

**University of Puget Sound
Institutional Review Board (IRB)
for the
Protection of Human Subjects:**

**Principles and Procedures Governing the
Use of Human Subjects in Research**

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Institutional Review Board
Office of the Associate Deans
University of Puget Sound
1500 North Warner
Tacoma, WA 98416
(253) 879-3207

The IRB is mandated to review all University--related research involving human subjects. Ultimately, conducting ethical research and informing and educating research subjects, are the responsibilities of the investigator. Persons needing assistance in preparing a proposal or deciding which type of review to submit should consult the university IRB webpage (<http://www.pugetsound.edu/institutional-review-board-irb>).

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The policies and procedures described below were established to guide the conduct of research involving human subjects, to protect the rights, well-being, and personal privacy of individuals, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of the University of Puget Sound.

Preface

The Institutional Review Board (IRB) is a group of faculty and community members formally designated to review and monitor research involving human subjects. The purpose of the IRB is to protect the rights and welfare of individuals who participate in research as subjects. The University of Puget Sound IRB has the responsibility to see that all research involving the use of human subjects is conducted under ethical and sound scientific principles that ensure that the rights of subjects are safeguarded and done in compliance with federal regulations.

In order to protect the rights and welfare of human subjects, the University of Puget Sound conducts research with human participants in accordance with the Department of Health and Human Services' (DHHS) *Belmont Report*: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The commitment to the Belmont basic principles of respect for persons, beneficence, and justice is codified in a legally binding Federalwide Assurance (FWA) between the University of Puget Sound and the [Office of Human Research Protections](#) (OHRP). The University of Puget Sound's FWA number is # **FWA00029111**.

Through its FWA, the IRB at the University has agreed to conduct the review of human subjects research in accordance with all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46). Information related to the University's FWA, including its current expiration date, can be viewed on OHRP's website <https://www.hhs.gov/ohrp/>.

Section 1. General Principles

The following general principles apply equally to all research involving human beings, whether carried out solely with University resources or with the assistance of outside funds. The University assumes responsibility for communicating and explaining these principles to faculty and for providing procedural guidelines.

- A. University of Puget Sound faculty, staff, and students recognize their responsibility for protecting the rights and welfare of human subjects.
- B. Appropriate professional attention and facilities shall be provided to insure the safety and well-being of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.

- C. Research involving children (i.e., persons under 18 years of age), other legal incompetents, and persons unable to give informed consent will be approved only with the permission of a parent or legal guardian or attorney-in-fact. Research involving a child, another legal incompetent, or a person unable to give informed consent will not be approved if there is a significant risk of suffering without the possibility of benefit to the individual subject.
- D. The confidentiality of information received from subjects in experiments or from respondents to questionnaires shall be protected, both during and after the conduct of a research activity, within the limits of the law.
- E. Before a potential subject participates in research involving risk or substantial stress or discomfort, these considerations shall be carefully explained to the subject; the investigator shall be satisfied that the explanation has been understood by the subject; and the written (or in approved cases, oral) consent of the subject, such consent containing the substance of the explanation, shall be obtained and kept as a matter of record.
- F. A request by any subject for withdrawal from a research activity shall be honored promptly without penalty or without loss of benefits to which the subject is otherwise entitled.
- G. The investigator shall make appropriate arrangements to make available the results of the study to the subjects, when completed. Researchers making a decision to select for study one population group over another shall, in the proposal, provide clear rationale for selecting one such group over another. In requiring rationale for such a selection, the University seeks to conform to the guidelines set forth by the NIH in the Office of Human Research Protection (OHRP) IRB Guidebook which can be accessed at www.hhs.gov/ohrp/irb/irb_guidebook.htm.

Section 2. Procedures

- A. The membership of the Institutional Review Board is constituted so as to assure a broad range of competencies. The Institutional Review Board has the following responsibilities:
1. To review on a continuing basis the University's policy and procedures with respect to the use of human subjects, and to grant exceptions and to provide guidelines where desirable or necessary.
 2. To serve where necessary as a referral board for complaints from subjects of research.
 3. To provide advice and guidance to investigators regarding the protection of the rights and welfare of human subjects.
- B. It is the obligation of each investigator to bring any proposed research involving the use of human subjects to the attention of the IRB.
- C. Review procedures are as follows:
Before beginning research that involves human subjects, the investigator shall submit an application or statement to the IRB which, together with any appropriate supporting material, provides an adequate basis for approval by the IRB as expedited or exempt or for transmittal, if required, to the full Institutional Review Board. If such further review is required, the Institutional Review Board will review the application in the light of the general principles in Section 1. The signature of the principal investigator (if faculty research) or faculty advisor (if student research) on the Application Cover Sheet signifies that the protocol has been reviewed and that the research is appropriate to the department and that the investigator is qualified to carry it out.
1. Exempt and Expedited Reviews
An IRB member may act on behalf of the full board to review and approve the following categories of research. Such protocols will be reviewed within 3 business days during the academic semesters:
 - a. 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.
 - b. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - c. Research involving survey or interview procedures, except where one or more of the following conditions exist: (1) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (2) the subject's responses, if they

became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (3) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. These exceptions do not pertain to survey or interview procedures when the respondents are elected or appointed public officials or candidates for public office.

- d. Research involving the observation (including observation by participants) of public behavior, except where one or more of the following conditions exist: (1) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (2) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (3) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- e. 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 subjects cannot be identified, directly or through identifiers linked to the subjects.
- f. Research that is not proposed for outside funding or is not controlled by a regulatory agency.

2. Full Board Review

- a. The investigator shall include in the application a description of the manner in which the rights and welfare of the participants will be assured, (e.g., how their physical well-being and privacy will be protected and how their informed consent will be obtained, or why fully informed consent is deemed unnecessary or impractical in the particular circumstances).
- b. No research within the purview of the Institutional Review Board shall be initiated until approval has been given.
- c. Any University approved research which undergoes modification must be resubmitted to the Institutional Review Board. It shall be the responsibility of the investigator to request such review prior to initiation of the modification.
- d. Approval of proposed research is granted for a period of one year commencing with the anticipated beginning date of the research.

Continuation or renewal proposals must also be reviewed by the Institutional Review Board.

- e. The Institutional Review Board will normally require that the written consent of a parent, guardian, or appropriate authority be obtained before a child may participate in any research that is of such a nature as to require review under these procedures.
- f. The proposed procedure and specific instruments (including tests, questionnaires, etc.) to be used in any research conducted by University students in connection with academic work must be reviewed by a supervising faculty member and by the Institutional Review Board.
- g. If a subject registers a complaint, the investigator shall attempt to relieve the complaint by explanation or by a change of procedure. If the investigator finds that the complainant cannot be satisfied, the complainant should be referred to the Office of the Associate Deans.

Section 3. How to Determine if Your Study Requires Full Board, Expedited, or Exempt Review

Does my project need IRB review?

OHRP updated its Decision Charts to reflect the revised Common Rule requirements. These graphic charts are designed to help you decide if an activity is research involving human subjects that must be reviewed by an institutional review board (IRB) and whether informed consent, or documentation of informed consent, can be waived.

Check out the updated decision charts at:

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html>.

Your project needs to be reviewed by the IRB if it meets **both** of the criteria below

- A. The project meets the federal definition of research: systematic investigation intended to produce generalizable knowledge. [45 CFR 46.102(d)]

- B. Human participants are involved. Human participants are living individuals about whom you are conducting research and gathering
 1. data through intervention or interaction with the individual, or
 2. identifiable private information. [45 CFR 46.102(f)]

If your project meets **either** criterion A **or** B, but not both, your project does not need IRB review. If your project meets **both** criteria, you need IRB approval before beginning your research. Generalizable knowledge refers to the planned dissemination of results in a public forum or academic publication. Classroom projects, for which such dissemination is beyond the scope of the course, are not research according to this definition.

What are the types of IRB review?

The federal government has established different levels of review, depending on the method and content of your research.

1. Full Board: must be reviewed by the full committee, requires IRB oversight and follow-up.
2. Exempt: requires no further IRB oversight or follow-up

3. Expedited: may be reviewed by one member on behalf of the full IRB, but requires IRB oversight and follow-up

The Puget Sound cover sheet asks your research advisor to give their best estimate of the appropriate level of review for your project. However, the final decision about types of review rests with the IRB. You can use the following checklist to estimate the level of review for your project.

