INSTITUTIONAL REVIEW BOARD
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Request for Exemption

If you are not sure if your research is considered human subjects research, please use the "Request for Determination of IRB Jurisdiction" checklist before submitting. Please contact the IRB with any questions at 503-352-1478 or email irb@pacificu.edu.

- Please read all information and follow the instructions as precisely as possible. All text in **red** is explanatory. Please delete it after filling out this template.
- Do not remove or change the heading. Leave the version date as it is. This corresponds to the date the template was last updated by the IRB.
- Do not change the margins of this template. All margins are set to 0.75 inches.
- Do not change the font (12 point, Times New Roman) used in this template.
- Do not remove any section or question from this template. If something does not apply, please state so.

Section A: Does exempt review apply?

To determine if your research qualifies for exempt review, please answer the screening questions below. If you answer **YES** to any of the following questions, your research is not exempt and the "Proposal to Conduct Human Subjects Research" form must be submitted for IRB review.

	YES	NO
Will the research expose participants to discomfort or distress beyond levels encountered in daily life or during educational/psychological testing (i.e., does this study involve more than minimal risk)?	_____	_____
Will the collected data include identifiers and be potentially damaging to a subject's financial standing, employability, or reputation?	_____	_____
Does the research include prisoners?	_____	_____

	YES	NO	N/A
For research proposed under **Category 1** (see next page), will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices?	_____	_____	_____
For research proposed under **Category 2** (see next page), will the research involve surveys or interview procedures with children (minors under the age of 18)?	_____	_____	_____
For research proposed under **Category 2** (see next page), will the research involve observations of the public behavior of children (minors under the age of 18), during which an investigator will participate in the activities being observed?	_____	_____	_____

For research proposed under **Category 4** (see next page), will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through linking identifiers? _____ _____ _____

If you answered **YES** to any of these questions, your application does **not** qualify for exempt review. **Stop completing this form** and complete the "Proposal to Conduct Human Subjects Research" form instead.

If you answered **NO** to all questions, please continue on with this form.

Only the IRB can certify that your research meets the exemption criteria requirements. You cannot make the final determination of exemption.

Section B: Indicate the applicable exemption category (21 CFR 56.104, 45 CFR 46.101).

___ **Category 1** includes research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

___ (1) research on regular and special education instructional strategies; or

___ (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

This applies only to normal educational research in regular educational settings.

___ **Category 2** includes research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, **unless**

(1) the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**

(2) 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.

This exemption does not apply to observational research involving sensitive aspects of the subjects' behavior or in settings where subjects have a reasonable expectation of privacy.

___ **Category 3** includes research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under Category 2 **if**

___ (1) the human subjects are elected or appointed public officials or candidates for public office; **or**

___ (2) federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research thereafter.

This applies only to elected officials. It does not apply to officials appointed via a regular hiring process.

Category 4 includes research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the ___ participants cannot be identified, directly or through identifiers linked to them.

All data must exist when the application is submitted. (If data will be used that is collected or will be collected for research purposes, complete the "Proposal to Conduct Human Subjects Research" form.) Data protected by HIPAA or FERPA statutes require appropriate documentation of permission for use, in addition to this form.

Category 5 includes research and demonstration projects which are conducted by or participant to the approval of department or agency heads, and which are designed to study, ___ evaluate, or otherwise examine

___ (1) public benefit or service programs;
___ (2) procedures for obtaining benefits or services under those programs;
___ (3) possible changes in or alternatives to those programs or procedures; or
___ (4) possible changes in methods or levels of payment for benefits or services under those programs.

This exemption is reserved for Federal Government Research and is not available for local IRB review. It is rarely applied to research at Pacific. See OHRP Guidance on Category 5.

___ **Category 6** includes taste and food quality evaluation and consumer acceptance studies, **if**

___ (1) wholesome foods without additives are consumed; **or**
___ (2) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an 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 USDA.

Category 7 includes emergency use of a test article, provided that such emergency use is reported to the IRB within five (5) working days. Any subsequent use of the test article at ___ the institution is subject to IRB review.

Emergency use means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

Section C: Provide the information requested below pertaining to your exemption.

1. What is the title of this study?

Enter information here.

2. Who are the research personnel and what is their contact information?

Modify the columns in the table below to fit the number of personnel involved in the study. Identify the role of each as indicated (e.g., principal investigator, faculty advisor, student investigator, research assistant, etc.). Dissertation readers need not be named. A faculty advisor must direct all student projects.

Name			
Role	Principal Investigator	Faculty Advisor	
Institution	Pacific University	Pacific University	
Program			
Email			
Telephone			

3. Provide an overview of the study.

a. What is the purpose of this study?
Briefly describe the hypothesis to be tested or the research question to be addressed.

b. What is the basis of this undertaking?
Briefly describe the nature of the project. Is it a program evaluation, action research, or a classroom activity?

c. What do you plan to do with the results of this study?
Enter information here about how the results will be used, either by you or other parties. How will the results be shared and/or disseminated?

