

SEATTLE PACIFIC UNIVERSITY

IRB APPLICATION FOR HUMAN SUBJECTS REVIEW

Title of project: _____

Expected Start Date for Data Collection: _____

Expected End Date for Data Collection: _____

Name of Principal Investigator¹: _____

Phone #: _____ E-mail: _____

Name of Co-Investigator(s)²: _____

Phone #: _____ E-mail: _____

Name of Co-Investigator(s): _____

Phone #: _____ E-mail: _____

Faculty Sponsor Name: _____

Faculty Sponsor signature: _____ Date: _____

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Directions: Submit **one hard copy** of the IRB application and research protocol / other material that will be given to participants to your School or College's IRB Member. It is estimated that the initial review process or any review of revisions will be completed within 3-5 weeks. Research that has more than minimal risk or includes vulnerable participants will be passed on to be reviewed by the entire Institutional Review Board (IRB) or a subset of members. If your study is passed on for further review, you will be notified. Please expect additional delays for expedited or full IRB review. **The IRB meets once each month between October and May so plan accordingly.**

Complete all information:

1. Data Intent:

- Will the data you propose to collect potentially be used in future grant proposals?
- Will the data potentially be used in a future study?
- Will the data potentially be used in teaching?
- Will the data potentially be published and/or presented at a conference?

¹ List SPU e-mails if SPU community member

² List all participating researchers. If PI is a student, the faculty / staff sponsor must be listed as a Co-investigator.

2. What is the purpose of your study? Please use clear, everyday language.

a. How does the literature support the purpose? Where does your study fit within the literature?

b. Please put supporting references in an appendix.

3. On whom do you expect to collect data?

a.

b. Age range _____

c. Maximum number to complete protocol _____

4. Who will recruit subjects?

Additionally:

- a. Attach the prose for any verbal or electronic correspondence
- b. Attach any flyers or announcements for websites
- c. Attach a list of recruitment locations³

³ The IRB member may ask you to attach support correspondence that you are able to recruit at listed locations

5. Is there a dual (e.g. Faculty/Student, Nurse/Client or Therapist/Client) relationship between the Investigators and the Participants?

If yes, please explain how coercion will be avoided.

6. Describe your protocol in a step-by-step way. If you need additional space, please attach a clearly marked appendix.

Additionally:

a. Clearly state what will participants be asked to do.

b. Where will the data be collected?

c. How will the data be collected? (Attach verbal script if applicable)

d. Who will collect the data? Please make sure you include their training certificates

e. If there are multiple options for participants (e.g. based on preliminary assessments), include a flowchart with clear tracks for each of the options.

7. List the equipment, surveys, and/or other measures you will be using. If you need additional space, please attach a clearly labeled form.

8. How do the protocol and measures fulfill the purpose of your study?

9. When applicable include the following as attachments:

- a. Datasheets or observation forms.
- b. Coding protocol(s).
- c. Questionnaire.
- d. Documentation that you have permission to use or reproduce material for your study (e.g. copyrighted, patented).

10. How long will the participant be involved in the study (give the maximum estimate of time)?

- a. If there are multiple sessions, please list the time per session as well as the total time.
- b. If the study takes place over a particular time frame, please list the total time frame as well (e.g. 6 hours over 6 months).
- c. If the timeline varies for different participants, please attach a table that outlines the differences.

Total Time	Number of Sessions	Time per Session	Time Frame
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

11. Risks:

- a. What are the potential risks--physical, psychological, social, legal or other—for the participants?

b. What is the likelihood and seriousness of each risk?

c. If beyond minimum risk, what other methods that do not involve risk were considered and why will they not be used?

d. How will you minimize potential risks?

12. Benefits:

a. What are the potential DIRECT benefits that may be gained by any individual participant for his/her participation?

- b. What are the potential benefits to society in general as a result of the planned work?

13. Confidentiality:

- a. How will you maintain the confidentiality of participant information?
- b. How and where will you store the consent forms for the three years that SPU requires consent forms to be stored? (Students must leave consent forms with their faculty advisor.)
- c. If the data are subject to HIPAA, how will you de-identify medical data?

14. Funding:

- a. Will you be giving monetary or academic credit for participation?
 - i. What is the exact amount you will be paying each participant?

 - ii. What is the total amount you expect to pay for all participants?

iii. What is the exact amount of credit that will be awarded to participants?

iv. Describe the non-research alternative offered to participants.

b. How will you pay for the monetary compensation?

i. If through a sponsor, include a copy of a grant award, contract, budget and equity interest documentation.

ii. If the contract, budget or equity interest changes during the research project, the researcher must notify the IRB. This includes the termination of a contract, a supplement to a contract, or an extension.

c. Do you have to pay for permission to use any of the equipment, surveys or other measures you will be using?

i. How much do you have to pay?

d. How will you pay for the equipment, surveys, other measures, or other study components?

i. If through a sponsor, include a copy of a grant award, contract, budget and equity interest documentation.

ii. If the contract, budget or equity interest changes during the research project, the researcher must notify the IRB. This includes the termination of a contract, a supplement to a contract, or an extension.

e. Conflict of interest?

