EXEMPT RESEARCH REQUEST

PURDUE INSTITUTIONAL REVIEW BOARD (IRB) REVIEW v.20160525

Research activities are exempt from IRB oversight when the ONLY involvement of human subjects falls witl one or more of the exempt categories listed below.

The exempt categories outlined below do not apply to research involving prisoners* or research involving a t article regulated by the FDA, unless the research meets the criteria for exemption described in 45 CFR 46.101(b)(and 21 CFR 56.104(d).

Research that otherwise could be exempt but that raises ethical concerns or requires measures to protect subje may be moved to a higher level of review (i.e. expedited or full IRB review).

Study activities may not be implemented until the investigator receives final written IRB notification the exempti has been granted.

* **PRISONER** – means any individual involuntarily confined or detained in a penal institution. The term i intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing [45 CFR 46.303(c)].

Check the appropriate category(ies) that applies to your research project:

☐	1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [45CFR46.101(b)(1)]
☐	2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless all of the following are true: (i) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation. [45CFR46.101(b)(2)] **NOTE: If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement) and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research involving children that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.**

☐	4. Research involving the collection or study of <u>existing</u> data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [45CFR46.101(b)(4)] **To qualify for this exemption, data, documents, records, or specimens must exist at the time the research is proposed and not prospectively collected.**
☐	**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. [45CFR46.101(b)(6) and 21 CFR 56.104(d)]

INVESTIGATOR INFORMATION

1. Principal Investigator contact information:

Name and Title	Department	Campus Address	Phone	Email	CITI Training Expiration Date

2. Co-Investigators and/or Key Personnel contact information:

Name and Title	Department/ Institution	Email	Directly Interacting with Subjects? Y/N	Accessing Identifiable Information? Y/N	CITI Training Expiration Date
			☐ Yes ☐ No	☐ Yes ☐ No	
			☐ Yes ☐ No	☐ Yes ☐ No	
			☐ Yes ☐ No	☐ Yes ☐ No	

3. Consultant(s) contact information:

Name and Title	Department/ Institution	Phone	Email	Directly Interacting with Subjects? Y/N	Accessing Identifiable Information? Y/N
				☐ Yes ☐ No	☐ Yes ☐ No
				☐ Yes ☐ No	☐ Yes ☐ No

What is "identifiable information?" Identifiable information is that information by which a subject can be identified directly (name, PU ID number, SS number, email, etc.), indirectly by triangulating multiple variables, (i.e., age, sex, race, profession, etc.) or through codes with links to the identity of a subjects.

How do I obtain the CITI certificates? Go to CITI at www.citiprogram.org. Log into the learner's account. Go to Course Completion History. On the far right side of the screen is a Completion Report. Click View. This will bring up the completion certificate which can be save to a computer.

4. Do the investigators or personnel have a significant financial interest in this study?
☐ **NO - If no, skip to question 6.**
☐ YES - If yes, proceed to question 5.

5. Has a Significant Financial Interest Disclosure Form been filed?
☐ NO - If no, refer to Financial Conflict of Interest: Policy and Procedures.
☐ YES - If yes, proceed to question 6 below.

6. Do the investigators or personnel have any other known conflict of interest in this study?
☐ NO
☐ YES - If yes, please explain the conflict:

STUDY INFORMATION

7. Study Title:

8. Anticipated Duration of Study: Please indicate when this project will end (mm/yr.):

9. Identify the characteristics or inclusion/exclusion criteria for subjects in this study:

10. Identify where the research data collection will occur.
Check all that apply:
☐ Purdue University, please identify campus:
☐ Other settings, please identify:

Research procedures or recruitment conducted outside of Purdue University need to have permission from an appropriate authority associated with that site.

STUDY PROCEDURES

11. Briefly state the research question using non-technical *lay language* that can be readily understood by someone outside the discipline.

