

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](#) for these categories.
 - 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 statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

INVESTIGATOR INFORMATION

1. Principal Investigator [See [Policy on Eligibility to Serve as a Principal Investigator for Research Involving Human Subjects](#) and [Education Policy for Conducting Human Subjects Research](#)]:

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

2. Co-Investigators and key personnel [See [Education Policy for Conducting Human Subjects Research](#) for research team role definitions]:

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

3. Consultants [See [Education Policy for Conducting Human Subjects Research](#) for research team role definitions]:

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

CONFLICT OF INTEREST

4. Do the investigators 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 [Conflict of Interest Disclosure Statement \(Form C-1\)](#) been filed?

- NO If no, refer to [Conflict of Interest: Policies and Management](#).
 YES If yes, proceed to question 6 below.

6. Do the investigators have any other known conflict of interest in this study?

- NO
 YES If yes, please explain the conflict: _____

STUDY INFORMATION

7. Check one of the following:

- This submission replaces a previous exemption IRB Ref.# _____
 This is a new study

8. Study Title:

9. Funding Source: Select one of the following options in the drop-down menu below.

Choose an item.

If using Sponsor-External Funds please identify the sponsor and grant/award number below:

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

Project END Date:	<input type="text"/>
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Participant Population – Children and Prisoners: A Category 2 exemption cannot be used for research involving children **except for** use of educational tests (e.g., standard tests for cognitive, diagnosis, aptitude, or achievement purposes) or observation of public behavior where the investigator(s) does not participate in the activities being observed. Exemptions **do not apply** for research involving prisoners/incarcerated individuals.

11. Identify the expected age range(s) of participants.

Check all that apply:

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

12. 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 specify population(s) here **PLUS** complete and attach Section L, International Research, of the [non-exempt research application](#) with the required supplemental materials:

- Internet
- Subject's Home
- Other location(s), please specify: _____

13. Briefly state your research question.

14. Describe the tasks participants will be asked to perform. Include information on frequency and duration of procedures; identify any educational tests to be used. **Reminder:** No sensitive information can be sought under this exemption if participants may be identified. Please refer to the [decision chart](#).

15. All surveys, instruments, interview questions, focus group questions, etc. to be used in the study must be submitted with this exemption request.

16. How will the data be recorded? Please note, the use of audio recordings, video recordings, and photographs, are permissible under this exemption category if used for memory purposes and must be destroyed no later than the end of the study. For example, interviews may be audio recorded for transcription purposes. Use of these procedures must be justified. If your study includes use of these recordings or photographs for purposes other than the purpose noted above, you should submit a [non-exempt application](#).

- Written Notes
- Audio – Please explain below why this procedure will be used.
- Video – Please explain below why this procedure will be used.
- Photographs – Please explain below why this procedure will be used.
- Internet

COMPENSATION

17. 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](#).

- NO If no skip to question 18.
- YES **If yes, please describe below the compensation type (e.g. monetary, extra credit, etc.) and how much.** Please be aware extra credit cannot exceed 3% of the participant's grade. When offering extra credit it is the obligation of the investigator to make the class instructor aware of the compensation guidance referenced above. Students must be made aware of an alternative non-research activity they can do to earn a comparable amount of extra credit.

RECRUITMENT

18. Check all that apply:

- The participants are elected or appointed public officials or candidates for public office.**
If the above applies, for what office is your participant population a candidate, or if the participant population currently holds a public office for which they were elected or appointed, provide the title(s) of

the office(s):

OR

- Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter (45 CFR §46.101(b)(3)(ii)).**
If the above applies, what federal statute(s) require(s) confidentiality?

- None of the above applies**

19. Describe the recruitment process to be used. Please specify how the research team will contact potential participants and any procedures used to protect participants' privacy.

20. All recruitment material(s) (e.g., advertisement, flyer, e-mail, letter, phone script, etc.) to be used in the study must be submitted with this exemption request.

21. Explain who will approach potential participants to recruit for the research study.

22. Is contact information for your participant population publicly available?

NO

YES If yes, skip to question 25.

23. Is contact information for your participant population obtained from records?

NO

YES Please specify: Medical Education Employment Other, specify: _____

24. If you are obtaining contact information from records that are not publicly available, please explain how you will obtain permissible access.

CONFIDENTIALITY

25. Will data be collected anonymously (i.e., without identifiers or codes linked to identifiers)?

YES If yes, skip to Principal Investigator's Assurance section.

NO If no, please describe the identifiers to be collected:

26. 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 you will keep it and who will have access to the data.

27. If using recordings or photographs, estimate when they will be transcribed and destroyed.

28. Will identifiable data be made available to anyone other than the research team?

NO

YES If yes, please identify below to whom data will be made available and the purpose for the disclosure.

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](#) 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. 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