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| RESEARCH EXEMPTION REQUEST – CATEGORY 6 Purdue University – Institutional Review Board |
| |  | | --- | | **INSTRUCTIONS** |   Failure to follow these instructions may result in the submission being returned to the principal investigator.   1. Use this form to request an exemption under Titles 45 CFR §46.101(b)(6) and 21 CFR §56.104(d). 2. Use lay language and spell out acronyms. Do not cut and paste from or refer to grant or abstract. 3. Study activities may not be implemented until the investigator receives final written IRB notification the exemption has been granted. 4. In order to qualify for either of these exemptions, the study must fall into one of the following categories. Additionally you may wish to consult the [decision chart](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c4) for these categories. 5. Research involving **PRISONERS\*** or other incarcerated individuals (or their existing data and/or specimens) do not qualify for exemption.   **Category 6** exempts taste and food quality evaluation and consumer acceptance studies,   * if wholesome foods without additives are consumed or * 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.   **\* PRISONER** – means any individual involuntarily confined or detained in a penal institution. The term is 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)]. |
| |  | | --- | | **INVESTIGATOR INFORMATION** |   **HAVE QUESTIONS about this section?**  [Principal Investigator Eligibility policy](http://www.purdue.edu/research/vpr/rschadmin/rschoversight/humans/policies.php)  [Your Role and Education Requirements guidance](http://www.purdue.edu/research/vpr/rschadmin/rschoversight/humans/which_course.php)  **1. Principal Investigator contact information:**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Name and Title** | **Department** | **Campus Address** | **Phone** | **Email** | **CITI Training Complete? Y/N** | |  |  |  |  |  |  |   **2. Co-Investigators and/or Key Personnel contact information:**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Name and Title** | **Department/ Institution** | **Phone** | **Email** | **Directly Interacting with Subjects? Y/N** | **CITI Training Complete? Y/N** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  |   **3. Consultant(s) contact information:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name and Title** | **University/ Institution** | **Phone** | **Email** | **Directly Interacting with Subjects or Accessing Identifiable Information? Y/N** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |  |  | | --- | | **CONFLICT OF INTEREST** |   **4. Do the investigators have a** [**significant financial interest**](http://www.purdue.edu/research/vpr/rschadmin/coi/index.php) **in this study?**  NO – Skip to question 6.  YES – Proceed to question 5.  **5. Has a** [**Significant Financial Interest Disclosure Form**](http://www.purdue.edu/research/vpr/rschadmin/coi/index.php) **been filed?**  NO – Refer to [Conflict of Interest: Policy and Procedures](http://www.purdue.edu/research/vpr/rschadmin/coi/index.php).  YES – Proceed to question 6 below.  **6. Do the investigators have any other known conflict of interest in this study?**  NO  YES – Please explain the conflict:   |  | | --- | | **STUDY INFORMATION** |   **7. Study Title:**  **8. Funding Source:** Select one of the following options in the drop-down menu below.  Sponsor-External Funds (Includes PRF, Kinley Trust and McCoy awards)  Identify the Sponsor and grant/award number:  Departmental Funding:  Other Self-Funded:  **9. Anticipated Duration of Study:**Please indicate when this project will end (MM/YYYY) |

**10. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?**

NO

YES – This study is not eligible for exemption. Please complete a Non-Exempt Research Application.

**11. Could disclosure of participants’ responses outside the research reasonably place participants at risk of criminal or civil liability or be damaging to participants’ financial standing, employability or reputation?**

NO

YES – This study is not eligible for exemption. Please complete a Non-Exempt Research Application.

**12. Does any part of the research require deception or incomplete disclosure?**

NO

YES – This study is not eligible for exemption. Please complete a Non-Exempt Research Application.

**13. Will prisoners\* be participants in the research?**

NO

YES – This study is not eligible for exemption. Please complete a Non-Exempt Research Application.

