INSTITUTIONAL REVIEW BOARD
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Proposal to Conduct Human Subjects Research

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.

1. What is the nature of the study are you submitting?

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.

a. What type of review are you requesting?

Ultimately, the IRB will determine if the type of review (full board, expedited, or exempt) you have requested is appropriate. If you believe your proposal is exempt, do not use this form. Download and use the "Request for Exemption" form instead.

___ Full Board Review

___ Expedited Review

In general, research may be considered for expedited review if it involves no more than minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate consent procedures.

b. Is this study a clinical investigation?

21 CFR § 50.3(c) – **Clinical investigation** means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

Synonyms: **clinical research**, **clinical study**, **clinical trial**

For a research study to be considered a clinical investigation the following components must be present:

✓ a test article

21 CFR § 50.3(j) – **Test article** means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

✓ one or more human subjects

21 CFR § 50.3(g) – **Human subject** means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

✓ an **Investigational New Drug Application (INDA)** (FD&C Sec. 505(i)) or an **Investigational Device Exemption (IDE)** (FD&C Sec. 520(g)) or future submission to the FDA for research or marketing permits

Even if there is only a remote possibility that you or your sponsor will seek future research or marketing permits, your study should be considered a clinical investigation.

Go to http://www.clinicaltrials.gov or the FDA's Code of Federal Regulations (CFR) Title 21 Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm) for more information.

- 21 CFR § 50 – Protection of Human Subjects
- 21 CFR § 56 – Institutional Review Boards
- 21 CFR § 312 – Investigational New Drug Application
- 21 CFR § 812 – Investigational Device Exemptions

___ Yes

___ No

2. What is the title of this study?

Enter information here.

3. 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			

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

a. If this is a clinical investigation, 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 § 50.3(e) – **Sponsor** means a person who initiates a clinical investigation, but who 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., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

21 CFR § 50.3(f) – **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., corporation or agency.

Typically, the sponsor or sponsor-investigator holds the INDA (21 CFR 312.40(a)(1)) or the IDE (21 CFR 812.40) and is responsible for reporting results to the FDA.

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.

5. What is the purpose of this study?

Provide enough relevant information to allow the IRB reviewers to understand the rationale and/or justification for the study and its merits (basic and/or applied), including any relevant study hypotheses and dissemination plans.

6. What are the relevant characteristics of the intended sample and the recruitment plan?

a. 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.).

b. Describe and justify the inclusion of any non-autonomous subjects.

If your intended sample draws from a non-autonomous population, which includes children and/or minors, cognitively impaired persons, prisoners or any other persons who require legal guardianship, complete this section. Otherwise, use N/A (not applicable).

Briefly describe the characteristics of the population of interest which make the subjects non-autonomous and provide a justification for their inclusion in the study.

If the proposed study includes prisoners (or data derived from prisoners) as subjects, also complete and attach the "Permitted Research Involving Prisoners" form to this proposal.

c. State the eligibility criteria.
List and describe the key characteristics necessary for participation in the study.

d. State the exclusionary criteria.
List and describe the criteria that would exclude subject participation in the study (e.g., pregnancy, specific medical condition, English language fluency, age, etc.).

e. 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.

For prisoner samples, procedures for the selection of subjects must be fair to all prisoners and immune from arbitrary intervention by prison authorities or other prisoners. Be sure to describe how your methodology achieves this. Unless you provide the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for your particular research project. Explain these features well.

7. What is the study methodology?

a. Identify the location of the study.
Identify where the data will be gathered, stored, and analyzed.

b. Describe the study materials, measures, and/or apparatus to be applied.
If the proposed study involves medical devices (21 USC 9, Section 321(h)) or drugs (21 USC, Section 321(g)(1)), you are required to complete the "Medical Device and/or Drug Study Information" form and append it to this proposal.

Name and explain each element so that its purpose is clear. Address the validity of any instruments that are not widely recognized outside of your discipline and provide references, if possible. If relevant, include appendices that describe and/or depict your proposed study tools. If possible, identify the independent and dependent variables, as well as the proposed statistical analysis. Including these elements will smooth the progress of the review.

c. Explain the procedures.
Denote the study design as appropriate. List in a step-by-step fashion how the study will unfold. 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.

d. 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.).

