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

Revised August, 2007

Institutional Review Board

Office of the Associate Deans

University of Puget Sound

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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 Department IRB designate.

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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.

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 or 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 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 as a referral board for the Department Review Committees.

3. To serve where necessary as a referral board for complaints from subjects of research.

4. 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 department IRB designate.

C. It shall be the responsibility of the IRB designate to refer the following for review by the Institutional Review Board:

1. All research supported by non-University funds in which such action is required by the sponsor.

2. Other research not thus supported, which involves the likelihood of risk or substantial stress or discomfort to the subject.

3. Research which includes the administration of personality tests, inventories, or questionnaires of a personal and sensitive nature, if subject identity is not anonymous.

4. Research involving health care procedures of any kind which are not principally for the benefit of the subject, or which include diagnostic or therapeutic measures that are not yet standard or generally acceptable.

5. Other research in which the subject is not fully informed as to the procedure to be followed.
6. Research involving special populations (e.g., children, prisoners, pregnant women, or individuals who are mentally or psychologically ill or incompetent).

7. Research involving the use or handling of body fluids.

Research not falling within categories 1-7 of this section may be approved by the department IRB designate, and must conform to the general principles in Section 1.

D. Review procedures are as follows:

Before beginning research that involves human subjects, the investigator shall submit an application or statement to the department IRB designate which, together with any appropriate supporting material, provides an adequate basis for approval by the IRB designate 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 department IRB designate 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. Departmental Review (Exempt and Expedited Reviews)

A department designate may act on behalf of the full board to review and approve the following categories of research:

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. Institutional Review Board (Full IRB 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. To expedite departmental consideration of proposals, including recommendation of approval or disapproval, a department chairperson or director may appoint an advisory committee of faculty in that discipline or University unit.

f. 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.

g. 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, who will refer such proposals to the department IRB designate for approval or for referral to the Institutional Review Board.

h. 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 department IRB designate, who then can refer the issues to the Institutional Review Board.

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

To determine whether your research project should be reviewed by the full IRB or is eligible for exempt or expedited review by the departmental IRB designate, use the following checklist:

(1) **Full IRB Review.** Does your research project:

_____ receive support from non-university sources that require full IRB approval?

_____ involve the likelihood of risk or substantial stress or discomfort to the subject?
____ involve personality tests, inventories or questionnaires of a personal and sensitive nature (see page 9) where subjects' identities will not be anonymous to the researcher?
____ involve sensitive aspects of a subject's behavior that could reasonably place a subject at risk of criminal or civil liability or be damaging to a subject's financial standing or employability?
____ involve sensitive aspects of a subject's behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol?
____ involve health care procedures that are not conducted for the primary benefit of the subject?
____ include diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice?
____ involve deception or procedures that are not known to the subject (e.g., the subject will not be fully informed)?
____ involve special populations (e.g., children, prisoners, pregnant women, or individuals who are mentally or psychologically ill, or incompetent)?
____ involve greater than minimal (i.e., moderate, high) risk to subjects (see page 9).
____ involve collection of blood samples or other body fluids in any amount?

If you checked any of the descriptors in (1) above, your research project must be submitted to the full IRB for review and receive full IRB approval before you commence your research. If you checked no descriptors in (1), go to (2) below.

(2) Expedited Review. Does your research project:
____ involve minimal risk (see appendix 2 for definitions)?
____ involve recording data from subjects 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 subject's behavior and in a manner that does not cause stress to subjects.

If you checked any of the descriptors in (2) above and no descriptors from category (1), your research project meets the criteria for Expedited Review, and must be submitted to and receive approval from your departmental IRB designate before you commence your research. If you checked no descriptors in (1) or (2), go to (3) below.
(3) **Exempt Review.** If you checked none of the descriptors in 1 or 2 above, your research is eligible for Exempt Review and must receive approval from your departmental IRB designate before you begin your research. Examples of research eligible for Exempt Review include:

- investigations of commonly accepted educational practices in established or commonly accepted settings.
- surveys or interviews in which responses will be recorded in such a manner that a subject cannot be identified directly or through identifiers linked to a subject.
- 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 subject cannot be identified directly or through identifiers linked to a subject.
- 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 subjects cannot be identified.

