Revised 8/11 **RESEARCH EXEMPTION REQUEST** Ref. # _____

(Category 6)
Purdue University
Institutional Review Board

Exemption under Title 45 CFR §46.101 and 21 CFR 56

(b)(6) exempts research involving 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 or the U.S. Department of Agriculture.

PLEASE BE AWARE that you cannot begin the project until you have received notification that the exemption has been granted.

1. Check one of the following:

☐ This submission replaces a previous exemption, IRB Ref #

☐ This is a new study

2. Project Title:

3. Anticipated Funding Source:

4. Principal Investigator *[See Policy on Eligibility to serve as a Principal Investigator for Research Involving Human Subjects]*:

Name, Title, Department, Building, Phone, Fax, E-mail address

5. Co-Investigators and key personnel *[See Education Policy for Conducting Human Subjects Research]*:

Name, Title, Department, Building, Phone, Fax, E-mail address

6. Consultants *[See Education Policy for Conducting Human Subjects Research]*:

Name, Title, Department, Building, Phone, Fax, E-mail address

7. Anticipated Duration of Study: Please indicate when this project will end.

Project END Date:	

Participant Population

8. Expected Age Range

Check all that apply:
- ☐ 0-7
- ☐ 8-17
- ☐ 18-64
- ☐ 65 and older

9. Describe location of subjects during research data collection

Check all that apply:
- ☐ Purdue University, specify campus:
- ☐ Elementary/Secondary Schools, specify:
- ☐ Community Center, specify:
- ☐ Other University Campus, specify:
- ☐ Subject's Home, specify:
- ☐ International Location, specify:
- ☐ Other location, specify:

Summary of Activities

(use lay language, do not cut and paste from or refer to grant or abstract)

10. Briefly state your research question.

11. Describe the tasks subjects will be asked to perform. Attach all surveys, instruments, interview questions, focus group questions, etc.

Samples

12. Describe the sample(s) to be used:

13. Document that all specific compound concentration levels are safe (i.e. below accepted exposure limits for human subjects; must be at or below Generally Recognized as Safe, GRAS):

Compensation

14. Will you give subjects gifts, payments, compensation, reimbursement, services, or extra credit?
☐ YES
☐ NO

If yes, please explain:

Recruitment

15. Describe the recruitment process to be used:
Attach a copy of any and all recruitment materials to be used (i.e. advertisements, bulletin board notices, e-mails, letters, phone scripts, or URLs.

16. Explain who will approach potential subjects to take part in the research study and what will be done to protect individuals' privacy in this process:

Confidentiality

17. Will the data be collected anonymously (without identifiers)?
☐ YES. Skip to end of document.
☐ NO. Describe the identifiers to be collected:

18. Describe provisions that will be taken to maintain confidentiality of data (i.e. surveys, audio, video, etc.):

19. Will the PI be able to identify subjects?
☐ YES
☐ NO

20. Will identifiable data be made available to anyone other than the PI?
☐ YES
☐ NO
If yes, explain who and why they will have access to the identifiable data:

Conflict of Interest

21. Do the investigators have a significant financial interest in this study?
☐ YES If yes, proceed to question 22.

☐ NO If no

22. Have you filed a Conflict of Interest Disclosure Statement (Form C-1)?
☐ YES If yes, proceed to question 23 below.
☐ NO If no, refer to Conflict of Interest: Policies and Management.

23. Do the investigators have any other known conflict of interest in this study?
☐ YES If yes, please attach an explanation identifying the conflict.
☐ NO

As principal investigator of this study, I assure 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.

Principal Investigator Signature: _____ Date: _____

Submit this signed form and attachments to the Human Research Protection Program office either via hardcopy or electronically. Forms received without signatures will be returned. A signed form and attachments can be submitted electronically as an email attachment to irb@purdue.edu. If a signed form is submitted electronically, a paper copy need not be submitted.

U.S Mail Address:
Human Research Protection Program
Purdue University
YONG, Rm. 1032
155 Grant Street,
West Lafayette, IN 47906-2114

Campus Address:
Human Research Protection Program
YONG 10th Floor, Rm. 1032

Need help? Contact HRPP office at 765-494-5942.
Office Hours: M-F 8-11 am 1-5 pm