**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:**

========================================================================

Directions: Please follow the guidelines available on the IRB website. Research that has more than minimal risk or includes vulnerable participants will be reviewed by the entire Institutional Review Board (IRB) or a subset of members. If your study requires further review, you will be notified. Please expect full IRB review to take at least a month. Check the website for IRB meeting dates.

**\*\*Please complete this application in another color to make your answers clearly visible.\*\***

**Complete all information**:

# Data Intent (Please respond Yes or No):

* 1. Will the data you propose to collect potentially be used in future grant proposals?
  2. Will the data potentially be used in a future study?
  3. Will the data potentially be used in teaching?
  4. Will the data potentially be published and/or presented in some public forum (e.g. guild conference, Twitter, videoconference)?

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.

***IRB application 09/18***

# Briefly and clearly state the purpose of your study? Please use clear, everyday language that is understandable to a non-specialist. Please do not write more than a page; this should be in the style of an abstract.

* 1. Provide a brief (500 words or less) and clear literature-based rational for your study addressing how the literature supports the purpose of your study and where your study fits within the literature.
  2. **Include supporting reference citations in an appendix.**

# On whom do you expect to collect data?

* 1. Women and / or Men
  2. Age range
  3. Minimum number necessary to complete protocol \_\_\_\_\_\_

# Who will recruit subjects?

# 5. Where will you recruit subjects?3

Additionally:

* 1. Attach the prose for any verbal or electronic correspondence
  2. Attach any flyers or announcements for websites
  3. 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

# 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.

# Describe your protocol in a step-by-step way using concise, every-day language. A flow-chart may be useful for clarity.

Additionally:

* 1. Clearly state what will participants be asked to do.
  2. Where will the data be collected?
  3. How will the data be collected? (Attach verbal script if applicable)
  4. Who will collect the data? Include training certificates in an appendix.
  5. If there are multiple options for participants (e.g. based on preliminary assessments), include a flowchart with clear tracks for each of the options.

# List the equipment, surveys, and/or other measures you will be using.

1. **State clearly and concisely (in everyday language) how the protocol and measures fulfill the purpose of your study.**
2. **When applicable include the following as appendices:**
   1. Datasheets or observation forms.
   2. Coding protocol(s).
   3. Questionnaire(s).
   4. Documentation that you have permission to use or reproduce material for your study (e.g. copyrighted, patented).

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

* 1. If there are multiple sessions, please list the time per session as well as the total time.
  2. 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).
  3. If the timeline varies for different participants, please attach a table that outlines the differences.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Protocol Description** | **# of Sessions** | **Time per Session** | **Time Frame (days, months?)** | **Total Time for this part of Protocol** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Risks:

* 1. What are the potential risks--physical, psychological, social, legal or other—for the participants?
  2. What is the likelihood and seriousness of each risk?
  3. If beyond minimum risk, what other methods that do not involve risk were considered and why will they not be used?
  4. How will you minimize potential risks?

# Benefits:

* 1. What are the potential DIRECT benefits that may be gained *by any individual participant* for his/her participation?
  2. What are the potential benefits to society in general as a result of the planned work?

# Confidentiality:

* 1. How will you maintain the confidentiality of participant information?
  2. 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.)
  3. If the data are subject to HIPAA, how will you de-identify medical data?

# Funding:

* 1. Will you be giving monetary or academic credit for participation?

Yes / No

* + 1. What is the exact amount you will be paying each participant?
    2. What is the total amount you expect to pay for all participants?
    3. What is the exact amount of credit that will be awarded to participants?
  1. How will you pay for the monetary compensation?
     1. If through a sponsor, include a copy of a grant award, contract, budget and equity interest documentation.
     2. 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.
  2. Do you have to pay for permission to use any of the equipment, surveys or other measures you will be using?
     1. How much do you have to pay?

$$

* 1. **Please explain how you will pay for the equipment, surveys, other measures, or other study components.**
     1. If through a sponsor, include a copy of a grant award, contract, budget and equity interest documentation.
     2. 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.
  2. Do you need to declare a conflict of interest based on your funding?

# 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**

* 1. 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.***This will require full IRB review and approval.***
  2. 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. This will require Full IRB review and approval.

# 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.

This will require full IRB review and approval.

# 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***