**OUTCOMES** of IRB review include (1) full approval; (2) full approval with minor corrections or clarifications; (3) Reconsideration after the investigator responds to identified concerns; or (4) Disapproval for reasons specified in writing to the investigator.
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. The faculty advisor must also sign the cover sheet if students are involved. The department IRB designate must also sign the cover sheet.

(2) 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.

(3) See Section 8 for instructions regarding renewals, modifications, reconsiderations, terminations, and requests for additional information.

(4) The protocol must follow the format below and must not exceed five (5) pages in length. Protocols longer than five pages will be returned to the investigator for revision and resubmission. The following paragraph subtitles must be used.

(A) Project Description: Describe the purpose of the research, the methods to be used including data collection procedures and any features of the research design that may involve special conditions or procedures for the subjects.

(B) Subject Recruitment:

1. Identify the number of subjects to be recruited for the research. Identify how and where subjects are recruited and the criteria that will be used to select and exclude subjects.

2. Describe the characteristics of the subjects with regard to age, sex, race, or other special affiliations or attributes which cause them to be included in the study population, institution status (i.e., patients or prisoners), and their general state of mental and physical health. Explain why it is necessary to use any particular population subgroups or special populations.

If the study involves students from the University of Puget Sound the following standard statement may be used: “The subject population will resemble the subject pool at the University of Puget Sound in terms of age, ethnicity and gender.” If this statement is used, it should appear in the same font type as the rest of the protocol. Do not use italics.
(C) **Confidentiality of Data:** Explain how data will be secured to safeguard identifiable records of individuals and how long such records will be kept before being destroyed.

The following standard statement may be used: "The names of participants will not appear on any materials containing their responses. All identifying materials such as the consent forms will be kept in a locked file in the ________ Department at the University of Puget Sound." **If this statement is used, it should appear in the same type font as the rest of the protocol. Do not use italics.**

(D) **Risks to Subjects:** Describe in detail any immediate or long range risks to subjects that may arise from the procedures used in the study. (Risks may be physical, psychological, social, legal or economic.) Clearly describe the precautions that will be taken to minimize these risks.

(E) **Benefits:** Describe the anticipated benefits to subjects, science, and/or society which may occur as a result of this study.

**Note:** Projects that involve the use or handling of body fluids in any amount must describe how the researcher(s) will conform to the University of Puget Sound Bloodborne Pathogen Exposure Control Plan and Policy. The policy can be found at: PROVIDE LINK.

(5) Qualifications of investigator(s), briefly summarized. (Please, do not include CV’s or biographical sketches). Students and other non-faculty investigators must be sponsored by a faculty member, whose signed, sponsoring letter must be included.

(6) References (if applicable).

(7) 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.

(8) Consent form(s). (See page 15 for consent form requirements. See Appendix 3 for consent form examples.)

**Number of copies required:**

Full board review: 1
Exempt and expedited review: 1
(See also the section on "Renewals" for exception to the number of copies required).
UPS IRB PROTOCOL #:

University of Puget Sound INSTITUTIONAL REVIEW BOARD

Application for Approval of Research Involving Human Subjects (Cover Sheet)
(application is due two weeks prior to the date of the IRB meeting on which the review is to occur.)

Please Check One: _____New Project  _____Renewal  _____Modification
(Attach Renewal/Modification Form)

Date of Submission:  ______________________________

Protocol Title:  ________________________________________________________________

Principal Investigator: Typed name:______________________________________
Signature: ________________________________________
Department or School: ____________________________________________
Telephone number: ____________________________________________

Co-Investigator: Typed Name:______________________________________
Signature:_________________________________________
Co-Investigator: Typed Name:______________________________________
Signature:_________________________________________

Faculty Advisor’s Statement (student projects only): I, _______________________ am the advisor for __________________________. My signature below indicates that I have read the attached protocol and have checked the contents with the IRB Guidelines.

Signature:____________________________________________

Source of Support (if any):
________________________________________________________________

Level of Risk to Human Subjects: _____High _____Moderate _____Minimal

Number of Subjects: _______
Are normal subjects involved?*  ______ yes  ______ no
Are children involved?*  ______ yes  ______ no

*Normal subjects are (a) appropriately selected controls for this protocol or (b) healthy volunteers. Children are minors under the age of 18.

