INSTITUTIONAL REVIEW BOARD
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Informed Consent

Complete this template only if you will be collecting data from or about adults who are legally capable of providing consent. If you choose to create your own informed consent document, please only submit the document that you plan to use in your research (do not complete and submit this template). However, ensure that you use required language from this template (in **blue**) in your created form.

- 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.
- All text in **blue** is standard language that **must** be used in your informed consent. Change the **blue** text to **black** once you have completed the 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 for the participants.

1. Study Title

Enter information here. Include the IRB project number in parentheses following your title.

2. Study Personnel

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. Study Invitation, Purpose, Location, and Dates

You are invited to participate in a research study about (insert a brief description of the study's purpose here followed by information about approval from the IRB, the timeline, the location, and any use of the study results).

4. Participant Characteristics and Exclusionary Criteria

Disclose all relevant eligibility requirements and exclusionary factors. Also, explain circumstances under which a subject may be removed by you from further participation without regard to their consent.

5. Study Materials and Procedures

The purpose of this section is to enable a potential participant to imagine what it will be like to be in this study. Be sure to address all of the following explicitly (a) the approximate number of participants, (b) a description of the procedures to be applied, (c) the expected duration and/or time commitment of the subject's participation, and (d) identification of any additional costs to the subject.

6. Risks, Risk Reduction Steps, and Clinical Alternatives

a. Anticipated Risks and Strategies to Minimize or Avoid Risk

Ensure that the risks described here and in the proposal are an exact match. Give an avoidance strategy for each risk.

b. Unknown Risks

It is possible that participation in this study may expose you (or an embryo or fetus, if you are or become pregnant) to currently unforeseeable risks. Delete the embryo/fetus/pregnancy clause if the study protocol does not reasonably present any risks in this situation.

c. Advantageous Clinical Alternatives

If the study involves clinical investigations, the consent form must clearly identify and explain any clinical procedures that are experimental and disclose appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subjects. If this issue is not relevant, state, "This study does not involve experimental clinical investigation(s)."

If the study involves clinical investigations, it is **not** acceptable to state N/A (not applicable) in this section. At the very least, state, "The alternative to participating in this research study is to not participate in this study and to seek treatment or care from a healthcare professional."

7. Adverse Event Handling and Reporting Plan

In the event that you become sick, injured, distressed, or otherwise uncomfortable as a result of your involvement in the research study, you may stop your participation immediately. If such an event occurs, promptly notify the principal investigator or the Pacific University Institutional Review Board.

If the investigator(s) become aware of an adverse event, the IRB office will be notified by the next normal business day for minor events (provide a list of minor events) and within 24 hours for major events (provide a list of major events).

Additional Boilerplate Language for Clinical Investigations

If you experience **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 being investigated (and such an event is observed by or reported to the investigator(s)) the IRB will be notified within 24 hours. These may include, but are not limited to events 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 potential serious harm to research subjects or others.

If you experience or are directly affected by an adverse event, you will be given the opportunity to withdraw any data collected from you during the study up to (describe the point in time that the data cannot be withdrawn, e.g., after the publication of the study results, after the destruction of the master key, after a participant submits her/his responses to an anonymous survey, etc.).

8. Direct Benefits and/or Payment to Participants

a. Benefit(s)

If there are no direct benefits to the research subjects, state, "There is no direct benefit to you as a study participant."

b. Payment(s) or Reward(s)

If there is no payment or reward planned, state, "Participants will not be paid for their participation."

Be sure the benefits and/or payments (or lack thereof) described here and in the proposal match. In considering benefits, remember that in this setting benefits refer to unique consequences available only to those who participate.

9. Promise of Privacy

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 to the participants.

If the object of this investigation is the use of (a) drug(s) or (b) medical device(s), you must include the following language:

A description of this clinical investigation will be available on http://www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

In addition, as part of ongoing compliance efforts, the Food and Drug Administration may inspect any and all records pertaining to this study. FDA auditors maintain strict confidentiality of all records reviewed.

10. Medical Care and Compensation in the Event of Accidental Injury

This section is a legal statement that must remain primarily as is. Use the provided language, plus additional study-specific material, as needed. The purpose of this statement is to make it perfectly clear that if a subject is injured while participating and it is not Pacific's fault, then Pacific will not pay for treatment or a penalty.

This statement likely is not necessary for interviews, focus groups, observational studies, surveys, or research that involves the use of standardized tests. In these cases, this section may be removed.

During your participation in this project it is important to understand that you are not a Pacific University clinic patient or client, nor will you be receiving complete state the appropriate kind of care (e.g., medical care, eye care, mental health care, physical therapy, etc.) as a result of your participation in this study. If you are injured during your participation in this study and it is not due to negligence by Pacific University, the investigator(s), or any organization associated with the research, you should not expect to receive compensation or medical care from Pacific University, the investigator(s), or any organization associated with the study. If you are injured and it directly is related to your participation in this study as a research subject, please contact the Pacific University Institutional Review Board at 503-352-1478.

11. Voluntary Nature of the Study

Your decision whether or not to participate will not affect your current or future relations with Pacific University and other collaborating agencies, if relevant. If you decide to participate, you are free to not answer any question or withdraw at any time without prejudice or negative consequences. If you choose to withdraw after beginning the study explain how this will be managed (e.g., subject compensation, what will happen to the subject's data collected prior to withdrawal, etc.). If you elect to deviate from the suggested language, it is essential that you clearly and fully communicate the plan(s) to the participants. If significant new findings develop (or are discovered) during the course of this research that could impact your decision to continue participation, such findings will be shared with you and you will be given the opportunity to withdraw from the study.

12. Contacts and Questions

The investigator(s) will be happy to answer any questions you may have at any time during the course of the study. If you are not satisfied with the answers you receive, please call the Pacific University Institutional Review Board at 503-352-1478 to discuss your questions or concerns further. If you have questions about your rights as a research subject, or if you experience a research-related injury of any kind, please contact the investigator(s) and/or the IRB office. All concerns and questions will be kept in confidence.

13. Statement of Consent

Modify the section below as appropriate for your study. To add custom content, copy and paste a line, and retype the needed text. Delete items as necessary. **Blue** text is mandatory. **Red** text is meant to be illustrative.

YES	NO	
_____	_____	I am 18 years of age or over.
_____	_____	All my questions have been answered.
_____	_____	I have read and understand the description of my participation duties.

_____ _____ I have been offered a copy of this form to keep for my records.

_____ _____ I voluntarily agree to participate in this study and understand that I may withdraw at any time without consequence.

_____ _____ I give permission for the investigator(s) to gather photo and/or video data for analysis, understanding that any published reports will not use my image(s) in any form.

_____ _____ I give permission for the investigator(s) to use (altered/unaltered) images in published reports that (do/do not) allow others to ascertain my identity.

_____ _____ I give permission for the investigator(s) to gather and use my genetic information only for the purposes specifically delineated in this consent form.

_____ _____ I give permission for the investigator(s) to examine my case file, but to use only the information specifically described above.

_____ _____

Signature Date

Participant

_____ _____

Printed Full Name Study Role

_____ _____

Signature Date

_____ _____

Printed Full Name Study Role*

*This individual must be trained in obtaining informed consent and have authorization from the principal investigator and/or faculty advisor to do so.