12. Study Design/Methods: Briefly explain how the study objectives will be accomplished.

COMPLETE 13-14 IF YOU SELECTED CATEGORY 4.

13. What publically available data/specimens will be accessed for this study?

14. What non-publically available data/specimens will be accessed for this study?

When were the data/specimens collected and under what circumstances? (i.e. tissue bank, data repository, institutional documents, prior research data)?

Which institution is responsible for the data/specimens?

Who is in charge of data/sample distribution?

What data/specimens will be obtained?

List all data elements:

Are subjects identifiable from the data, directly or indirectly?

- ☐ YES
- ☐ NO

Will the data be coded (with a data link maintained by the provider)?

- ☐ YES
- ☐ NO

Will the data be coded, with no link that would allow re-identification of subjects?

- ☐ YES
- ☐ NO

For data/specimens from a non-Purdue provider, the investigator should first contact the provider of the data/specimens to ask if a signed agreement is required by their institution. All

agreements and requests for contractual document signature must be sent to Purdue University Sponsored Programs Services Contracting (spscontr@purdue.edu).

Has a written agreement been entered into between Purdue and provider?

☐ YES
☐ NO

Attach a copy of the agreement.

If you will be accessing Purdue student records or involving the Purdue Registrar to distribute recruitment information, a Data Agreement between the Investigator and the Purdue Registrar must accompany this Request.

COMPLETE 15-19 BELOW IF YOU SELECTED CATEGORY 1, 2, OR 6 ON THE EXEMPT RESEARCH CHECKLIST.

15. What study procedures will subject participate in?

16. When will the activities occur (for Exempt Category 1 Only)? Check all that apply:
☐ During Class Time
☐ Outside of Class Time**, indicate which activities will occur out of class time**

17. Confirm that all instruments, surveys, questions, etc. are included with this application.
Please upload these to COEUS.
☐ YES
☐ NO, please explain:

18. Will the activity occur regardless of whether you are conducting research or not?
☐ YES
☐ NO, please explain:

19. Will the activity be a food tasting study under Category 6?

☐ YES; please explain,

☐ NO

RECRUITMENT

19. Briefly describe how potential subjects will be identified for recruitment. For example, how will schools, teachers and or students be identified for recruitment?

20. Briefly describe how potential subjects will be contacted and who will contact them.

PRIVACY & CONFIDENTIALITY

21. Indicate below how the investigator will receive/record the research data.

- ☐ No identifiable data received/recorded – **Go to Investigator's Assurance.**
- ☐ Coded data received; investigators have NO access to code key.
- ☐ Coded data will be received; investigators have access to code key.
- ☐ Identifiable data received/recorded by investigators – **Go to Q 23.**

22. Identify who will code and/or link the study data?

23. Describe what provisions, if any, will be taken to maintain confidentiality of identifiable data (e.g., surveys, audio, video, etc.). Please state where the data will be stored, how long it will be kept and who will access it.

24. Will identifiable data and/or coded (linked) data be made available to anyone other than the research team?

☐ NO
☐ YES - If yes, please identify to whom data will be made available, the reason for the disclosure and attach a copy of any data transfer agreements.

25. Indicate below what will happen to the identifiable data at the end of the study.

☐ Identifiers will be permanently removed from the data and destroyed.
☐ Recordings will be transcribed in a timely manner without identifiers and destroyed.
☐ Identifiable or coded data with existing code key will be retained for future use.

PRINCIPAL INVESTIGATOR'S ASSURANCE

By submitting this Request, I give my assurance that the information supplied in this form and attachments are complete and correct. I have read the **Researcher Responsibilities** and will conduct this research in accordance with these requirements. I will close this study with the IRB as soon as the study is complete. If I leave Purdue before the three-year record keeping requirement has passed, my regulatory file for this study will be left with a records custodian whose identity will be made known to the IRB.

Submit this form and attachments to the Human Research Protection Program office electronically via CoeusLite.