

APPENDIX L Exempt Research Application Form

Applicable Policy – 45 CFR 46.101(b)

Instructions:

- Complete this application only if you believe your study qualifies as exempt research based on the categories below. 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 IRB Review form (Appendix B) to again proceed through the IRB review process.

1. Research Protocol Title

2. Investigator(s) Contact Information

Principal Investigator [the person responsible for the overall conduct of the project]:
(Name, Degree, Department, Address, Phone, Human Participant Research Certification)

Collaborating Investigators: (for each: Name, Degree, Department, University, Address, Phone, Human Participant Research Certification)

3. Duration of Study

Anticipated Time to Complete the Study: _____

4. Research involving these vulnerable groups CANNOT be exempt:

- Children
- Mentally impaired
- Fetuses
- Pregnant Women
- Human *in vitro* fertilization
- 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 IRB Review (Appendix B).

5. Category of Exemption: Please indicate your exemption category choice by completing the relevant categories from the list below. Please note: 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. By selecting one or more of the categories below, the applicant is indicating that the research involves only these activities.

KEY: Solid box: All items in the box must be true Dotted box: One item in the box must be true.

Category 1 (All 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
- The research is NOT subject to FDA regulation (e.g.; drug, devices, or biologics)

Category 2 (All 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

When the research involves children as participants, the procedures are limited to:

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Observation of public behavior where the investigator(s) will **NOT** participate in the activities being observed

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.

The research is **NOT** subject to FDA regulation (e.g.; drug, devices, or biologics)

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

The research is **NOT** subject to FDA regulation (e.g.; drug, devices, or biologics)

Category 4 (All 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

Information¹ 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

¹Protocol must contain what information is recorded and how it is recorded.

The research is **NOT** subject to FDA regulation (e.g.; drug, devices, or biologics)

Category 5² (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

The research is **NOT** subject to FDA regulation (e.g.; drug, devices, or biologics)

² 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

6. Project Description (Provide detail sufficient for the IRB to determine eligibility for exemption)

a. Purpose and general description, including experimental design: _____

b. Number of study participants: _____

c. Study population/specimens/data (e.g., healthy adults age 18-45): _____

d. Participant recruitment process (include copies of all recruitment materials): _____

e. If you will be using a questionnaire, survey or interview procedure, please indicate the setting where the research will take place (NOTE: Interview or survey research involving children cannot be exempt from IRB review.): _____

7. Category 1 Details (Complete only if you selected Category #1 in Section 5 above)

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

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

8. Category 2 or 3 Details (Complete only if you selected Category #2 or #3 in Section 5 above)

a. Number and age range of participants: _____

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

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

d. 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? _____

e. (Category 3 only) Procedures that will be used to select elected or appointed public officials or candidates for public office as the only participants in this project: _____

f. (Category 3 only) 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: _____

9. Category 4 Details (Complete only if you selected category #4 in section 5 above)

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

b. 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): _____

c. Number of people whose data will be collected: _____

d. 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): _____

e. 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 individual having access to the records as part of usual clinical or academic activities: _____

f. Attach a copy of the data collection sheet that details the data to be collected for this project. If a data collection sheet is not being attached to this application, explain why:

10. Financial Information

a. 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) What is the dollar amount, if applicable, and method of payment? _____
- 3) When and how is the compensation provided to the subject? _____
- 4) What is the effect on compensation if a subject does not complete the study?

b. Is there any internal or external funding (e.g., grants, contracts, gifts, etc.)?

Yes No

If yes: 1) Name of Sponsor or Grant Program: _____

2) Attach a copy of the proposal and/or award document.