8. What risk(s) accompany participation in this study?

a. Specifically identify and briefly describe the various risks to which participants may be exposed.

Risks can be physical, social, emotional, legal, or economic.

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)). **Please specify whether the proposed study presents minimal risk or greater than minimal risk, and justify your categorization.**

b. Describe the likelihood of these risks occurring, how they can and will be minimized, and how they will be handled should they occur.

Enter information here. Note that each identified risk should have an associated minimization strategy.

For prisoner samples, you must anticipate and identify when there may be a need for follow-up examinations or care (after participation has ended) and provide adequate provisions for such, taking into account the varying lengths of individual prisoners' sentences. Be sure you inform participants of this fact in the consent materials.

c. Describe any element(s) of deception or meaningful withholding of information associated with the study methodology.

Address this issue explicitly. If deception or information withholding is involved, a debriefing is usually required. Explain the debriefing process here, being sure to offer participants a chance to withdraw their data explicitly once all the elements have been disclosed.

d. Describe any treatment alternatives that may be advantageous to subjects, if clinical investigations are involved.

This section is relevant for studies involving clinical investigations. The purpose is to clearly identify any clinical procedures that are experimental and disclose the existence of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject. If you are collecting normative data or are not conducting clinical investigations, then you may simply state, "This study does not involve clinical investigation(s)."

If there is no known comparable alternative to receiving an experimental treatment, the stated alternative should be to not participate in the study and to seek normal care from a licensed care provider.

9. How will adverse events be handled and reported?

The IRB must be notified promptly when an unexpected adverse reaction occurs **(see Section 17 of the IRB Policies and Procedures)**.

Explicitly state that you will notify the IRB promptly and explain how you will manage the event. It is recommended that for serious adverse events, the IRB be notified within 24 hours. For other adverse events, notification by the next normal business day is recommended. **In no circumstances should notification occur later than one week after the event.**

Keep in mind that adverse research events can cover a wide spectrum of possibilities. They may include, but are not limited to, those potential risks that have already been identified. They can consist of unexpected events as well. The IRB considers adverse event reporting as mandatory and crucial for clinical investigations. Medical and/or clinical research examples are given below. Review and integrate those that are relevant to your particular study.

- A serious adverse event is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure. Serious adverse events include those that
  - are fatal or life threatening;
  - result in significant or persistent disability;
  - require or prolong hospitalization;
  - result in a congenital anomaly and/or birth defect; or
  - represent other significant hazards or potentially serious harm to research subjects or others.
- Unexpected serious adverse events are those that have not been described in the
  - package insert for a given drug or brochure (for FDA investigational agents);
  - approved protocol; or
  - informed consent document.
- Adverse research events include, but are not limited to
  - physical or psychological and/or emotional harm or injury (e.g., emotional distress triggered by study questions about emotionally charged life events, etc.);
  - threats to privacy or safety;
  - an unusual number of participant withdrawals or drop-outs;
  - breaches of confidentiality; or
  - subject complaints about the experimental procedures or investigator conduct.

Use as much of the language provided here as possible. Modify it as necessary while maintaining the intent and compliance requirements.

Be sure to specifically address how affected research subjects will be dealt with/informed as appropriate.

10. 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.

Also, note that for prisoner samples, you must offer adequate assurance that parole boards will not take into account a prisoner's research participation when making decisions regarding parole. Be sure you clearly inform prisoners in advance that participation in the research will have no effect on parole decisions.

a. Describe the specific unique benefits subjects will realize via their participation in this study, if any.

Enter information here.

b. Describe the payment or other reward participants will receive, if any.

Enter information here.

11. 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).

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.

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.

12. 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.

13. How will participant assent be obtained and documented?

Complete this section only if you will be collecting data from minors or individuals who are not legally capable of providing their own consent. Otherwise, use N/A (not applicable).

While children (or non-autonomous adults) may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent to or dissent from participation. Out of respect for individuals as developing persons, all should be asked whether or not they wish to participate in the research, particularly if the research (a) does not involve interventions likely to be of benefit to the subjects, and (b) the person can comprehend and appreciate what it means to be a volunteer for the benefit of others. The IRB must determine for each protocol – depending on such factors as the nature of the research and the age, status, and condition of the proposed subjects – whether all or some of the subjects are capable of assenting to participation. Thus, the justification provided by you is critically important in performing valid evaluations.