For Instructional Use Only – Not a Form

HOW TO COMPLETE A HUMAN SUBJECTS REVIEW COMMITTEE APPLICATION

Each section of the application is accompanied by a short explanation of the kind of information that the Institutional Review Board (IRB) and Human Subjects Division (HSD) needs to meet its obligations.

UNIVERSITY OF WASHINGTON
Human Subjects Division, Box 359470

APPLICATION: Human Subjects Review, Full Board or Subcommittee

DO NOT SUBMIT THIS PAGE TO HSD

PLEASE NOTE:

Do not complete this form if you are a member of the Cancer Consortium and your proposed research is cancer-related and not a repository. Your research must be reviewed by the Cancer Consortium IRB administered by the Fred Hutchinson Cancer Research Center (FHCRC) IRB instead of the UW IRB. If you are unfamiliar with this process, see the Cancer Consortium website http://www.cancerconsortium.org/en.html or contact Cancer Consortium Clinical Research Support at 206-667-4520, or CRScustomerservice@fhcrc.org. For a list of Cancer Consortium members, see http://is-ext.fhcrc.org/sites/consortium/ccdb/members.php.

Do not complete this form if your research involves obtaining data from, or interacting with clients of, the Washington State Department of Health or Department of Social and Human Services. Your research must be reviewed by the Washington State IRB instead of the UW IRB. If you are unfamiliar with this process, see the WA State IRB website http://www.dshs.wa.gov/rda/hrrs/ or contact their office at: 360-902-8075, or wsirb@dshs.wa.gov.

If this project requires full IRB Committee Review.

Collate into three complete packets:

- Three copies of this form.
- Three copies of all relevant materials (advertisements, consent forms, data collection forms, debriefing statements, drug information summary, instruments, questionnaires, etc.)

Add:

- One full free-standing copy of each—Research Proposal (see specific instructions in Section VII for Center, Program, and Institutional Training grants); Grant or Contract; Protocol and Investigator's Brochure (for clinical trials); Thesis or Dissertation Proposal (students only)

If this project requires Minimal Risk ("Expedited") Review. (See the documents called SOP Expedited Review and WORKSHEET Expedited Review Eligibility for information and a description of the eligibility requirements)

Collate into two complete packets:

- Two copies of this form.
- Two copies of all relevant materials (advertisements, consent forms, data collection forms, debriefing statements, drug information summary, instruments, questionnaires, etc.)

Add:

- One full free-standing copy of each—Research Proposal (see specific instructions in Section VII for Center, Program, and Institutional Training Grants ; Grant or Contract; Protocol and Investigator's Brochure (for clinical trials); Thesis or Dissertation Proposal (students only)

(Please note that it is ultimately HSD staff and IRB who make the review level determination.)

Send to:
Human Subjects Division, Box 359470, Seattle, WA 98195.

When preparing double-sided copies, please make sure that each item (e.g., IRB application, consent form, questionnaires, etc.) begins on the front page of a new piece of paper.

Incomplete or handwritten forms are not accepted.
When completing the form, do not leave blanks, and use 10 point type or larger.
The contents of this application and attachments will be kept confidential within the limits of the law.
For more information visit the HSD website at http://www.washington.edu/research/hsd/ or call (206) 543-0098.

UNIVERSITY OF WASHINGTON

Human Subjects Division
Box 359470
APPLICATION: Human Subjects Review

BOX FOR COMMITTEE USE ONLY
MASTER ☐ COMM. ☐ INVESTIGATOR ☐

APPLICATION NO.

The box in the upper right hand corner will include the application number by which applications are filed in the Human Subjects Division database. (Database of Research Activities or DORA.)

I. PRINCIPAL INVESTIGATOR (Provide all the information requested. Change of PI requires a modification. All paper-based correspondence will be directed to this person. Please list the mailing address for paper-based correspondence. You may designate a contact person other than yourself in section II., below.)