Has this proposal been or will it be submitted to other Human Subjects Review Boards, departmental committees, or community agencies for review and approval?

____ Yes (attach approval letters)
____ No

To be completed by the Departmental IRB Designate:

This proposal qualifies for  ______ expedited review
______ exempt review
______ full board review

____________________________________
(Signature of Departmental IRB Designate)
Section 5: Submission Packets for IRB Review

The following list identifies the materials that need to be submitted to the Institutional Review Board, Jones 212, two weeks before the meeting date on which the review is to occur. (In the case of Exempt or Expedited Review, the materials are to be submitted to the Departmental IRB designate).

- **Full Board Review:**
  1. copy of the protocol
  1. copy each of any questionnaires, interview formats, or other survey instruments
  1. copy of the cover sheet
  1. copy of the consent form(s) (see Section 6)

- **Expedited Review:**
  1. copy of the protocol
  1. copy each of any questionnaires, interview formats, or other survey instruments
  1. copy of the cover sheet
  1. copy of the consent form(s) (see Section 6)

- **Exempt Review:**
  1. copy of the protocol
  1. copy each of any questionnaires, interview formats, or other survey instruments
  1. copy of the cover sheet
  1. copy of the consent form(s) (see Section 6)
  1. letter establishing exemption from school/department
Section 6: Elements of Informed Consent and Consent Form Requirements

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, and must follow these guidelines:

(1) The first page of the consent 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. (The stamp will go in the upper right hand corner of the first page of the consent form.)
(3) The consent form must have one of these general titles:

Consent to Act as a Subject in an Experimental Study,

Consent to Act as a Subject in a Research Study, or

Consent to Act as a Subject in a Clinical Research Study.

Parental Consent for a Child to Act as a Subject in an Experimental Study, a Research Study or a Clinical 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. University e-mail addresses are acceptable. Personal e-mail addresses are not acceptable. Non-faculty members must list their faculty sponsor(s).

(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: (Description, Risks and Benefits, Alternative Treatments, etc.). This format assists the reviewers and the investigator to insure 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.”) The remainder of the description should include:

- Purposes and Goals of the study
- 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. during eight weeks.

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 mention 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. If this statement is used, it should appear in the same type font as the rest of the consent form. Do not use italics. (NOTE: Such new information and any change in the project should be sent to the IRB for review and approval prior to discussion with 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." **If this statement is used, it should appear in the same type font as the rest of the consent form. Do not use italics.**

**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 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."

**If this statement is used, it should appear in the same type font as the rest of the consent form. Do not use italics.**

*********************************************************************
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 videotapes 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.

**NOTE:** If this statement is used, it should appear in the same type font as the rest of the consent form. Do not use italics. **This statement is only applicable to those studies that do not require the HIPAA statement above.**

*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 should be adapted to your specific protocol.

*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.

**NOTE:** If this statement is used, it should appear in the same type font as the rest of the consent form. Do not use italics.
VOLUNTARY CONSENT: (This paragraph 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 ____________. Any questions I have concerning my rights as a research subject will be answered by the Office of the Associate Deans (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.

NOTE: If this statement is used, it should appear in the same type font as the rest of the Consent form. Do not use italics.

__________________________  ____________________________
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 have witnessed the above signature.

NOTE: If this statement is used, it should appear in the same type font as the rest of the Consent form. Do not use italics.

Signature of Investigator or Member of Research Staff:____________________
Date: ______________________________
Investigator/Research Staff

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
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

Witness

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 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 consent 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 of 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 spouse, 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 spouse, 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.
Section 7: Renewals, Modifications, Reconsiderations, and Terminations

Renewals: Renewals of approved protocols are mandatory and must be approved at least 30 days 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 IRB number.

(2) The completed and signed Renewal/Modification form (See page 41)

(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 five-page IRB protocol, highlighting any changes indicated on the Renewal/Modification form and copies of the Qualifications of Investigators and references sections. Copies of the protocol (see page 20) 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:

(1) Exempt Review if the proposal was previously considered exempt and there have been no changes, adverse reactions, or unexpected side effects. Submit: 1 copy.

(2) Expedited Review if the proposal was previously approved by the expedited review process. Submit: 1 copy.

