**HRP-503c-EXEMPT STUDY PROTOCOL**

**Exempt Research Protocol Template Instructions:**

This template is designed for investigator-initiated research studies written and designed by a Purdue University investigator.

This template is only for studies that are considered exempt. Exempt research must be **minimal risk** and fit into at least 1 of 6 exempt categories.

* **Exempt research is not the same as “not human subjects research.”** Exemptresearch specifically refers to studies that meet the regulatory definition of “human subjects research” but are **exempt from certain regulatory requirements**.
* Exempt research must be submitted to the HRPP in PERA and receive a determination prior to initiating any research activity including recruitment.

All sections must be addressed. Respond to all applicable instruction prompts. For those that do not apply, type “N/A.” Once complete, upload this and all other study documents in the PERA application SmartForm.

Text in **BLACK** font and the gold instruction boxes indicate Purdue standard language or reference information and must remain on the page and unchanged.

Delete instructions/examples in **RED** font and replace with applicable study-specific language using black font.

**Study Title** (Insert title here)

|  |  |
| --- | --- |
| **Principal Investigator/Faculty Advisor** | Name: Click or tap here to enter text. |
| Department: Click or tap here to enter text. |
| Telephone Number: Click or tap here to enter text. |
| Institutional Email Address: Click or tap here to enter text. |
| **Student Investigator (if applicable)** | Name: Click or tap here to enter text. |
| Current Academic Status: Click or tap here to enter text. |
| Department: Click or tap here to enter text. |
| Telephone Number: Click or tap here to enter text. |
| Institutional Email Address: Click or tap here to enter text. |

**Table of Contents**

[1. Exempt Justification 5](#_Toc407795058)

[2. Objectives 6](#_Toc705790916)

[3. Study Design & Procedures 6](#_Toc97262116)

[4. Participant Population 7](#_Toc41373096)

[5. Cost to Participants and Incentives to Participate 9](#_Toc117555226)

[6. Informed Consent Process 9](#_Toc1506254344)

[7. Privacy of Participants 10](#_Toc1489805897)

[8. Confidentiality and Management of Study Materials 10](#_Toc184282748)

[9. Educational Records 11](#_Toc624073311)

[10. Bibliography 12](#_Toc1235352136)

|  |  |
| --- | --- |
| **Categories and criteria for exempt research** | |
| **Select all categories that describe the research project.** | |
| ☐ | 1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
| ☐ | (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:  (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.  (ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or  (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)). |
| ☐ | (3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:  (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;  (B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or  (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)).  (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.  (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. |
| ☐ | (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:  (i) The identifiable private information or identifiable biospecimens are publicly available;  (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; |
| ☐ | (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or  possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.  Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. |
| ☐ | (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. |

# **Exempt Justification**

|  |
| --- |
| **1.1** Describe how the proposed research meets the criteria for exemption. Reference the exempt research table above and address each category you selected. |

Click or tap here to enter text.

**For Category 1 be sure you:**

* Describe how the research activity, not the instructional material or curriculum, is a “normal educational practice”.
* Describe how the study will not likely adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.

**For Category 3 research, provide the following additional information.**

* Describe how the intervention activity qualifies as “harmless, painless, and not physically invasive”.
* Is there any reason to think that participants may find the intervention activity offensive or embarrassing? Explain why or why not.

# **Objectives**

|  |
| --- |
| **2.1** Describe the purpose of the study. |

Click or tap here to enter text.

* Clearly and succinctly state the purpose of the study (e.g., research questions and/or study objectives).
* In experimental designs, objectives may be stated as hypotheses to be tested.

# **Study Design & Procedures**

|  |
| --- |
| **3.1** Provide information about all research interactions, interventions, and activities that are to be performed. |

Click or tap here to enter text.