Name _____ Title _____ Position _____
Home Institution (or source of paycheck)
UW Student? Home institution is UW. _____
Home UW Department (if applicable) _____ Division _____

UW Position or appointment (choose the most appropriate one):

Faculty:	[ ] Regular Faculty Appointment	[ ] Research Faculty Appointment	[ ] Clinical Faculty Appointment
	[ ] Visiting Faculty Appointment	[ ] Dual Appointment with PNNL	
	[ ] Other (describe):		
Student:	[ ] Matriculated Undergraduate Student	[ ] Graduate or Professional Student (matriculated or approved "On Leave")	[ ] WWAMI Student
[ ] Resident or Fellow at the UW or Local VA		[ ] UW Administration or Staff	[ ] None

Campus Box # _____ Other Address if not at UW _____
Telephone _____ Fax _____ e-mail _____

The first person listed should the Principal Investigator (PI) and will be the person in whose name the application is filed. This is the person with ultimate authority for the project.

II. IRB CONTACT PERSON (Provide all the information requested. Change of Contact Person requires a modification. If this section is completed, all paper-based correspondence will be directed to this person.)

Name _____ Title _____ Position _____
Home Institution (or source of paycheck) _____
Home UW Department (if applicable) _____ Division _____

UW Position or appointment (choose the most appropriate one):

Faculty:	[ ] Regular Faculty Appointment	[ ] Research Faculty Appointment	[ ] Clinical Faculty Appointment
	[ ] Visiting Faculty Appointment	[ ] Dual Appointment with PNNL	
	[ ] Other (describe):		
Student:	[ ] Matriculated Undergraduate Student	[ ] Graduate or Professional Student (matriculated or approved "On Leave")	[ ] WWAMI Student
[ ] Resident or Fellow at the UW or Local VA		[ ] UW Administration or Staff	[ ] None

Campus Box # _____ Other Address if not at UW _____
Telephone _____ Fax _____ e-mail _____

For the convenience of the study team, if there is someone other than the Principal Investigator who is taking administrative responsibility for this study, you may list this person in Section II. We will contact this person in addition to the Principal Investigator regarding the project. Please note that this person does not have signatory authority.

III. TITLE OF PROJECT: _____

Provide a concise, descriptive title. The title may or may not be the same as the title of any grant or contract proposals, but it should be meaningful both to the investigators and the IRB.

IV. SIGNATURES: The undersigned acknowledge that: 1. this application is an accurate and complete description of the proposed research; 2. the research will be conducted in compliance with the recommendations of and only after approval has been received from the Institutional Review Board (IRB). The lead researcher is responsible for all aspects of this research, including: reporting any serious adverse events or problems to the IRB, requesting prior IRB approval for modifications, and requesting continuing review and approval.

A. Investigator:

_____

TYPED NAME PLUS SIGNATURE **DATE**

B. Faculty sponsor (for student):
Change requires a modification.

_____

TYPED NAME PLUS SIGNATURE **DATE**

C. The Chair, Dean, or Director acknowledges the researcher is qualified to do the research, sufficient resources will be available, and (if no external funding review occurred) there was an internal review of scientific merit.

_____

TYPED NAME PLUS SIGNATURE **DATE**

The first investigator must sign and date the application on line A., the faculty sponsor (in the case of student research) must sign and date the application on line B., and the chair of the department of the first investigator must sign and date the application on line C.

_____ _____ APPROVE ☐ DISAPPROVE ☐

IRB COMMITTEE SIGNATURE DATE

Subject to the following restrictions: _____

_____

_____

Period of approval is from_____ through_____

☐ Subject numbers are approved as described in this IRB Application unless otherwise indicated above in "Subject to the following conditions" or in an accompanying letter.

Information in this box includes the signature of the committee chair who approved the application, the date it was approved, the period of approval, and any contingencies for the approval. Contingencies could include, for example, submission of a letter of approval from the Radiation Safety Committee or from some other agency that had not yet approved the application. Minor revisions of the consent form may be included as contingencies to approval. It is the investigator's responsibility to comply with the contingencies as soon as possible.

