survey procedures, interview procedures and methods of observation of public behavior to be used:

If participants will not be identifiable, directly or through identifiers linked to the participants, how will this be accomplished?

If participants will be identifiable, how will disclosure of the participants' responses outside the research not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation?

Procedures that will be used to select elected or appointed public officials or candidates for public office as the only participants in this project:

Cite the federal statute(s) that require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter:

☐ ***Category 4***

Both of the following are true:

☐ The research involves the collection or study of existing data, documents, records, pathological

specimens, or diagnostic specimens (i.e., the materials to be collected or studied exist at the time that applicant makes first application to the IRB).

☐ At least one of the following is true:

- ☐ These sources are publicly available
- ☐ Information is recorded in such a manner that both of the following are true
  - ☐ Participants cannot be identified directly
  - ☐ Participants cannot be identified through identifiers linked to them

Source of the existing data to be collected for this project:

Date range of the data to be collected (Provide specific dates and state whether the data will be in existence at the time you submit this application to the IRB):

Describe either how the information to be collected is available publicly or how the information will be recorded so that participants cannot be identified either directly or through identifiers linked to them. (e.g. Study data will not include direct identifiers or a code linking data to participant's identity):

Indicate who will access medical or academic records and how they have valid clinical or academic access to these records (e.g., involved in the patients' care). Valid access is defined as an individual having access to the records as part of usual clinical or academic activities:

☐ ***Category 5***[1]

All of the following are true:

☐ The project is a research or demonstration project

☐ The project is conducted by or subject to the approval of Department or Agency heads

☐ The project is 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

[1] *According to OHRP, this exemption is most appropriately invoked with authorization or concurrence by the funding agency.*

☐ ***Category 6***

All of the following are true:

☐ The research involves a taste and food quality evaluation and consumer acceptance studies

☐ One of the following is true:

- ☐ Wholesome foods without additives will be consumed
- ☐ A food will be consumed that contains a food ingredient and both of the following are true:
  - ☐ The food ingredient is at or below the level to be safe
  - ☐ The food ingredient is for a use found to be safe
- ☐ A food will be consumed that contains an agricultural chemical or environmental contaminant and one of the following is true:
  - ☐ The agricultural chemical or environmental contaminant is at or below the level found to be safe by the Food and Drug Administration

☐ The agricultural chemical or environmental contaminant is at or below the level approved by the Environmental Protection Agency

☐ The agricultural chemical or environmental contaminant is at or below the level approved by the Food Safety and Inspection Service of the U.S. Department of Agriculture

Financial Information

Will subjects be paid or otherwise compensated for research participation? ☐ Yes ☐ No

If yes, please respond to the following questions:

1) What is the nature of any compensation to subjects? Include cash, gifts, research credit, etc.

2) When and how is the compensation provided to the subject?

3) What is the effect on compensation if a subject does not complete the study?

Is there any internal or external funding (e.g., grants, contracts, gifts, etc.)? ☐ Yes ☐ No

If yes, name of Sponsor or Grant Program (attach a copy of the proposal and/or award document):

Investigator Statement

By signing this form, I acknowledge and agree that all information submitted is accurate.

Investigator signature	Date

If the PI is a student, the Faculty Advisor must also sign.

As faculty advisor for the named student investigator, I assume the roles and responsibilities required to oversee the conduct of this research, prevent harms to subjects and foster benefits to the subjects. I will report any changes in the project, adverse events, or incidents to the IRB which may affect the conduct of this project.

Faculty Advisor signature	Date