1) **Full IRB Review.**

If your project meets **ANY** of the following criteria, then it will require review by the full IRB committee:

- _____ receives support from non-university sources that require full IRB approval
- _____ involves greater than minimal risk (e.g., physical, psychological or emotional, legal, social or economic, etc.) to participants than they would likely encounter every day
- _____ involves personality tests, inventories or questionnaires of a personal and sensitive nature where participants' identities will not be anonymous to the researcher and/or where the information you collect can be connected back to individual study participants
- _____ involves sensitive aspects of a participant's behavior that could reasonably place a participant at risk of criminal or civil liability or be damaging to a participant's financial standing, employability, educational advancement, or reputation.
- _____ involves sensitive aspects of a participant's behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol
- _____ involves active deception or procedures that are not known to the participant (e.g., the participant will not be fully informed)
- _____ involves health care procedures that are not conducted for the primary benefit of the participants
- _____ includes diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice

_____ involves special populations (e.g., prisoners, pregnant women, or individuals who are mentally or psychologically ill, or incompetent)

_____ involves subjects under 18 years of age and involves more than minimal risk

_____ involves collection of blood samples or other body fluids in any amount

If any of these apply to your research, your project will need approval from the full Board before you begin your research. Your next step is to prepare a research protocol and submit it to the IRB for review. If none of these apply, then go to (2) below.

2) Exempt Review. If your research did not meet **any** of the criteria for full review, it will qualify for either exempt or expedited review. Examples of exempt research may include:

_____ surveys or interviews in which responses will be recorded in such a manner that a participant **CANNOT** be identified directly or through identifiers linked to a participant **AND** any disclosure of participants' responses outside the research will **NOT** place the participants at risk of civil or criminal liability, or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

_____ investigations of commonly accepted educational practices in established or commonly accepted settings.

_____ observations of public behavior.

_____ collection or study of publicly available existing data, documents, records or specimens.

_____ collection or study of existing data, documents, records or specimens in which information will be recorded in such a manner that a participant cannot be identified directly or through identifiers linked to a participant.

_____ research or demonstration project conducted by or subject to approval of the U. S. Department of Health and Human Services for the purpose of studying procedures, benefits, changes, and payments of entitlement programs.

_____ analysis of information from educational tests that will be recorded in such a manner that participants cannot be identified.

If you checked **any** of the descriptors in (2) above and **no** descriptors from category (1), your research project probably meets the criteria for **Exempt Review**. Your next step is to prepare a research protocol and submit it to the IRB for review. Your protocol likely can be reviewed by one IRB member on behalf of the full Board and, if it is approved for **Exempt** status, will require *no further oversight or follow-up from the IRB*. If you checked no descriptors in (1) or (2), go to (3) below.

3) Expedited Review

The third category allows for expedited review. Does your research project:

- involve only minimal risk (e.g., physical, psychological or emotional, legal, social or economic, etc.) to participants, or only as they would likely encounter every day?
- involve participants under 18 years of age with at most minimal risk to subjects?
- involve recording data from participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice?
- involve analysis of voice recordings made for research purposes?
- involve moderate exercise by healthy volunteers?
- involve the collection or study of existing data, documents, records or specimens?
- involve research on individual or group behavior, or characteristics of individuals, without manipulation of a participant's behavior and in a manner that does not cause stress to participants that is greater than they would encounter in everyday life?

If you checked any of the descriptors above, and none in (1) or (2), your project probably meets the criteria for **Expedited Review**. Your next step is to prepare a research protocol and submit it to the IRB for review. Your protocol likely can be reviewed by one IRB member on behalf of the full Board. If, after requests for modifications, the individual reviewer still disapproves of the protocol, it shall go to the Full Board for review and decision. If it is approved with **Expedited** status, your project will be subject to continued oversight and follow-up with the IRB and you will be required to submit requests for modification to methods, sampling, etc. should the need arise.

Section 4: Protocol Preparation Guide

Protocols must be assembled in the order given below.

- (1) The cover sheet must be properly completed. All investigators must sign it. For research where the student is the primary investigator, the faculty advisor must also review the protocol and sign the cover sheet. A faculty signature indicates they have reviewed the protocol, determined that it meets IRB guidelines, and that all named investigators are qualified to carry out the project.
- (2) Student researchers, faculty advisors, and faculty or staff researchers are required to complete training modules related to conducting research on human subjects. The CITI program is mandatory and completion certificates for all researchers (primary or co-investigators) and the faculty advisor involved in carrying out the research study must be included with the IRB application.
- (3) If for any reason co-investigators are not able to sign the cover sheet, letters of support signed by them must appear directly beneath the cover sheet.
- (4) See Section 8 for instructions regarding renewals, modifications, reconsiderations, terminations, and requests for additional information.
- (5) The protocol must follow the format below. If possible, keep the protocol to five pages or less, exclusive of supporting materials such as questionnaires, CITI documentation, and consent forms. The following paragraph subtitles must be used.
 - (A) **PROTOCOL DESCRIPTION:**
 1. **Introduction:** Introduce the topic of your research with background information and citations.
 2. **Purpose:** Clearly state what your study seeks to address and why this is important.
 3. **Exposition:** Explain how your project adds to or expands the body of **knowledge** that relates to your topic.
 - (B) **METHODS AND MATERIALS:** For each of the following subheadings explain how you will conduct your research.
 1. **Subject Recruitment:**
 - a. What is the total number of subjects?
 - b. How and where subjects will be recruited (word of mouth, posters on campus, emails, etc.)? Provide any recruitment materials (e.g., sample flyers, sample emails, etc.) in an appendix.

- c. What are the criteria, if any, by which subjects will be included or excluded (gender, athletes, age, race, etc.)?

If the study involves students from the University of Puget Sound the following standard statement may be used:

“The subject population will resemble the _____ Department at the University of Puget Sound in terms of age, ethnicity, and gender.”

- d. How will you obtain informed consent?
- e. Are there any special conditions or procedures that will be necessary for the project? If no, write N/A.
- f. Does your proposed study (a) involve non-English speakers, or (b) take place outside of the United States? If yes, review the International Research Policy (<https://www.pugetsound.edu/institutional-review-board-irb/policy-for-international-research/>) and address all questions as they relate to your study. If no, write N/A.

2. Risks to Subjects:

- a. All studies carry at least minimal risk. Explain the nature of risks that might occur to the subjects from participating in this study (physical, psychological, social, legal, or economic). See the IRB website for additional information on how to classify risk: <https://www.pugetsound.edu/institutional-review-board-irb>
- b. Describe the precautions you have taken to minimize risks.

3. Instrumentation: Describe any equipment, surveys, software, etc. that will be used in the study, and include validity and reliability of the instrumentation if relevant. Provide copies of materials in an appendix as relevant.

4. Data collection: Procedures of data collection need to be clearly described (e.g., how many times the subject must be tested or interviewed, how long will the session last, what is the subject to actually do during the testing session or interview, are there treatments/interventions, for ethnographic research methods specify interview type (structured, semi-structured, unstructured) along with questions and/or interview guide, etc.).

5. Data Analysis: Explain clearly how the data will be analyzed (e.g. qualitative research themes, ANOVA, t-tests, etc.).

- (C) **CONFIDENTIALITY OF DATA:** Explain how data will be secured to safeguard identifiable records of individuals. This may include how and where the data will be housed, how the data will be recorded (audio or visual tapes, paper/pencil, etc.), how long the data will be kept, how it will be disposed of, who will have access to the data, etc. If applicable, describe deception and/or assent procedures.

If applicable, the following standard statement may be used:

“The names of participants will not appear on materials containing their responses. All identifying materials such as the consent forms will be kept in a locked file cabinet in the _____ Department at the University of Puget Sound.”