4. What is the nature of your intended sampling and data collection activities?

Complete section (a) if you will be gathering new data for your study. Complete section (b) if you will be using data that already exists. If your study will include both types of data, complete both sections. Section (c) addresses all data collected for and/or used in the study.

a. Does the study involve interaction or intervention with living people?
If yes, describe the nature of the interaction or intervention. If no (e.g., observational data), describe why it does not constitute interaction or intervention.

i. Describe the intended sample size and the relevant demographics.
Some considerations include age range, sex or gender, ethnic or minority status, and health status. Please include a brief rationale for the proposed sample size (e.g., a priori power calculation, amount for a counterbalanced design, etc.).

ii. Delineate the recruiting plan.
Recruitment activities may not begin prior to IRB approval.

Explain your proposed recruiting plan and/or methods. How, where, and when will you contact potential research subjects? Include copies of your fliers, notices, etc. in the appendices.

iii. Explain the procedures.
Denote the study design as appropriate. List in a step-by-step fashion how and where the new data will be gathered. In reading this, the IRB reviewers should be able to imagine exactly what it would be like to be a participant in every condition of the proposed research. Include

the expected duration and/or time commitment of the subjects' participation and identify any additional costs.

iv. **State the timeline for recruitment, data collection, analysis, and dissemination.**
Recruiting will begin once IRB approval has been obtained. Data collection will begin…continue as appropriate; be sure to include an end date (month and year). You are strongly encouraged to describe your planned outlets for study findings (e.g., A&S Senior Project Day; the publication of a formal thesis or dissertation which will be made available in the library; local, regional, national, or international scientific and/or professional meetings, etc.).

v. **How will you protect the privacy of your participants?**
Explain the specific steps you will take to protect the personal information your participants provide. Make it clear whether the results will be kept in a confidential or an anonymous manner, keeping in mind that it cannot be both. A promise of confidentiality means that although names can be associated with corresponding data (e.g., a master key of names and study ID numbers, etc.) steps will be taken to minimize the possibility that someone other than you can access this information. Regardless of whether or not participant identities can be linked to data, a claim of anonymity indicates that no one knows the identities of the participants (not even you as an investigator).

You must consider, anticipate, and have plans for situations where it may be necessary to break confidentiality. If child abuse is known or strongly suspected, you are required to notify the appropriate authorities. If a participant is believed to be a threat to oneself or others, you should notify the appropriate authorities. The conditions under which you may break confidentiality must be described in the proposal and the informed consent.

vi. **Explain how the minimal risk criterion is met.**
For a study to qualify as minimal risk, the probability and magnitude of harm or discomfort anticipated in the research (for subjects) must not be greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (21 CFR 56.102(i), 45 CFR 46.102(i)).

vii. **Does participation in this study provide direct benefit or compensation?**
Benefit and compensation are different notions not to be used interchangeably. Claiming that participants will benefit means that they will gain a clear and demonstrable advantage that could not obtained unless they participated in the study. Many studies are simply non-beneficial. Compensation is an outright payment or some form of material reward given to subjects in acknowledgment of their participation.

viii. **How will informed consent be obtained and documented?**
If a consent form will be used, please include it with your submission documentation. You may use either an IRB form or provide your own document, as appropriate. In addition, please describe the process through which consent will be gathered. (Don't simply say, "See attached form.")

If you are requesting an alteration or waiver to any informed consent requirements, including documentation of informed consent (e.g., signed consent for anonymous surveys), complete a "Request to Alter or Waive Informed Consent" form. Submit this

form with your exempt protocol application for IRB review and approval to alter or waive consent.

b. Does any data that will be used in this study already exist? (Was it created by someone else for an unrelated purpose?)
Enter information here.

i. Is the data set, as it exists, expected to remain private, by law?
Enter information here (e.g., medical or educational records protected by HIPAA or FERPA).

ii. Do you have ready access to the identities of the individuals from whom the information was obtained (through the agency with which you are working)?
Enter information here.

iii. If all personal identifiers have been removed from the data source, could you re-identify the data?
Enter information here.

iv. Explain in precise detail the nature of the data you will be using. Note where it is housed, how you will gain or be permitted access, and how participant privacy will be protected.
Enter information here.

v. State the timeline for analysis and dissemination.
Analysis will begin once IRB approval has been obtained. Continue as appropriate; be sure to include an end date (month and year). You are strongly encouraged to describe your planned outlets for study findings (e.g., A&S Senior Project Day; the publication of a formal thesis or dissertation which will be made available in the library; local, regional, national, or international scientific and/or professional meetings, etc.).

c. How will the data and study materials be treated after the study is complete?
Study data and consent forms must be maintained securely for, at minimum, three years after the completion of the study. You should discuss who will have access to the study materials and where the data will be securely retained. Consent forms should be kept separately from study data.

5. Who is sponsoring and/or funding this study? Are there any potential conflicts of interest?

a. If this is a clinical investigation as defined in Category 6 or Category 7 (21 CFR 56.104), list and describe who is sponsoring this study. Provide addresses for all key sponsors.
Enter information here. If your study is not a clinical investigation, use N/A (not applicable).

21 CFR § 56.102(j) – **Sponsor** means a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

21 CFR § 56.102 (k) – **Sponsor-investigator** means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

b. List and describe any funding for this study.
Enter information here.

c. Describe any potential or apparent conflict(s) of interest that may exist.
Enter information here.

6. Describe any relevant authorizations.

Describe if permission is required from a study location (i.e., to conduct your study at that location, etc.), and, if so, how that permission will be obtained. Provide documentation (e.g., letters of supports, etc.) of any authorizations you secure to the IRB.