(3) Full Board Review is required if the proposal was originally reviewed by the full IRB
   (a) Submit: 1 copy if the protocol involves low risk, if there have been no significant changes in the protocol or the consent form(s), and no adverse reactions, or unexpected side effects
have occurred.

(b) **Submit: 1 copy** if the protocol involves greater than minimal risk, or if there have been significant changes, adverse reactions or unexpected side effects.

If questions arise about the renewal procedures or the number of copies to submit, please contact the IRB Chair.

**Modifications:** 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 are not expeditable. The IRB Chair, or the departmental IRB designate shall decide 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.

**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.**
Termination

When a project is terminated, the principal investigator must within 90 days send a written notification to the IRB and submit a final progress report. See form for yearly report or termination in Appendix 4. The IRB reference number must be included.
University of Puget Sound INSTITUTIONAL REVIEW BOARD
Renewal/Modification Form

Check one or both: _____ Renewal       _____ Modification

Investigator's name:

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.

NAME _____________________________________________________________
ADDRESS _________________________________________________________
TELEPHONE _______________________________________________________
ADVISOR __________________________________________________________

Submit application no later than two weeks before the date of the IRB meeting on which the review is to occur.

COVERSHEET
Completed
Typed
Signed (investigators, department IRB designate, and if appropriate, faculty advisor)

ABSTRACT

PROTOCOL (5 pages maximum)
Pages numbered
Introduction and brief background
Specific aims
Materials and methods
  a. project description, including testing, instrumentation, interventions, etc.
  b. how subjects are chosen
  c. why specific subject population chosen
  d. source of subjects
  e. method of obtaining informed consent
  f. costs and payments
  g. flow chart (if applicable)
  h. significance of the research

PROTECTION OF HUMAN SUBJECTS: (Risk/Benefit Ratio)
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)

QUALIFICATIONS OF INVESTIGATOR(S)
Faculty: Short biographical sketch
______ Student: Short biographical sketch and letter from faculty advisor supporting the project.

CONSENT FORMS
Procedural Details:
______ a. Page 1 is on appropriate institution letterhead with 1” or greater margin at top
______ b. Title (consent form title and project title are the same)
______ c. Pages numbered (protocol and consent form numbered separately).
______ d. List all investigators, addresses, and business telephone numbers
______ e. Blank for subjects’ initials in lower right corner of each page of consent form.
______ f. Signature line for subject, witness, parent, corroborator.

Separate Consent Forms for:
______ a. adults in treatment group
______ b. control group
______ c. children
______ d. parent or guardian
______ e. other

CONTENT
______ Description of study written in non-technical language
______ Risks/benefits
______ 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

ADVISOR'S STATEMENT (if applicable):
I, ________________________________, am the Advisor
for ________________________________. My signature below indicates
that I have read the enclosed protocol and have checked the contents with the IRB
Guidelines. Below (or on separate page) I have indicated this student's qualifications
to perform this research.

Qualifications:

Advisor's signature
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 his or her 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 his or her 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 his or her 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 his or her participation in the activity is not determined by any illness or dysfunction that he or she exhibits.

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 his or her 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' workscope, 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

A. Consent form illustrating survey research with explanation of sensitive information from Department of Psychology:
(Note that the line for subjects to initial each page is not shown.)

UNIVERSITY of PUGET SOUND
Est. 1888

Consent to Act as a Subject in a Research Study

TITLE: The Effects of Personality and Habits on Health

INVESTIGATORS: Jill Nealey-Moore, Ph.D. David R. Moore, Ph.D.
(253) 879-8580 (253) 879-8612

DESCRIPTION: You will complete a packet of questionnaires assessing a variety of topics including:
your current health and health habits, aspects of personality, mood, social relationships, and your experiences in close relationships. Participation is expected to take no longer than 60 minutes. Participation in this study makes you eligible to complete a set of follow-up questionnaires in 4-5 months, should you choose to do so.

RISKS AND BENEFITS: Participation in this study involves minimal risk. Some questions are of a sensitive and personal nature and thus could induce mild discomfort for some participants. However, if you find any content uncomfortably sensitive, you are free to omit any questions that you feel uncomfortable answering. Benefits of participation include the potential for increased insight into one’s own personal characteristics and health habits, as well as the opportunity to gain experience and familiarity with the process of conducting research in psychology.