**14. Identify the expected age range(s) of participants.**

Check all that apply:

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|  | Under18 (See the above participant population information). |
|  | 18-64 |
|  | 65 and older |

**15. Indicate location of participants during the research data collection.**

Check all that apply:

Purdue University, please specify campus:

Elementary/Secondary School, please specify school(s):

Community Center, please specify:

Other University/College, please specify:

International Population(s), please complete and submit **Appendix G, International Research**

Internet

Subject’s Home

Other location(s), please specify:

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

**17. Will your study involve consuming wholesome food(s) without additives?**

NO

YES – Identify the food(s) to be consumed.

**18. Will your study involve consuming a food ingredient at or below a level, and for a use, generally recognized as safe (GRAS)?**

NO

YES – Identify the food ingredient and explain how it is GRAS.

**19. Will your study involve consuming a agricultural chemical or environmental contaminant at or below a level, and for a use, found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency or the Food Safety and Inspection Service or the U.S. Department of Agriculture?**

NO

YES – Identify it and submit documentation of approval from the relevant agency.

**20. Describe the tasks participants will be asked to perform.** Include information on frequency and duration of procedures.

**21. Will surveys, evaluation instruments, interview questions, etc. be used in the study?**

NO

YES – Identify them and submit them Exemption Request.

**22. Describe the sample(s) to be evaluated.** Include information on frequency and duration of procedures.

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| **COMPENSATION** |

**23. Will you give the participants gifts, payments, compensation, reimbursement, or services in return for their participation in the research study? Please see** [**Compensation for Research Participation**](http://www.purdue.edu/research/vpr/rschadmin/rschoversight/humans/approval.php)**.**

NO

YES – Describe the compensation type (e.g. monetary, extra credit, etc.) and amount:

**Extra credit** – When extra credit is used as compensation for research participation, it cannot exceed 3% of the participant’s grade. The investigator is obligated to make the class instructor aware of this limit and the requirement that students be offered an alternative non-research activity, comparable in time and effort, to earn a comparable amount of extra credit.

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| **RECRUITMENT** |

**24. Identify below all recruitment procedures and materials used in the study.** Submit a copy of all materials or text summaries for phone calls and media advertisements.

Face-to-face contact

Flyer(s)

Letter (s)

Phone

Email(s)

Media Advertisement(s) – Indicate below the media outlet used

newspaper

radio

television

social media site(s) – identify media site(s) below:

**25. Briefly describe how** potential participants will be contacted and identify **who** will contact them.

**26. Is participant contact information publicly available?**

NO

YES – Skip to question 29.

**27. Will you obtain participant contact information from records?**

NO – skip to question 29.

YES – Indicate record type below.

Education records

Employment records

Medical Records

Other – Explain:

**28. Explain how you will have permission to access the records identified above.**

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| **CONFIDENTIALITY** |

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

No identifiable data received/recorded – **skip to Principal Investigator’s Assurance**

Identifiable data received/recorded by investigators

**30. 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.

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

NO

YES – Identify to whom data will be made available and the reason for the disclosure.

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

Identifiers permanently removed from the data and destroyed

Recordings transcribed without identifiers and destroyed

Identifiable or coded (that can be linked) data are retained

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| **PRINCIPAL INVESTIGATOR’S ASSURANCE** |

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*](http://www.purdue.edu/research/vpr/rschadmin/rschoversight/humans/approval.php) and will conduct this research in accordance with these requirements.

Principal Investigators 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](mailto:irb@purdue.edu). If a signed form is submitted electronically, a paper copy need not be submitted.

U.S Mail Address: Campus Address:

Human Research Protection Program Human Research Protection Program Purdue University YONG 10th Floor, Rm. 1032

YONG, Rm. 1032

155 Grant Street, Need help? Contact HRPP office at 765-494-5942.

West Lafayette, IN 47906-2114 Office Hours: M-F 8-11 am 1-5 pm