- (D) **BENEFITS:** Describe the anticipated benefits to subjects, science, and/or society, that may occur as a result of this study.
- (E) **QUALIFICATIONS OF INVESTIGATOR(S):**
1. If a *faculty member* is an investigator please summarize their qualifications: e.g., Jamila Jensen is an associate professor in the Department of Psychology and has conducted and published many research studies dealing with Social and Cross-Cultural Psychology.
 2. If a *student* is an investigator, please indicate why they are qualified to conduct the research: e.g., Jane Johnson is a senior in the Department of Psychology and has taken the following classes which provide her the skills to conduct this research: Developmental Psychology, Applied Psychological Measurement, Cross-Cultural Psychology and Social Psychology.
- (F) **REFERENCES:** Provide the list of references you cited throughout the protocol (e.g., *Introduction* section, *Methods and Materials* section, etc.). Projects that involve the use of medications, dietary supplements, or any substances that will be introduced into the body must include referenced information regarding the known side effects of those substances.
- (G) **CONSENT FORMS:** Consent forms are required for most research involving human subjects. Please see the instructions for consent forms in the IRB Handbook, Section 6. Include a copy of your consent form with the protocol.

Section 5: Submission Packets for IRB Review

The following list identifies the materials that need to be submitted to the Institutional Review Board. **For full board review please refer to the IRB website for a list of deadlines (<http://www.pugetsound.edu/institutional-review-board-irb>).**

All submission packets must contain:

- 1x copy of the cover sheet with all required signatures
- 1x copy of the protocol with all required sections completed
- 1x copy of the consent form(s) (see Section 6)
- 1x copy of each investigator's CITI certificate (includes advisors)
- 1x copy each of any questionnaires, interview formats, or other survey instruments
- 1x copy of recruitment materials (e.g., flyers, if applicants)

****If the project has been reviewed by another IRB, that decision letter must be included.**

(Effective November, 2021, the University of Puget Sound is a member of the SMART IRB Agreement, enabling standardized reliance agreements between research institutions. Please enquire with our IRB Chair for details on how this works.)

The protocol should also include any letters from participating groups or facilities that verify their knowledge and approval of the research.

Please assemble these materials into a single PDF document, and submit the PDF electronically via the form that appears when you click the "Submit an IRB Protocol" button on the IRB webpage (<https://www.pugetsound.edu/institutional-review-board-irb>).

Section 6: Elements of Informed Consent and Consent Form Requirements

We recommend the researcher reads paragraph 46.116 of title 45 of the Code of Federal Regulations (45CFR46) before designing the consent forms. Informed consent shall be documented by the use of a written consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form. Consent forms document that the research project has been adequately explained to the subject. Consent forms need to be written in clear, concise, non-technical language appropriate for the research subjects, and must follow these guidelines:

- (1) The first page of the consent form must be duplicated on institutional or department letterhead.
- (2) The upper margin of the first page must be **at least one inch below the letterhead to allow room for the IRB approval stamp**. (For printed forms, the stamp will go in the upper right hand corner of the first page of the consent form.)
- (3) The consent form must have the following title:
Consent to Act as a Subject in a Research Study

If the consent form is directed for minors then the following title should be used:

Assent to Act as a Subject in a Research Study

For research involving minors, parental consent is also required. For parental consent the following title should be used:

Parental Consent for a Child to Act as a Subject in Research Study

- (4) The consent form must have the same official title as the title listed on the protocol.
- (5) List all investigators with names, the address of the department at the university and a university phone number. Do not include personal phone numbers, personal e-mail addresses, or personal messaging application addresses. University e-mail addresses should be used. Non-faculty or staff members must list their faculty sponsor(s) and the sponsor's contact information.
- (6) List the source of external support for the study, if applicable.
- (7) Provide a space for the subject's initials in the lower right corner of each page of the consent form. Pages must be numbered.

- (8) Informed Consent for Competent Adults and Adolescents must be formatted with the following standard paragraph subtitles, listed and explained below. This format assists the reviewers and the investigator to ensure that all required information is included.

DESCRIPTION: The first two sentences should give a brief, non-technical explanation of the study and identify why a particular subject is asked to be in the study. (Example: “The purpose of this study is to determine how people with different types of illnesses solve problems. You have been asked to participate because you have been diagnosed as having one of these illnesses.”)

A brief description of the methods that incorporates the following (if applicable) should also be included:

- Duration of participation
- Time sequences for stages or steps in participation

- Rest periods when indicated
- Tests or diagnostic procedures, and/or questionnaires
- Volume of blood to be drawn, in terms of tablespoons or ounces (tablespoon=15 ml.); maximum allowable amount-450 ml (if applicable)

RISKS AND BENEFITS: Include all reasonably foreseeable risks and discomforts associated with participation in the study. Such risks could be physical, psycho-social, or legal. Also include the specific precautions that will be taken to avoid such hazards. For example, if blood is to be drawn, mention the possibility of a bruise or soreness at the site of venipuncture, or a spasm with loss of blood flow at the site of arterial puncture. Include any potential benefits to the subject or to scientific knowledge. The benefits should be described as **possibly** occurring rather than implying a promise of improvement, benefit, etc.

ALTERNATIVE TREATMENTS: This is only applicable to research in which there is a choice of therapeutic interventions.

NEW INFORMATION: If applicable, the form should include the statement:

“New information gained during the time the research is in progress and which is relevant to participation will be provided.”

(NOTE: Such new information and any change in the project should be sent to the IRB for review and approval prior to discussion with the subject.)

COST AND PAYMENTS: Include any cost or payment to the subject, or reimbursement for related expenses. Mention any conditions affecting payment and time of payment. **If there are no costs or payments associated with participation in the study include a statement such as:**

“There are no costs for participating in this study. You will not be paid for your participation.”

APPROVAL TO USE AND DISCLOSE HEALTH INFORMATION: Any study that involves the use of protected health information (PHI) needs to include the following statement.

Federal and state laws require care providers to protect the privacy of your health information. Volunteering to participate in this study means that your health information that relates to this study may be collected, used and disclosed to carry out the study. This includes health information about you that was collected prior to, and in the course of the study. Information may be collected from you by interviews or from your medical records. Examples of the health information that may be collected include, but are not limited to, personal information (such as name, address, gender, age, etc.), your medical history, personal habits, and physical tests and measures.

By signing this consent form, you are authorizing the research team to have access to your study-related health information. The research team includes the investigators listed on this consent form only. Your health information will be used only for the study purpose(s) described in this research consent form. Your health information will be shared, as necessary, with any other person or agency as required by law. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

By signing this study consent, you are authorizing the research team to use and share your study-related health information until the end of the research study. The study records will be confidentially shredded for your security when storage is no longer required.

You may withdraw your approval to use and share your study related health information at any time by contacting the Principal Investigator (insert investigator’s name here) in writing, email or phone. If you withdraw this approval, you may no longer participate in this study. The study related health information that has already been collected may still be used to preserve the integrity of the study, including a disclosure to account for your withdrawal from the study. However, the use or sharing of future health information will be stopped.

Use asterisks to separate the sections of the consent form using the pronoun "you" from those using the pronoun "I".

CONFIDENTIALITY: Assurance of protection of confidentiality must be included in the consent form.* **Describe your plans, and include the *appropriate* sections of the following statement:**

I understand that any information about me obtained from this research, including answers to questionnaires, history, laboratory data, findings on physical examination, or audio or video recordings will be kept strictly confidential. Information that will carry personal identifying material will be kept in locked files or on password-protected computers. I do understand that my research records, just like hospital records, may be subpoenaed by court order. It has been explained to me that my identity will not be revealed in any description or publication of this research. Therefore, I consent to such publication for scientific purposes.

*Modification of this basic rule may be made in the case of deception studies and other extraordinary circumstances. It is not yet clear whether the courts will allow researchers to keep research records confidential in criminal proceedings.

RIGHT TO REFUSE OR END PARTICIPATION: **The following is a suggested paragraph which must be adapted to your specific protocol. (If this is for a course assignment, students who are participating should be made aware that they will not be penalized for withdrawing from the study.)**

I understand that I am free to refuse to participate in this study or to end my participation at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled.

VOLUNTARY CONSENT: **If you use the following standard statement it should be on the same page as the signature.**

I certify that I have read the preceding or it has been read to me and that I understand its contents. Any questions I have pertaining to the research have been and will be answered by Principal Investigator (insert investigator's name here), email and phone number or the Office of the Associate Deans (253-879-3207). A copy of this consent form will be given to me. My written signature or electronic consent means that I have freely agreed to participate in this experimental study.