15. Consent Documentation

Assume documented informed consent is required for your research proposal. *You must complete the consent checklist on the next page and include it in your application package for each consent or assent form.*

SPU's IRB Committee will inform you as to whether this will be waived for your particular research.

Please note: All hard copies of informed consent will be stamped by the IRB upon approval. Only stamped IRB consent forms can be used by the PIs.

In the event of electronic informed consent (e.g. electronic survey), the SPU IRB # and expiration date must be included

- a. If working with vulnerable populations (children, prisoners, mentally ill, intellectually disabled) describe how consent (e.g. prisoner) or assent (i.e. children) will be obtained.
- b. Please note when you plan to work with children, that you must include a form for Parental Consent in addition to the Children's Assent Form.

16. Deception:

If any deception (i.e., withholding of complete information) is required for the validity of this activity, explain why this is necessary and attach a debriefing statement (see sample on IRB website). Additionally attach procedures and script for the debriefing process.

17. Responsible Conduct of Research:

You must provide (ATTACHED TO THIS APPLICATION) copies of RCR training (within the past five years) for all researchers who will have direct contact with research participants or who will see any identifiable data.

You can complete authorized training through the following on-line training site:
<http://phrp.nihtraining.com/users/login.php>

Informed Consent Required Elements Checklist

Complete if you have documented informed consent as part of your study

(Type **NA** if item is not applicable to your study.)

_____ Provide the reading level associated with the informed consent (Do a Spell Check with Readability Options checked). Is this level appropriate for the participants?

Investigators

- ☐ Consent forms must state **who is conducting the research**, provide contact information for anyone who will collect data and clearly labeled that the research is sponsored by SPU. The IRB encourages the use of SPU logo or letterhead.

Purpose

- ☐ Use of word "study," "research," "evaluation" or "investigation" to describe activity
☐ An informed explanation of the **purpose** of the research
☐ Explanation for why the participant was invited to participate in the study
☐ Number of participants expected to participate in the study

Procedures

- ☐ A description of the **procedures** to be followed
☐ Identification of any **experimental treatments, procedures, or devices**
☐ A disclosure of any appropriate **alternative procedures** or courses of treatment
☐ The **location(s)** where the procedures will be done
☐ The expected total **duration** of participation and that of each phase of multi-phase protocols

Risks

- ☐ A description of the reasonably foreseeable **risks** and discomforts, or a statement that the research does not involve risks beyond those encountered in everyday life, as appropriate.

Emergency Medical / Psychological Treatment

- ☐ Studies involving exercise testing or supervised physical activity include emergency policies and procedures.
☒ An explanation of any **costs** to the subject for research-related procedures, hospital stays, use of equipment, lost compensation or insurance, or extraordinary transportation requirements
☒ As appropriate, an explanation as to whether any **compensation** or **medical treatment** is available if injury occurs, what it would consist of (if any), or where further information may be obtained.

Benefits

- ☒ A description of possible direct **benefits** to each subject, which may reasonably be expected from the research, or a statement that individual subjects may not directly benefit from participation though there may be benefits to general knowledge or to society.

Confidentiality

- ☒ A statement describing the extent to which **confidentiality** of records identifying subjects will be maintained, including who will have access to and the methods for securing such records.

Compensation

- ☒ An explanation of any **gratuities** for participation and, if appropriate, procedures to **prorate** amounts for subjects who withdraw before completing the research protocol

Who to Contact

- ☐ The name(s), title(s), local toll-free telephone number(s), and e-mail addresses of the **person(s) to contact for answers to questions about the research**, including those for the responsible project investigator, if different
☐ An invitation to contact the **IRB Office** (IRB@SPU.edu) for **information about the rights of human subjects** in SPU-approved research.
☐ As appropriate, the name(s), title(s), and daytime and evening telephone number(s) of the **person(s) to contact in the event of a research-related injury, adverse effect, or complaint**

Participation and Alternatives to Participation

- ☐ A statement that participation is **voluntary**
☐ A statement that **subjects may refuse to participate or may discontinue participation** at any time during the project without penalty or loss of benefits to which they are otherwise entitled
☒ For surveys and interviews, a statement that subjects may **skip any questions** they don't wish to answer
☒ No language through which subjects are made to **waive** any **legal rights**, including any release of the university or its agents from liability or negligence

Near the Signature Line

- ☐ A statement that **participants will be given a copy** of the consent form

After IRB Approval

- ☒ SPU IRB number and expiration date are placed on informed consent and any other recruitment material.

Please note: All hard copies of informed consent will be stamped by the IRB upon approval. Only stamped IRB consent forms [and recruitment posters] can be used by the PIs.

In the event of electronic informed consent (e.g. electronic survey), the SPU IRB # and expiration date must be included

FOR IRB USE ONLY

Date Received	Date Responded
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Date Approved (If Applicable): _____

IRB Number Assigned: _____

Expiration Date: _____