|  |
| --- |
| RESEARCH EXEMPTION REQUEST – CATEGORY 2 or 3 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 Title 45 CFR §46.101(b)(2) or (3). 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 2** involves **ONLY** the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:   * information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and * any disclosure of the human 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, or reputation.   **Category 3** involves the use of **ONLY** the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under category 2 if:   * the human subjects are elected or appointed public officials or candidates for public office; or * federal statue(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.   **\* 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 or personnel have a** [**significant financial interest**](http://www.purdue.edu/research/vpr/rschadmin/coi/index.php) **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**](http://www.purdue.edu/research/vpr/rschadmin/coi/index.php) **been filed?**  NO - If no, refer to [Financial Conflict of Interest: Policy and Procedures](http://www.purdue.edu/research/vpr/rschadmin/coi/index.php).  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. Funding Source:** Select all that apply:    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  **10. Identify the expected age range(s) of participants to be included or targeted for this research and for which there is a reasonable expectation of enrollment into this research study.**  Check all that apply:   |  |  | | --- | --- | |  | under 18 years of age | |  | 18-64 | |  | 65 and older |   **11. Identify where the research data collection will occur.**  Check all that apply:  Purdue University, please identify campus:  Elementary/Secondary School(s), please identify school(s):  Community Center, please identify:  Other University/College, please identify:  International Population(s) studied in their home country or within the US. Please identify the population(s) and the location of the data collection below. A**LSO** Section L, International Research, of the [non-exempt research application](http://www.purdue.edu/research/vpr/rschadmin/rschoversight/humans/forms.php) must be completed and submitted with this exemption request in addition to the required supplemental materials:  Internet  Subject’s Home  Other location(s), please identify:  **12. Will the study collect data from focus group(s)?**  NO  YES  **13. Will elected or appointed public officials, or candidates for public office, participate in the research?**  NO  YES – Identify which public office(s) participants either hold or are candidates for:  **14. Will prisoners and/or individuals involved in court-ordered programs or community corrections (or their data and/or specimens) be participants in the research?**  NO  YES - If yes, the research does not qualify for exemption. Please complete and submit a Non-Exempt Research Application for review by the convened board (aka full review).  **15. Will the research involve surveys or interview procedures with participants under age 18?**  NO  YES - If yes, the research does not qualify for exemption. Please complete and submit a Non-Exempt Research Application for review.  **16. Will the research involve observations of participant behavior and the investigators will interact with those participants?**  NO  YES - If yes and the participants will be **under age 18**, the research does not qualify for exemption. Please complete and submit a Non-Exempt Research Application for review.   |  | | --- | | **STUDY PROCEDURES** | |

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

**18. Will survey procedures be used?** Survey procedures cannot be used with children under 18 years of age.

|  |  |
| --- | --- |
|  | YES - Identify all surveys to be used **AND** submit them with this exemption request. |
|  | NO |

**19. Will interview procedures be used?** Interviewprocedures cannot be used with children under 18 years of age.

|  |  |
| --- | --- |
|  | YES – Describe the interviews **AND** submit all interview questions/scripts with this exemption request. |
|  | NO |

**20. Will educational tests be conducted?**

|  |  |
| --- | --- |
|  | YES - Check the test categories to be used below and identify each test in the text box below. If the study tests do not fit into the categories below, the study does **NOT** qualify for this exemption. |
|  | NO - Skip to question 21. |

Cognitive – Identify test(s) below and submit with exemption request.

Diagnostic – Identify test(s) below and submit with exemption request.

Aptitude – Identify test(s) below and submit with exemption request.

Achievement – Identify test(s) below and submit with exemption request.

Identify the tests to be used:

**21. Will observations of public behavior be made?** Observational research involving sensitive aspects of a participants’ behavior, or in settings where subjects have a reasonable expectation of privacy, does **NOT** qualify for exemption.

|  |  |
| --- | --- |
|  | YES – Describe the observations **AND** identify the venue(s) where data will be collected. |
|  | NO |

**22. Will audio, visual or image (e.g., photograph) recordings be made?**

|  |  |
| --- | --- |
|  | YES - Indicate below the type of recordings to be used. Check all that apply. |
|  | NO - Skip to question 23. |

Audio recordings

Video recordings

Image recordings/photographs

**Use of audio, visual or image (e.g., photographs) recordings are only permissible under these**

**Exemptions if:**

1. **they are used for memory purposes ONLY to assist investigators in ensuring the accuracy of their collected data; AND**
2. **they will be destroyed once transcribed.**

Explain in the text box below why the above-checked recording procedure(s) is necessary and how it meets both criteria **a** and **b** above.

**23. Will any other procedures be used to collect data in the study?** Please note, in most cases procedures that do not fall under those identified in questions **18-22** above do not qualify for exemption under these categories 2 and 3.

|  |  |
| --- | --- |
|  | YES - Identify all other procedures to be used in the study. |
|  | NO |

|  |
| --- |
| **PRIVACY & CONFIDENTIALITY** |

**24. Does this research involve the collection of any data that falls under any federal statute(s) requiring, without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter?**

|  |  |
| --- | --- |
|  | YES - Identify the regulation(s): |
|  | NO |

**25. Describe the provisions to protect the privacy interests of the participants.** Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants’ expectations of privacy.

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

No identifiable data received – **Skip to question 30.**

Coded data received; investigators have NO access to code key – **Skip to question 30.**

Coded data will be received; investigators have access to code key

Identifiable data received/recorded by investigators

**27. 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.

**28. 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 and the reason for the disclosure.

**29. 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

|  |
| --- |
| **RECRUITMENT** |

**30. 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:

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

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

NO

YES - skip to question 35.

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

NO

YES – Indicate record type below.

Education records

Employment records

Medical Records

Other – Explain:

**34. Explain how you will have permissible access to the records identified above.**

|  |
| --- |
| **COMPENSATION** |

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

NO - Skip to Principal Investigator’s Assurance section.

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.

|  |
| --- |
| **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.

Campus Address: U.S Mail Address:

Human Research Protection Program Human Research Protection Program

YONG 10th Floor, Rm. 1032 Purdue University

765-494-5942 YONG, Rm. 1032

[irb@purdue.edu](mailto:irb@purdue.edu) 155 Grant Street

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

**QUESTIONS?** Call our office at 765-494-5942 or attend walk-in hours.

WALK-IN HOURS – Come speak to a Protocol Analyst

Monday 9:30 am - 11:30 am  
Tuesday 2:00 pm - 4:00 pm  
Thursday 9:30 am - 11:30 am