Date

Subject Name (Printed)

Subject Signature

Witness

(About the witness signature: If a non-English speaking subject is unexpectedly encountered, it is still possible to obtain informed consent, even when a translated consent form is unavailable. The process is called a **short form consent** and consists of an oral presentation of a study summary containing the information in the consent form presented in the subject's native language and accompanied by a translated short form consent document (Common Rule 45 CFR 46.117, FDA regulations 21 CFR 50.27) This means that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation, usually the translator. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative (i.e., the script). Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. Please see the section below for requirements for oral consent forms.)

INVESTIGATOR'S CERTIFICATION: You may use the following statement:

I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participating in this research study. I have answered any questions that have been raised, and have witnessed the above signature.

Signature of Investigator or Representative: _____

Date: _____

Investigator/Representative (printed): _____

All consent forms must be signed by the subject. If possible, the subject should be allowed to study the consent form for 24 hours before signing. The investigator is responsible for explaining the research and the form to the subject. One copy of the consent form must be placed in the project file, and another copy must be given to the subject.

INFORMED CONSENT FOR MINORS AND INCOMPETENT ADULT SUBJECTS

If the subject is a minor between the ages of 13 and 17, both the parent or guardian and the child must give informed consent. The following statement must be added to all consent forms for subjects in this category:

ACKNOWLEDGEMENT OF PARENT OR GUARDIAN:

For Adolescents:

I, _____, have also read the preceding and agree to the participation of my child, _____.

Date

Parent/Guardian Signature

Witness (for Short Form only)

If a minor is below the age of 13, the informed consent of the parent or guardian must be obtained and the child must be given an explanation of the research. There is a moral obligation on the part of the investigator and the parents (or guardian) to assist the child to understand his/her/their role in the project. Therefore, under most circumstances, the IRB requires that a simplified consent form be read and explained to children six to twelve years of age. This may entail the use of a consent form especially prepared to facilitate understanding by a minor of such age because even though a parent or guardian has provided consent, the child must also assent to be a subject and sign the form if possible.

Elements of a child's assent form are:

1. simple familiar English, not slang; written in child-friendly language.
2. an explanation of the reason for asking the child to be in the study including:
 - the purpose of the study
 - procedures
 - risks or discomforts -- physical or psychological
 - benefits, if any
 - right to refuse or withdraw
 - investigator's willingness to answer questions

When a subject is unable to understand a research project due to age, maturity, psychological state, or brain disease or injury, such a project should not be undertaken unless it provides a reasonable expectation of benefit to the subject and does not interfere with a treatment program. When incompetent adults are sought as subjects for research, the partner, parent or legal guardian must give informed consent. The consent form should be similar to that for competent adults with appropriate blanks for insertion of the subject's name and for indicating the relationship of the subject's representative to the

subject. Make certain that necessary changes are made, recognizing that the signer is not the subject (i.e., a revised right-to-refuse paragraph).

ADDITIONAL INFORMATION REGARDING INFORMED CONSENT

The subject or legal representative has the right to withdraw consent at any time prior to or during the study. The term "legal representative" refers to the person who substitutes judgment and consents to participation in the best interest, and on behalf of the subject, and may include the subject's partner, parent or legal guardian of a minor or incompetent individual. The exact relationship of the subject's representative shall be entered on the form.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the standard elements of informed consent, or waive the requirement to obtain informed consent, only if the IRB determines that the research could not be done without the waiver or alteration.

In addition, the Board must find and document either (1) that the purpose of the research is to demonstrate or evaluate (a) federal, state, or local benefit or service programs which are not themselves research programs; (b) procedures for obtaining benefits under these programs; or (c) possible changes in or alternatives to these programs or procedures; or (2) that the research involves no more than minimal risk to the subjects; that the waiver or alteration will not adversely affect the subjects' rights and welfare; and that whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If deception is a significant element in the research, the investigator must provide a detailed explanation in the protocol and assurance that adequate debriefing will be carried out as soon as possible after completion of deception.

A signed "long" consent form to document consent is generally required. In specified circumstances, the requirement of a signed written consent form may be waived altogether. The investigator must establish the need for departure from usual informed consent.

Consent with non-English speaking subjects

- (1) Consent must be obtained in the subject's native language.
- (2) Consent forms must be translated into the subject's native language.
- (3) If translation of the form is not possible the principal investigator must use an approved translator to obtain consent (verbal or written). The protocol must describe who this translator is, and their qualifications.

Oral consent:

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

In the protocol, the researchers must specify why their research could not practically be carried out without the written consent, as in item (3) above.

Oral consent is often used in ethnographic research, and oral scripts must be used. After reading the oral script to the subject, the researcher must specifically ask if the subject consents to being a participant in the described study, and must obtain a clear affirmative answer before proceeding.

(a) Oral consent scripts must describe key participation and consent issues. Upon completion of the oral consent process, the researcher signs and dates the oral consent script indicating that consent has been obtained from the participant, thereby producing no documentation connecting participants with the project.

(b) Oral consent scripts utilized by ethnographic researchers also often double as project information sheets that can be left with subjects for further consultation.

(c) Oral consent scripts must include the researcher's contact information, the supervisor's contact information (if applicable), and the Associate Dean's contact information. Note that student-researchers should provide subjects with their university email address, and are forbidden from including their personal phone number.

Electronic Informed Consent (eIC):

University of Puget Sound's IRB is following the rules and guidelines specified in *Use of Electronic Informed Consent - Questions and Answers - Guidance for Institutional Review Boards, Investigators, and Sponsors*, issued December 2016 by the U.S. Department of Health and Human Services, Office for Human Research Protections.

Electronic informed consent cannot be used for protocols that involve greater than minimal risk to human participants or that involve vulnerable populations or where children are involved.

Such protocols must obtain written signatures in the presence of study personnel. Nevertheless, the IRB will consider protocols where any or all of the consent process takes place remotely and is not personally witnessed by study personnel, and where the electronic system includes a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR (see 21 CFR 11.100(b)). Examples of various methods that could be used include verification of a state-issued identification or other identifying documents or use of personal questions, biometric methods, or visual methods. In such cases the researchers must describe in detail which electronic and software applications will be used to ensure such identification.

For minimal risk research where no children or vulnerable populations are involved, a system for obtaining electronic signatures or consent is allowable, without the identity verification requirements for greater than minimal risk research. Since there are many methods for obtaining electronic consents or signatures, the researcher must specify in detail which method and which software application they plan to use. The electronic system that supports the eIC must be secure with restricted access (see 21 CFR 11.10 and 11.30) and should include methods to ensure confidentiality regarding the subject's identity, study participation, and personal information after informed consent has been obtained.

When electronic survey platforms are used (such as qualtrics or Survey Monkey), there must be a way for the subject to positively consent to participating in the survey before being led to the question section.

Section 7: Renewals, Modifications, Reconsiderations, Disapprovals, and Terminations

Guideline on Renewals, Modifications, Reconsiderations, Disapprovals, Terminations, and Sanctions

The fundamental charge of the Institutional Review Board (IRB) is to protect human research subjects. Approval by the IRB is for a period of 1 Year from date of submission and researchers are to notify the IRB within 30 days of termination of an approved project. An annual report to the IRB is required of all approved protocols.

Renewals

Once approved, a protocol is valid for 1 year from date of submission.

- A. Renewals of approved protocols are mandatory and must be approved at least 30 days (90 days if expiry is over the summer) before the anniversary of the original approval date. The principal investigator must submit the following, in the order given:
- (1) A new cover sheet. Include the original protocol number.
 - (2) The completed and signed Renewal/Modification form (update with new page)
 - (3) Progress Report indicating the following:
 - (a) Number of subjects entered in study.
 - (b) Description of adverse reactions or unexpected side effects.
 - (c) Summary of the results of the investigation to date.
 - (4) The protocol, highlighting any changes indicated on the Renewal/Modification form. Copies of the protocol (see page 15) must be submitted even if it is unchanged from the prior year.
 - (5) Consent form(s), even if unchanged from the previous year. Any changes that have been made should be highlighted.