COSTS AND PAYMENTS: Psychology 101 students will receive two units of research credit for participating in this study. Students in other psychology courses may or may not receive credit, and should consult with their instructor. If students are not eligible to receive research credit, they will be paid $5.00 for participation.

CONFIDENTIALITY: I understand that any information about me obtained from this research, including answers to questionnaires, laboratory data, or audio or videotapes will be kept strictly confidential. Information that will carry personal identifying information 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. 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 Jill Nealey-Moore and David Moore. Any questions or concerns I have regarding my rights as a research subject will be answered by the Office of the Associate Dean (253-879-3207). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this 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
B. Consent which includes use of health related information from 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
Ann Wilson, PT, M.Ed
Clinical Associate Professor

CO-INVESTIGATORS
Jo-An Malahy, SPT
Alison Read, SPT
Melissa Scialabba, SPT
Chloe Woodrow, 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 videotapes 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

________________________________________________________________________
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
CLINICAL RESEARCH STUDY

PRINCIPAL INVESTIGATORS: Alika Antone, Carrie Fenlason, Julie Garner, Anne Haas, Shelley Vessey and Sarah Westcott
Department of Physical Therapy, 1500 N. Warner, CMB 1070, Tacoma, WA 98416; 253-879-2895; swestcott@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 theses 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 he/she 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 or her 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 or her 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 or she 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 disabilities. 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 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 videotapes 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.
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 Sarah Westcott, 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
CLINICAL RESEARCH STUDY

PRINCIPAL INVESTIGATORS: Alika Antone, Carrie Fenlason, Julie Garner, Anne Haas, Shelley Vessey and Sarah Westcott
Department of Physical Therapy, 1500 N. Warner, CMB 1070, Tacoma, WA 98416; 253-879-2895; swestcott@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
Appendix 4. Yearly IRB Report form

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 #: ___________  Date of Approval: ________________

Project Title: ____________________________________________________________

________________________________________________________________________

Principle Investigator(s): __________________________________________________

CMB: _________  email: ___________________________  Phone: __________

1. Project status (please check one):

   Ø Complete ___________  Ø Ongoing ________________
       completion date ________________  estimated completion date ___________
   Ø 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?

   Ø no  Ø 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?

   o no
   o 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).

Please return completed form to:
Institutional Review Board
CMB 1020
Appendix 5: Frequently Asked Questions

Frequently Asked Questions

1. How can I determine if my project qualifies for an expedited review?

Consult the UPS IRB web page and examine the document titled *Principles and Procedures Governing the Use of Human Subjects in Research*. This document can be found at [http://www2.ups.edu/dean/irb/](http://www2.ups.edu/dean/irb/). Section 3 of the Principles and Procedures document provides a checklist that will help you determine the appropriate level of IRB Review. A protocol is eligible for “expedited” review if risks are minimal, participants are healthy and over 18 years old, procedures are noninvasive, existing records or specimens are being studies, or behaviors are not being manipulated in a manner that causes stress. If any of the categories in Section 1 are checked, Full IRB Review is required.

2. What is the deadline for submitting protocols to the IRB to insure that it is reviewed at the next meeting?

Researchers should deliver appropriate number of copies to the Office of Associate Deans two weeks prior to the meeting. When you submit a protocol to the IRB, it is distributed to campus IRB members by campus mail and it is sent to the community representative by US mail. Submitting the protocol two weeks in advance of the meeting allows time for delivery and review prior to the deliberation.

3. When does the IRB meet?

A schedule of IRB meeting dates can be found on the IRB homepage.

4. Can protocols be submitted and reviewed in the summer?

The IRB routinely meets from September through May. Applicants should plan ahead and submit protocols for research that is planned for during the months of June, July, and August, at or prior to the May meeting. (The IRB will make an effort to convene to review protocols during the summer months, however it is difficult to contact and get feedback from the Committee members, so response times will likely not be rapid.) Protocols submitted over the summer that schedule data collection during the next academic year will be reviewed at the September meeting.