**Research Design**

|  |
| --- |
| **3.2** Identify and describe the research design appropriate to answer the question(s) under study.   * Describe the type of research proposed (e.g. experimental, correlational, survey, qualitative). * Describe the specific study design that will be used (e.g. pre-test /post-test control group design, cross-sectional design) * Describe the study intervention if applicable (e.g. procedure, curriculum) |

Click or tap here to enter text.

**Detailed Study Procedures**

|  |
| --- |
| **3.3** Describe the procedures sufficiently to justify their use in answering the defined research question(s). |

Click or tap here to enter text.

|  |
| --- |
| **3.4** Describe procedures for data collection. Be sure to specify the source records that will be used to collect data about participants. Upload all surveys, scripts, and data collection forms/spreadsheets to the Other Attachments section of the SmartForm. |

Click or tap here to enter text.

|  |
| --- |
| **3.5** Describe the timeline for participant evaluations and the duration of project participation, for both individual study activities and total study participation, when applicable. |

Click or tap here to enter text.

# **Participant Population**

|  |
| --- |
| 4.1 Specify the participant population(s). Check all participant groups that apply. For any population other than adults, complete the applicable appendix. |
| ☐ Adults  ☐ Adults with impaired decision-making capacity  ☐ Children (In Indiana those under 18 years of age)  ☐ Economically or educationally disadvantaged  ☐ Immigrants  ☐ Non-English-speaking individuals  ☐ Pregnant women/fetuses (only if pregnant women will be intentionally recruited and/or studied)  ☐ Prisoners  ☐ University Students  ☐ Employees |

|  |
| --- |
| **4.2** Describe the sample population from which the study team plans to either recruit or access private, identifiable information for the research. If student pools are involved, please specify the applicable pool. |

Click or tap here to enter text.

**Number of Participants at Purdue University**

|  |  |
| --- | --- |
| 4.3 The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval. | |
| Indicate the number of participants to be enrolled locally by Purdue researchers. | Click or tap here to enter text. |
| For multi-site studies, indicate the total number of participants to be enrolled across all sites. | Click or tap here to enter text. |

|  |
| --- |
| **4.4** Explain how this number was derived (e.g., meets statistical power, limited population). |

Click or tap here to enter text.

**Participant Identification**

|  |
| --- |
| **4.5** Describe how potential participants will be identified (e.g., advertising, individuals known to the investigators, record review). |

Click or tap here to enter text.

|  |
| --- |
| **4.6** Explain how the investigator(s) will gain access to this population, as applicable, and provide evidence that you will be able to recruit the necessary number of participants to complete the study. |

Click or tap here to enter text.

**Participant Recruitment and Selection**

|  |
| --- |
| **4.7** Describe how potential participants will be screened or otherwise determined to be eligible. |

Click or tap here to enter text.

|  |
| --- |
| **4.8** Describe the recruitment process, including the setting in which recruitment will take place.Describe how, when, and who will recruit participants for the study. Identify general strategies for participant recruitment and retention (e.g. use of research participant pools, online recruitment services, community advisors, newspaper, local flyers) and indicate where recruitment will occur. Include rationale for why the strategy will be appropriate for reaching the targeted study population |

Click or tap here to enter text.

**NOTE:** The final versions of recruitment materials require IRB approval prior to use. Upload the materials to the documents page of the application SmartForm.

|  |
| --- |
| **4.9** Explain how the recruitment process respects potential participants' privacy.   * Using a query to identify potentially eligible individuals prior to accessing identifiable information directly. * Accessing educational records in a private setting. * Limiting the number of study team members accessing identifiable information. |

Click or tap here to enter text.

# **Cost to Participants and Incentives to Participate**

**Potential Costs/Reimbursements**

|  |
| --- |
| **5.1** Describe any potential costs participants or their insurer will incur as a result of study participation (e.g., parking). Indicate here which costs, if any, will be reimbursed or covered by the study. |

Click or tap here to enter text.