For renewals, there are three types of review (submit one copy for either):

- (1) Exempt Review if the proposal was previously considered exempt and there have been no changes, adverse reactions, or unexpected side effects.
- (2) Expedited Review if the proposal was previously approved by the expedited review process.
- (3) Full Board Review is required if the proposal was originally reviewed by the full IRB

- A. If renewal has not been granted by the time of protocol expiry, all research involving human subjects pertaining to the study **must stop** until renewal has been authorized.

- B. Any renewal or update that is submitted to, and accepted by the IRB begins a new 1 year effective period.
- C. If renewal is accompanied by modifications, see below.

If questions arise about the renewal procedures, please contact the IRB Chair.

Modifications

Federal regulations require that the IRB review and approve any changes in the approved research *prior to implementation except when necessary to eliminate apparent immediate hazards to subjects.*

Modifications to protocols can be made at any time during the annual approval period. Some modifications are expeditable. A modification that changes the risk level or significantly changes the project's goals or methodology is not expeditable, and may need to be reviewed and approved by the full IRB. The IRB Chair shall decide on the appropriate review process. When a modification is made and approved, the actual approval date for the project will not change. The modification will merely be acknowledged. The annual renewal will still be due on the anniversary of the original approval date.

The procedures set forth above for renewal are to be followed also when modifying a protocol. The packet should be put together in the same order as a renewal except that a progress report is not required .

When submitting modifications to an existing protocol, and/or consent form(s)

- A. All research pertaining to the study **must stop** until approval of modification(s).
- B. List page numbers and sections where modifications are made and highlight them.
- C. Include a brief statement describing/justifying any deletions/changes.
- D. All modifications must be incorporated into the cover sheet, protocol, and consent form(s), as applicable.
- E. If the principal investigator on the project changes, the registration information for an IRB must be updated within 30 days after changes occur. Submit modification to the IRB.
- F. Any new or added investigators must submit current CITI certificates.
- G. Use the renewal/Modification forms for all these changes (see below).

Reconsiderations

When an IRB-reviewed proposal requires significant modifications that warrant reconsideration of the proposal at a subsequent meeting, 1 copy of the reconsideration packet must be assembled as follows, and submitted no later than 2 weeks before a scheduled IRB meeting.

- (1) Cover sheet
- (2) Letter from IRB requesting modifications

- (3) Letter from investigator addressing concerns
- (4) Protocol
- (5) Consent form(s)
- (6) Attachments, etc.

All copies must have modifications highlighted.

Disapprovals

If the IRB votes to disapprove a research protocol, it will include in its written notification a statement of the reasons for its decision, based on specific Federal regulatory criteria.

- A principal investigator may appeal this decision within 30 days by writing a letter to the IRB requesting reconsideration.
- At the discretion of the chair, the investigator may make such an appeal in person and/or in writing to the IRB.
- An appeal of a disapproved research project must be reviewed at a full board meeting.
- After review and discussion of appeal materials and/or presentation by the researcher, the IRB will vote by simple majority whether to approve the appeal and allow the research to commence.
- If the IRB upholds its vote to disapprove, suspend, or terminate a project, the decision may not be appealed again. Nor may it be reversed by any administrator, other officer or agency of University of Puget Sound, state government or Federal government. The IRB retains the final authority for approval of proposed research with human subjects.

Termination of Project

When a project is terminated, the principal investigator must

- A. within 30 days send a written notification to the IRB and submit a final progress report (using the Yearly Progress report form).
- B. The IRB protocol number must be included. (Progress report form attached below in Appendix 4)
- C. No further contact with the participants will take place and all data and/or samples are to be permanently de-identified.
- D. A termination report must be submitted even if
 - I. the study is never initiated, and no enrollment takes place; and
 - II. a Primary Investigator leaves without requesting a change in PI.
- E. Following study closure, the researcher may not contact study subjects for further data collection.
- F. If the need for more data collection arises, the PI must inform the IRB immediately. The PI may request that the IRB re-open the study by submitting a renewal form, or a new protocol submission and review may be required.

Further, the IRB shall also have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head (see **§46.113**

Suspension or termination of IRB approval of research,

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111>).

Sanctions

University faculty, staff, and students who are found to be in violation of IRB policies and/or committing Research Misconduct may be subject to sanctions relating to their participation in research involving human subjects. Depending on the severity of the violation, sanctions may involve a written warning, temporary suspension of the research, termination of the research, or the permanent destruction of collected research data. Actions taken by the IRB and the University also will be subject to Federal reporting guidelines.

UPS IRB PROTOCOL #:

**University of Puget Sound INSTITUTIONAL REVIEW BOARD
Renewal/Modification Form**

Check one or both: Renewal Modification

Investigator's name:

Protocol Number: _____

Protocol Title: _____

_____ I am requesting renewal and I certify that I have made no modifications in the protocol or consent form(s) since the last approval date.

_____ I am requesting approval of the following modifications in the protocol and/or consent form(s) which are listed below. (List page numbers and sections where modifications are made and highlight them, and include a brief statement describing/justifying any deletions/changes.)

_____ I am requesting both renewal and approval of the following modifications in the protocol and/or consent form(s) which are listed below. List page numbers and sections where modifications are made and highlight them, and include a brief statement describing/justifying and deletions/changes. All modifications must be incorporated into the cover sheet, protocol, and consent form(s), as applicable.

Modifications requested: (attach additional sheets if necessary)

Appendix 1:

Investigator's Checklist

Please use this checklist to ensure that your protocol meets IRB requirements.

Submit application for full board review before the deadline indicated on the IRB website

<https://www.pugetsound.edu/institutional-review-board-irb>

Applications for exempt and expedited review may be submitted at any time.

COVER SHEET

- _____ Completed
- _____ Typed
- _____ Signed (investigators, and if appropriate, faculty advisor)
- _____ CITI Training Certificate of Completion attached

PROTOCOL (5 pages maximum)

- _____ Pages numbered throughout

(A) Protocol Description

- _____ 1. Introduction
- _____ 2. Purpose
- _____ 3. Exposition
- _____ 4. References

(B) Methods and Materials

1. Subject Recruitment

- _____ a. Number of subjects
- _____ b. How and where subjects are recruited
- _____ c. Criteria for inclusion and exclusion
- _____ d. Method of obtaining informed consent
- _____ e. Special conditions or procedures (if applicable)
- _____ f. International research considerations (if applicable)

2. Risks to Subjects

- _____ a. Risks to subjects
- _____ b. Precautions to minimize risks

3. Instrumentation

4. Data collection

_____ **5. Data analysis**

_____ **(C) CONFIDENTIALITY OF DATA:**

- _____ Procedure used to protect confidentiality
- _____ Manner of recording information
- _____ Use of audio and visual tapes and their disposition
- _____ How long identifying information will be kept
- _____ Deception or assent (if applicable)

_____ **(D) BENEFITS**

- _____ Benefits of the research

_____ **(E) QUALIFICATIONS OF INVESTIGATOR(S)**

- _____ Faculty: Qualifications for conducting the research
- _____ Student: Qualifications for conducting the research

CONSENT FORMS

Procedural Details:

- _____ a. Page 1 is on appropriate institution letterhead.
- _____ b. Project title (identical title used on consent form and project).
- _____ c. Pages numbered (protocol and consent form numbered separately).
- _____ d. List all investigators, email addresses, and business telephone numbers (personal numbers, e.g., cell phone numbers may not be used).
- _____ e. If consent form is longer than 1 page, line for subject's initials appears in lower right corner of each page of consent form.
- _____ f. Signature lines for all that apply to a specific study, e.g., subject, witness, parent, corroborator.

Consent forms are required for all individuals who need to consent. Separate consent forms are required for individuals who experience different levels of the study. For example, adults in a treatment group, the control group, parents/guardians all require separate consent forms. Children require assent scripts/forms dependent on age and purpose of study. Additional consent forms may be needed given a specific study's design.