5. What are the common mistakes that tend to appear on IRB protocols?
a) Underestimating the level of risk to participants;

b) Highly technical or poorly described procedures which are central to a study;

c) Consent forms that are not written in a language that is comprehensible to the potential participant (especially children);

d) Incomplete applications and missing signatures;

e) The investigator fails to clarify the criteria for including or excluding subjects (by age, gender, disability, presence or absence of symptoms, etc.).

f) The investigator fails to show how potential subjects will be protected adequately during the process of recruiting subjects; or the investigator fails to document all the steps in the recruitment process (including fliers that will be posted; permissions from a clinic, etc.)

g) The investigator fails to use straightforward English to explain the protocol.

h) The number of subjects varies throughout the protocol and/or between the protocol and the consent forms.

i) The investigator fails to be specific about the end of the project; anticipated date of conclusion of data gathering; and destruction of confidential materials;

j) The investigator fails to file a final report with the IRB.

6. What is the difference between a classroom assignment (or student project) and research that would require an IRB protocol?

Research involves generalizable knowledge and dissemination of findings. Therefore, it is entirely possible that a classroom assignment can constitute research requiring IRB review. There is no firm boundary between assignments and research that would exempt all assignments from IRB approval. It is strongly suggested that faculty consult with the department IRB designate regarding assignments that might require IRB review.

7. What are some examples of research with human subjects conducted at the University of Puget Sound?
Common forms of research involving human subjects at the university generally include some kind of formal experiment, individual interviews, and surveys. Experiments involving deception, surveys soliciting sensitive information, and investigations that audiotape, videotape, or digitally store participants’ images or responses have been frequently reviewed by the UPS IRB.

8. Do surveys and questionnaires constitute research that require an IRB protocol?

Yes. The protocol must be reviewed by the department IRB designate. The designate may determine that the protocol is exempt from IRB review or that the protocol meets the standards for expedited review. The checklist on the IRB homepage specifies conditions where survey and questionnaires must be reviewed by the full IRB.

9. What kind of pilot study can I conduct before preparing a protocol for the IRB?

All research, including pilot studies, must be reviewed by the departmental IRB designate before any participants are contacted. In many cases, full IRB review must be obtained before pilot studies can be conducted.

10. How do I secure permission from subjects to use audio or video tapes during the interview/procedure?

Participants must agree to have their voices or images recorded. Also, they must be provided with enough information about the experiment to allow informed consent to be recorded. Examples of these forms can be found on the IRB homepage.

11. If I’m distributing an anonymous survey, do I need to go through the IRB?

Yes. Discuss your protocol with the department IRB designate.

12. If I’m interviewing people informally and won’t use people’s real names, do I need to go through the IRB?

Yes. Discuss your protocol with the department IRB designate.

13. Must all experiments using vulnerable populations undergo a “Full IRB Review”?

Yes. Extra caution is always required when vulnerable groups such as children or pregnant women are involved.

14. I’m planning to obtain and study blood and body fluids. Do I need to get the approval of the IRB?
Yes. Discuss your protocol with the department IRB designate.

15. What is the “IRB Protocol”?

The IRB protocol is a standard procedure for gaining approval for investigations using human subjects. The protocol describes risks and benefits, specifies what will happen during the investigation, and explains how participants are protected from physical, psychological, and emotional risks.

16. Who is the IRB Designate for my department?

Department IRB Designates are listed on the IRB homepage.

17. What is the role of the Department IRB Designate?

The department IRB designate is the representative of the IRB at the department level. The designate can review a protocol and classify it as “exempt” if certain standards are met. Also, the designate can classify a protocol as “expedited” if different standards are met. These judgments are not subjective. For example, if the investigation uses deception or asks for sensitive information, the designate must refer the protocol to the full IRB for review. You can get an idea about whether your protocol is exempt, expedited, or requires full IRB review by consulting the IRB homepage, but every protocol needs to be reviewed by your department IRB designate.

18. When should I send my protocol to the IRB?

Protocols should arrive at the Office of the Associate Deans at least 2 weeks prior to the next scheduled meeting.

19. Will the IRB keep a copy of my protocol on file?

Yes. Your protocol and your final report will be retained for three years.

20. Who do I talk to if I have questions about the IRB?

You can contact your department IRB designate or any of the members of the IRB Committee.