**Incentives**

|  |
| --- |
| **5.2** Describe any compensation or other incentives (e.g., cash payments, gift cards, classroom credit) that will be offered to potential participants. Include the amount and timing of all incentives or compensation, the form of compensation (e.g., cash, check, gift card), and how the compensation will be received (e.g., mailed, in person, online). This information must also be included in the consent form. |

Click or tap here to enter text.

**NOTE:** Reimbursements are not considered incentives.

# **Informed Consent Process**

|  |
| --- |
| **6.1** Describe the consent process. Explain when and where consent will be obtained and how participants or their legally authorized representatives will be provided with sufficient opportunity to consider participation. |

Click or tap here to enter text.

|  |
| --- |
| **6.2** If deception (i.e., procedure in which investigators deliberately mislead participants during research by withholding information or providing false information) is being used, describe if, how and when you are debriefing participants. |

Click or tap here to enter text.

# **Privacy of Participants**

|  |
| --- |
| **7.1** Describe the steps that will be taken to protect participants’ privacy and make them feel at ease with the research situation in terms of the questions being asked and the procedures being performed. |

Click or tap here to enter text.

**NOTE:** Privacy refers to a person’s desire to place limits on with whom they interact or whom they provide personal information. Privacy is about the person and protection of their information leading up to and during the act of data collection, as opposed to confidentiality which is about the management/protection of data after it is collected.

Examples:

* Conducting an interview in a private place where others cannot hear what is said.
* Limiting the number of study personnel who access private information about a participant.

# **8. Confidentiality and Management of Study Materials**

|  |
| --- |
| **8.1** Describe the steps that will be taken to secure study data. |

Click or tap here to enter text.

Consider:

* Training
* Authorization of access
* Password protection, encryption
* Certificates of confidentiality
* Separation of identifiers and data during storage, use, and/or transmission.

**NOTE:** Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information and Sensitive data, including research health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see the [**Secure Purdue Data Classification and Handling Procedures**.](https://www.purdue.edu/securepurdue/data-handling/index.php)

|  |
| --- |
| **8.2** If identifiable data will be collected, indicate what will happen to identifiable data at the end of the study (e.g., kept identifiable, coded, deidentified). If identifiers will be maintained, provide the rationale supporting this request. If the data will be deidentified, describe the process. If transcriptions of audio recordings will be made, please include details of who/what transcription service will be transcribing the data. |

Click or tap here to enter text.

**NOTE:** In general, research data should be deidentified at the end of a project unless there is a compelling reason to maintain linked identifiers.

|  |
| --- |
| **8.3** If data or biospecimens will be shared broadly with outside groups or Open Science, describe those procedures. |

Click or tap here to enter text.

**NOTE:** Research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable data).

# **9. Educational Records**

|  |
| --- |
| 9.1 Are you accessing or collecting information that is a part of the students’ educational record? |
| No  Yes  NOTE: Education Records are any records held by the educational institution including records related to an individual student's performance, records typically found in transcripts (grades/courses/GPA/test scores), student work products such as tests, homework assignments and interactions with online student learning systems. Education records of students in most K-12 and colleges/universities are subject to regulations under the Family Educational Rights and Privacy Act (FERPA).  Permission to use Purdue students’ data comes from the Office of the Registrar. Please submit a [Student Data Agreement Request](https://service.purdue.edu/TDClient/32/Purdue/Requests/ServiceDet?ID=80) to them prior to or at the time of PERA submission. A completed agreement must be uploaded into the PERA SmartForm in Other Attachments before an approval from the HRPP/IRB may be granted.  Permission from K-12 schools must be in written form, see HRP-SCHOOL LETTER and upload to PERA SmartForm Local Site Documents. |

|  |
| --- |
| 9.2 Describe how you have permission for this for research purposes. Note that as the instructor of a course, you do NOT have permission to view education records for research purposes. |

Click or tap here to enter text.

# **10. Bibliography**

Click or tap here to enter text.