Content:

- _____ Description of study written in non-technical language no greater than 8th grade reading level
- _____ Risks/benefits clearly described

- _____ Alternative treatments, if applicable
- _____ Costs and payments, if applicable
- _____ Confidentiality and use of protected health information
- _____ Dean's phone number
- _____ Right to refuse or end participation
- _____ No compensation for injury, if applicable
- _____ Voluntary consent
- _____ Acknowledgment of parent, if applicable
- _____ Investigator's certification

Appendix 2: Definitions

1. **Adverse Effect:** An adverse effect is any physiological, psychological, or social outcome of an investigation which is detrimental to a subject. An adverse effect may be anticipated or unanticipated. For the purpose of review, the following information is needed:

New Applications: Information on adverse effects which most likely or only possibly may occur, based on the literature, previous studies, and other reliable sources. In addition to listing possible adverse effects, applications should indicate the probability that any adverse effect could occur.

Renewal Applications: The same information is required as for new applications, as well as information on adverse effects which have occurred during the study to date.

2. **Anonymity:** In the context of these guidelines "anonymity" means that no one knows the identity of the subject. No identification of subjects should be possible by the procedures employed or by the information solicited. An example would be a mailed questionnaire with directions for subjects not to sign their names, where no code is used, where responses to questions will not reveal identities, and where the subject group is sufficiently large to avoid inadvertent identification.
3. **Assent:** Assent is a child's affirmative agreement to participate in research after an adequate explanation has been provided. The absence of a child's objection does not constitute assent.
4. **Certification:** If a funding or sponsoring agency of research requires certification that research proposals are appropriately reviewed and approved by a University review board, it shall be the responsibility of the researcher to obtain and have completed all appropriate documents.
5. **Confidentiality:** Where the identity of subjects is known by name, by specific data, or by appearance, it is usually necessary to make provisions for confidentiality. Data should be stored in a locked file cabinet (or should be similarly protected) accessible only to the investigator and their authorized staff or representatives. No identifying information including recordings (e.g., photographs, tapes, documents), should be released except with the express permission of the subject.

Where confidentiality in reports of results or in reports of specific incidents of interest to the scientific community cannot be assured, this information must be included in the consent form. In those instances where unique information is received but was not

anticipated at the time of consent, later consent for the release of identifying information should be obtained.

Only personal information necessary to a research activity should be solicited from subjects.

To avoid an inadvertent break of confidentiality, data should be coded, with the names of participants and other identifying information retained only on a master list to be securely stored separate from the data.

In double--blind studies (e.g., drug studies), an appropriately designated individual should retain a copy of the key to the code and a listing of the drug and the dosage to be taken by each subject; and should be available to break the code if necessary.

In some circumstances, it may be necessary to break confidentiality. If this is foreseen, the study subjects should be informed of this possibility on the consent form. An example would be subjects who engage in or have engaged in illegal activities. Because of legal interests, a risk exists that the data or the investigators might be subpoenaed; prospective subjects must know this prior to consenting.

6. **Deception:** Deception occurs whenever information about an activity is deliberately withheld from subjects. A dilemma may arise in some research when fully informed consent may itself have injurious effects on the subject, or it may invalidate the experiment, as in the use of placebos or double--blind studies.
7. **Incompetent:** In the context of the human subjects review process, an individual who is unqualified to give or is incapable of giving informed consent is considered to be incompetent. An incompetent may be a minor, an adult who has been declared legally incompetent, or an adult whose competency may be questioned because of an illness or an unusual circumstance.
8. **Informed Consent:** The ethical and professional codes governing the use of human subjects in research provide that no research involving human subjects should be undertaken without the informed and voluntary consent of the human subject, or the consent of their authorized representative if the subject lacks the capacity to consent.

When a subject's consent is obtained, it must be "informed" consent (i.e., the knowing consent of an individual or their legally authorized representative, so situated as to be able to exercise free power of choice without the presence of excessive inducement or any element of force, fraud, duress, or other form of restraint or coercion). Further, consent should be a reasoned judgment to participate in an activity in full recognition of what will, or could, happen. In most cases, the investigator must discuss with the subject, in language

that can be readily understood, all matters pertinent to the decision to participate. The consent form should contain the essence of the discussion between the investigator and the subject.

9. **Institutional Review Board:** Institutional Review Board (IRB) is the term used for a committee or group which has been formally designated by an institution to review and approve research involving human subjects.
10. **Intermediary:** An intermediary is an individual or organization that in another capacity has contact with a prospective subject population and that cooperates with an investigator by obtaining consent from prospective subjects for the release of their names and addresses or telephone numbers to the investigator. The intermediary should avoid seeming to endorse a particular research activity.
11. **Minimal Risk:** Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
12. **Personal and Sensitive:** Examples of personal and sensitive information are: some demographic data; questionnaires, inventories, and scales which elicit subjective responses; opinions on sensitive issues or about other individuals or groups; and records, such as medical, academic, photographic, audio tapes, and videotapes.
13. **Right to Privacy:** The right to privacy is the right of individuals to decide for themselves how much they will share with others their thoughts, their feelings, and the facts of their personal lives.
14. **Risk:** There are different types of risks to which human subjects may be exposed that are inherent in various research procedures. Risk is most obvious in medical and behavioral science research projects involving procedures which may induce a potentially harmful altered physical state or condition. Some examples are: the removal of organs or tissues for study, reference, transplantation, or banking; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exercise; and subjection to deceit, public embarrassment, or humiliation.

There is a wide range of medical, social, and behavioral projects in which no immediate physical or psychological risk for the subject is involved (e.g., those involving the use of personality inventories, interviews, questionnaires, observations, photographs, tapes, records, and stored data). However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, or constitute a threat to the subject's dignity, all of which pose another type of risk.

- 15. Scientific Merit:** The University reviewing committee must consider scientific merit, that is the potential for contributing to knowledge, in order to help determine whether or not the potential benefits of the research to individuals or to society outweigh the risks.

In cases in which there would be moderate or high risk and in which there are problems in determining scientific merit, consultants may be used in making this determination. Research will not be approved when the risk is significant and the project lacks scientific merit.

- 16. Subject:** A subject is a human being whose physical, intellectual, emotional, or behavioral condition is investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. If a person, such as a family member, employer, or teacher, is asked to provide information about another individual, then both individuals are considered to be subjects. The subject may be an adult, a minor, a student, a patient, military personnel, a resident of an institution for the mentally retarded, or a prison inmate.

It is useful to distinguish between normal subjects and those who are of interest because of an illness or dysfunction. A subject is considered to be a normal subject if their participation in the activity is not determined by any illness or dysfunction that they exhibit.

The definition of "subject" excludes all accepted and established service relationships, such as the normal relationship of patients to physicians, students to professors, and other clients to professionals, in which the patient, student, or client is receiving aid or services intended only to meet their own personal needs or the overriding needs of society. The professional--client relationship has the welfare of the client as the primary objective, whereas the investigator--subject relationship has the discovery of new knowledge as its primary objective. This difference may not be fully understood by the subject who is also a client and can result in the investigator's gaining consent without free decision, in part due to a trust based on a presumed role which the investigator is not necessarily fulfilling at that time. If doubt exists as to whether the procedures to be employed are for the personal needs of the client, the activity should be considered to involve subjects whose rights and welfare are to be protected in accord with these guidelines.

The normal employee--employer relationship, in which legitimate services are tendered for salary, wages, or remuneration in keeping with customary written or oral contracts, is also excluded from the definition of "subject." Payment of volunteers, however, does not alter their status as subjects. If doubt exists as to whether the procedures are within the normal limits of the employees' work scope, the employees should be considered to be participating as human subjects, and their rights and welfare must be protected.

- 17. Subject Advocate:** A subject advocate is an individual who participates in the consent process on behalf of an adult subject who has not been declared legally incompetent, but whose ability to give informed consent is in question. The subject advocate should be a family member, a close friend, or someone who knows the subject well enough to attest to the subject's probable agreement to participate.

Appendix 3. Consent Form Examples

Before assembling the Consent Form, we suggest you read Part 46.116 of the Title 45 Code of Federal Regulations. Part 46.116 lists the basic elements of informed consent as follows:

“In seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others that may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject;
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- (9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - (ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

RIGHT TO REFUSE OR END PARTICIPATION: I understand that I am free to refuse to participate in this study or to end my participation at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled. Additionally, I may refuse to answer any question or set of questions contained in the questionnaires if I choose to do so, without any adverse impact on my participation in this study.

VOLUNTARY CONSENT: I certify that I have read the preceding or it has been read to me and that I understand its contents. Any questions I have pertaining to the research will be answered by [the names of the investigators]. Any questions or concerns I have regarding my rights as a research subject will be answered by the Office of the Associate Dean (253-879-xxxx). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this study.

Date

Participant's signature

INVESTIGATOR'S CERTIFICATION: I certify that I have explained to the above individual the nature, potential benefits, and possible risks associated with participating in this research study, have answered any questions that have been raised, and have witnessed the above signature.

Date

Investigator's signature

Example B: Consent which includes use of health related information from the Department of Physical Therapy: (Note that the line for subjects to initial each page, and letterhead on top of first page is not shown.)

Consent to Act as a Subject in a Research Study

Effects of Exercise during Dialysis on Quality of Life for Patients with End Stage Renal Disease.

PRIMARY INVESTIGATOR

[First and Last Name], PT, M.Ed
Clinical Associate Professor

CO-INVESTIGATORS

[First and Last Name], SPT
[First and Last Name], SPT
[First and Last Name], SPT
[First and Last Name], SPT

University of Puget Sound
Physical Therapy Department
1500 N. Warner St. CMB 1070
Tacoma, WA 98416
(253) 879-3524 or (253) 879-3281

Project Description: You are being asked to participate in a study to examine the effects of exercise during hemodialysis on your quality of life and how tired you get while performing your usual daily activities. You have been asked to participate because you have a diagnosis of end-stage renal disease. Your doctor has agreed that it is safe for you to participate in this study. The first part of the study will last for seven weeks. For the first week, you will be asked to complete a health related questionnaire called the modified Kidney Disease Quality of Life and a brief questionnaire called the Fatigue Severity Scale during each of your regular dialysis sessions before any participation in exercise. It will take approximately 20 minutes to complete these two questionnaires. This will be followed by a six-week period of gentle exercises that you will do each day while you are receiving dialysis. The exercise sessions will be approximately 45 minutes long and will occur sometime during the second hour of each dialysis session. You will be asked to complete the Kidney Disease Quality of Life questionnaire and the Fatigue Severity Scale again two and four months after the exercise portion of the study is over.

Benefits: Information learned from this study may help others with end-stage renal disease improve their quality of life and manage their fatigue. You may personally experience an increase in energy, an improved sense of well-being, better endurance and the ability to complete

your daily activities more effectively. You may also have less pain, fewer muscle cramps, and less joint stiffness.

Risks: The risks associated with participating in this study are minimal. The risks may include interruption of the vascular access site for hemodialysis so a dialysis session could not be completed, an excessive increase in heart rate or blood pressure, fractures or the chance of a medical emergency such as heart failure. The following steps will be taken to minimize these risks and assure your safe participation. You will not be asked to move the limb that your access site is in to reduce the chance of disrupting your dialysis session. Your blood pressure will be checked periodically while you are exercising. You will be asked to tell the research team how hard you are working during each activity and you will not be asked to do any activity that you feel is making you work too hard. You will be given rest breaks whenever you ask for them. The exercise session will be stopped immediately if you experience chest pain, a rapid heart beat, dizziness, leg cramps, extreme tiredness, blurred vision, or shortness of breath. There is almost no risk of fractures in this study because you will not be doing any heavy weight lifting and you will be carefully supervised throughout each session. In the event of a medical emergency, the Emergency Medical System will be activated according to the protocol established for the Dialysis Unit at St. Joseph Medical Center.

Cost and Payments: There are no costs for participating in this study. You will not be paid for your participation.

Approval to Use and Disclose Health Information: Volunteering to participate in this study means that your health information that relates to this study may be collected, used and disclosed to carry out the study. This includes health information about you that was collected prior to and in the course of the study. Information may be collected from you by interviews or from your medical records. Examples of the health information that may be collected include, but are not limited to, personal information (such as name, address, gender, age, etc.), your medical history, the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures.

By signing this consent form, you are authorizing the research team to have access to your study-related health information. The research team includes the investigators listed on this consent form and other personnel involved in this specific study. Your health information will be used only for the study purpose(s) described in this research consent form. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

By signing this study consent, you are authorizing the research team to use and disclose your study-related health information until the end of the research study (November 30, 2005). The study records will be confidentially shredded for your security when storage is no longer required.

You may withdraw your approval to use and share your study related health information at any time by contacting the Principal Investigator in writing. If you withdraw this approval, you may no longer participate in this study. The study related health information that has already been collected may still be used to preserve the integrity of the study, including a disclosure to account for your withdrawal from the study. However, the use or sharing of future health information will be stopped.

.....

Confidentiality: I understand that any information about me obtained from this research, including answers to questionnaires, history, laboratory data, findings on physical examination, or audio or video recordings will be kept strictly confidential. Information that will carry personal identifying material will be kept in locked files. I do understand that my research records, just like hospital records may be subpoenaed by court order. It has been explained to me that my identity will not be revealed in any description or publication of this research. Therefore, I consent to such publication for scientific purposes.

Right to Refuse or End Participation: I understand that I am free to refuse to participate in this study or to end my participation at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled.

Voluntary Consent: I certify that I have read the preceding or it has been read to me and I understand its contents. Any questions I have pertaining to the research have been and will be answered by Ann Wilson (253) 879-3524. Any questions I have concerning my rights as a research subject will be answered by the Office of the Associate Deans at the University of Puget Sound (253) 879-3207. A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this experimental study.

Date

Subject Signature

Witness

Investigator's Certification: I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participating

in this research study, have answered any questions that have been raised, and I have witnessed the above signature.

Date: _____

Investigator/Research Staff Member

Example C: Adult consent form with child assent form example from Department of Physical Therapy: (Note that the letterhead on top of first page is not shown.)

**INFORMED CONSENT
TO ACT AS A SUBJECT IN A
RESEARCH STUDY**

PRINCIPAL INVESTIGATORS: [First and Last Names of the Investigators]
Department of Physical Therapy, 1500 N. Warner, CMB 1070, Tacoma, WA 98416;
253-879-2895; xxxxxxxx@ups.edu

STUDY TITLE: Assessment of the Pediatric Clinical Test of Sensory Interaction for Balance Using a Single Rater System

SUBJECT'S NAME:

Please read the following materials to make sure that you are informed of the nature of this study and of how you and your child will participate in it, if you agree to do so. Signing this form will indicate that you and your child understand what the study is about and that you have decided to participate.

PURPOSE/DESCRIPTION OF STUDY:

You and your child are being asked to participate in a research study to learn more about children's standing balance and limb stiffness. Specifically we would like to develop the Pediatric Clinical Test of Sensory Interaction for Balance (P-CTSIB) using only one tester as opposed to two. We will also compare these scores to a reaching test, a timed walk test, a questionnaire about your child's functional motor abilities and a limb stiffness test. Your child has been chosen to be in the study because your child is between the ages of 6 and 12 years old and either has or does not have a motor development delay. You and your child will be asked to participate in the study on one day, with the opportunity to come back for a second shorter visit (30 min.), to repeat the P-CTSIB balance test. Testing on the first day will last approximately one hour.

PROCEDURES:

1. We will measure your child's balance as they stand with feet together and hands on hips under the following six different conditions:
 - 1- eyes open on flat ground
 - 2- eyes closed on flat ground
 - 3- wearing a special hat that changes vision on flat ground
 - 4- eyes open standing on soft foam

Subject's Initials _____

- 5- eyes closed on soft foam
- 6- wearing a special hat that changes vision on soft foam
- 2. We will measure your child's ability to reach from a standing position.
- 3. We will measure your child's walking speed by asking him, her, or them to rise from a chair, walk three meters, and sit back down in the chair.
- 4. You will be given a questionnaire about your child's ability to perform functional movement skills.
- 5. We will measure the stiffness of your child's leg. Stiffness will be measured by having the child swing their leg for twenty swings while supported.

RISKS AND BENEFITS:

There is a risk that during the P-CTSIB, reach test, and timed walking test your child might lose his, her, or their balance. Although a risk of falls is possible in any test assessing balance, the risk of falls in this study is very small because one investigator stands near your child during each of these tests. Your child will wear a loose belt around the waist so the investigator can hold on to it to protect your child from falling. If your child does not like any of the testing he/she/they will be able to stop at any time.

The benefit of you and your child's participation in this study is in assisting us in the development of a test for use with children with motor disability. If you would like your child's results on the testing, these can be provided to you. For your child's participation in this study, he/she/they will receive a toy or prize.

COST AND PAYMENTS:

There is no cost to participate in this study, and no monetary compensation will be given for participation. A small toy or prize will be given to your child for taking part in the study.

CONFIDENTIALITY:

I understand that any information about me or my child obtained from this research, including answers to questionnaires, history, laboratory data, findings on physical examination, or audio or video recordings will be kept strictly confidential. Information carrying personal identifying material will be kept in locked files. I do understand that my and my child's research records, just like hospital records may be subpoenaed by court order. It has been explained to me that my identity will not be revealed in any description or publication of this research. Therefore, I consent to such publication for scientific purposes.

RIGHT TO REFUSE OR TO END PARTICIPATION:

I understand that I am free to refuse my participation and my child's participation in this study or to end our participation at any time and that our decision will not adversely affect our care at this institution or within our school program, or cause a loss of benefits to which we might otherwise be entitled.

Subject's Initials _____

VOLUNTARY CONSENT:

I certify that I have read the preceding or it has been read to me and that I understand its contents. Any questions I have pertaining to the research have been or will be answered by [First and Last Name], PhD, PT at the University of Puget Sound (253-879-2895). Any questions I have concerning my rights as a research subject will be answered by the Office of the Associate Dean (253-879-3207). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate and to allow my child to participate in this experimental study.

SIGNATURES:

I have read or discussed this document with one of the investigators involved in the project and agree to participate and to have my child participate.

Signature of Subject

Date

Consent Signature of Parent or Person Legally
Responsible for Subject

Date

Signature of Witness

Date

INVESTIGATOR'S CERTIFICATION:

I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participating in this research study, have answered any questions that have been raised, and have witnessed the above signature.

Signature of Investigator or Member of Research Staff

Date

**CHILDREN'S INFORMED ASSENT
FOR SUBJECTS AGES 6-12
TO ACT AS A SUBJECT IN A
RESEARCH STUDY**

PRINCIPAL INVESTIGATORS: [First and Last Names of the Investigators]
Department of Physical Therapy, 1500 N. Warner, CMB 1070, Tacoma, WA 98416;
253-879-2895; xxxxxxxx@ups.edu

STUDY TITLE: Assessment of the Pediatric Clinical Test of Sensory Interaction for Balance
Using a Single Rater System

SUBJECT'S NAME:

* This form will be read to the child to ensure comprehension.

You are being asked to be in a research study, but before you decide to be in it, we want to tell you about it so you can ask questions.

The people in charge of this study would like you to do some tests that measure your balance.

The reason we are asking you to be in this study is because you are between 6 and 12 years old and either have or do not have trouble keeping your balance. The purpose of this study is to learn more about how children keep their balance when they are standing.

These tests should be fun. We do not expect you to be uncomfortable during any of the tests. No needles or medicine are involved in the study. If you decide you do not like any of the tests you can stop at any time. All you need to do is tell us you want to stop. For doing our tests you will receive a small prize.

First we will measure your balance by asking you to stand in one spot very still with your eyes open and closed and with a funny helmet on. Next we will have you reach as far as your can while keeping both feet still. We will then see how fast you can get up from a chair, walk to the piece of tape on the floor and sit back down in the chair. Lastly, we will have you swing your leg back and forth.

This test may help us learn more about how different children balance. Hopefully, someday, it will help children who have trouble keeping their balance.

The other choice you have is to not do anything at all. You do not have to be in this study and you can stop at any time. Stopping or not being in the study will not upset anyone.

Do you have any questions? Do you want to do the tests?

My _____ (parent/guardian) knows about this test and wants me to be in this study.

Child's Signature

Date

Parent/Guardian Signature

Date

Investigator Signature

Date

Witness Signature

Date

Example D: Oral Consent

Please refer to the Oral Consent section on page 24 for more information about the requirements. (To help facilitate ethnographic research, the IRB has entered into a Memorandum of Agreement (MoU) with the Department of Sociology and Anthropology (SOAN) that allows oral consents without asking for IRB permission in the protocol. SOAN researchers should consult this MOU before structuring their consent form.)

The oral consent form should be brief and clear, using 8th grade level language. The researcher must read the entire text to the subject and must obtain a clear and audible “yes” before signing the form and giving a copy to the subject.

Here is an example from the Department of Sociology and Anthropology:

Oral Informed Consent Form

Exploring the Urban Infrastructure of Transnational Labor Migration in Nepal

XXXX XXXXXXXX [Researcher Name]
University of Puget Sound

I am currently an undergraduate student in the Department of Sociology and Anthropology at the University of Puget Sound in the United States. I am working on a project that aims to better understand the ways in which the urban landscape has changed within Nepali communities in response to transnational labor migration.

I would like to explain the purpose of this interview and how I intend to use the information that you share with me. If you have any questions while I explain this, please feel free to stop me at any point. Once I have told you more about my project you will be able to decide if you would like to participate in the interview or not.

The research that I am conducting will be used for a paper and presentation in the Department of Sociology and Anthropology at the University of Puget Sound in Tacoma, WA. Approximately 19 other individuals will be interviewed for this project.

The interview should take about one hour. Participation in this interview is completely optional. During the interview you will be asked about your experiences with labor migrations and the changing urban landscape. Additionally, you will be asked questions regarding neighborhood and personal history. I will be replacing your name with a pseudonym and changing any identifying information that you choose to share. I encourage you to help in the processes of picking a pseudonym. All potentially identifying information, including all transcriptions and

recordings of these interviews, will be stored on my personal computer in a file that is password protected.

Should you want to stop participating in this interview at any time, please let me know. You will not be penalized in any way should you choose to end the interview. Please feel free not to answer any questions that you do not want to.

I would like to record in order to ensure that I correctly and accurately remember the information that you contribute during this interview. All interview recordings will be stored in a password-protected file on my personal computer and I will be the only one using them and the only one who has access to them. I also invite you to participate in this project without being recorded.

Do you have any questions? If you come up with questions later, my contact information is below.

Phone: (307)-XXX-XXXX

Email: xxx@xxx.xxx

If you have any questions about your rights as a participant in this research, you can contact Andrew Gardner, Professor of Anthropology at the University of Puget Sound, at gardner@pugetsound.edu.

You can also contact the Associate Dean of University of Puget Sound at 253-879-3207.

Would you be willing to participate in this study?

Interview ID#: _____ Interviewer Signature: _____

Date: _____

Appendix 4. Yearly IRB Report form

Informational Follow-up IRB Approved Research Project

The fundamental charge of the Institutional Review Board (IRB) is to protect human research subjects. Approval by the IRB is for a period of one-year and researchers are to notify the IRB within 90 days of termination of an approved project. An annual report to the IRB is required of all approved protocols. To help simplify this process, please respond to the following questions pertaining to the status of your approved research project. The purpose of this follow-up form is not to have researchers provide self-incriminating documentation in the event of an unanticipated occurrence during the study, it is merely to inform the IRB of the status of the project and report on any modifications made to the originally proposed protocol.

IRB Protocol #: _____

Project Title: _____

Principal Investigator(s): _____

email: _____

Phone: _____

1. Project status (please check one):

- Complete _____ completion date
- Ongoing _____ estimated completion date _____
- Discontinued

On a separate page, please state why the study was discontinued.

2. During the course of conducting a research project sometimes it becomes necessary and/or prudent to alter experimental protocols. Did any circumstances require significant modification in the investigative protocol for which you will be seeking IRB approval?

- no yes

If yes, what changes were made and why? (Please use an additional page to explain changes.)

3. During the course of conducting the research project did any event occur that may have placed a human subject(s) at risk or caused any human subject to be harmed?

no

yes

If yes,

a. please describe the situation (use a separate page if necessary).

b. please describe efforts undertaken to minimize harm to the subject or modify the protocol to reduce the probability of similar harm occurring to future subjects (use a separate page if necessary).