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED

V. TYPE OF NEW SUBMISSION

[ ] **IRBshare**

[ ] **MINIMAL RISK**
(The research meets the **definition of minimal risk** and falls into one or more **expedited review categories. You are done with this table.**)

[ ] **FULL COMMITTEE**

[ ] Full Committee (The research involves **greater than minimal risk** and requires review at a convened meeting of the IRB)

[ ] Full Committee (The research involves **no more than minimal risk** but does not fit into one of the expedited review categories)

[ ] **METHODS:**

Please mark the boxes to indicate the methods which best describe your study:

[ ] **Social-Behavioral Procedures/Considerations**

[ ]	Observational	[ ]	Population-Based Field Study
[ ]	Behavioral Interventions	[ ]	Surveys/Questionnaires
[ ]	Interview/Focus Groups	[ ]	Other – Describe:

[ ] **Medical Procedures/Considerations**

[ ]	Bio-hazardous Substances	[ ]	Investigational/Approved Devices
[ ]	Controlled Substances	[ ]	Radiation Exposure
[ ]	Emergency Treatment	[ ]	Substance Abuse Treatment (with medication)
[ ]	Gene Transfer Study	[ ]	Surgical Procedures
[ ]	Stem Cell Research	[ ]	Genetic Testing
[ ]	Magnetic Resonance imaging (MRI)	[ ]	Complementary/Alternative Medicine
[ ]	Investigational/Approved Drugs and Biologics	[ ]	Other – Describe:

[ ] **DOES YOUR RESEARCH INVOLVE OR IS IT ASSOCIATED WITH ANY OF THE FOLLOWING:**

[ ] Emergency Medicine
[ ] Pregnant Women as a Target Population
[ ] Genetics
[ ] Stem Cells
[ ] Neuroscience
[ ] College of Arts and Sciences
[ ] College of Education
[ ] Dentistry
[ ] Infectious Disease
[ ] HIV/AIDS
[ ] Psychiatry
[ ] Rehabilitation Medicine
[ ] Psycho-Social Drug Abuse Research
[ ] Alaska Native/American Indian (ANAI)
[ ] Public Health
[ ] Global Health
[ ] Health Services
[ ] Quality of Care / Quality of Life
[ ] Health Prevention / Health Education
[ ] Nursing

HSD uses this information to help assign your application to the appropriate IRB that is either assigned to your department, or has the most expertise in your field of research.

VI. PRIMARY RESEARCH ROLES

Some research projects are conducted by a large team of individuals. Other projects can be performed by only one or two individuals. The IRB does not need to know the name of every member of your research team - instead, the IRB wants to know who is fulfilling the following specific roles for your research. Note that the same individual may play multiple roles. If it is necessary to identify an individual by name, this will be specified below. Each section below must be completed.

1. Information for **individuals identified by name:**

The individuals below need to be identified by name. If these individuals change during the course of the research, a Modification approval from the IRB is needed before making the change.

Subject Contact Person (to answer questions, receive complaints or reports of side effects, etc.)

Check here if the same as: [ ] Lead Researcher [ ] IRB Contact Person
If one of these boxes is checked, you do not need to complete the rest of this table.

Name _____ Title _____ Position _____

Home Institution (or source of paycheck)
UW Student? Home institution is UW. _____

Home UW Department (if applicable) _____ Division _____

UW Position or appointment (choose the most appropriate one):

Faculty: [ ] Regular Faculty Appointment [ ] Research Faculty Appointment [ ] Clinical Faculty Appointment
[ ] Visiting Faculty Appointment [ ] Dual Appointment with PNNL
[ ] Other (describe): _____

Student: [ ] Matriculated Undergraduate Student [ ] Graduate or Professional Student (matriculated or approved "On Leave") [ ] WWAMI Student

[ ] Resident or Fellow at the UW or Local VA [ ] UW Administration or Staff [ ] None

Campus Box # _____ Other Address if not at UW _____

Telephone _____ Fax _____ e-mail _____

Study Coordinator

Check here if the same as: [ ] Lead Researcher [ ] IRB Contact Person [ ] Subject Contact Person
If one of these boxes is checked, you do not need to complete the rest of this table.

Name _____ Title _____ Position _____

Home Institution (or source of paycheck)
UW Student? Home institution is UW. _____

Home UW Department (if applicable) _____ Division _____

UW Position or appointment (choose the most appropriate one):

Faculty: [ ] Regular Faculty Appointment [ ] Research Faculty Appointment [ ] Clinical Faculty Appointment
[ ] Visiting Faculty Appointment [ ] Dual Appointment with PNNL
[ ] Other (describe): _____

Student: [ ] Matriculated Undergraduate Student [ ] Graduate or Professional Student (matriculated or approved "On Leave") [ ] WWAMI Student

[ ] Resident or Fellow at the UW or Local VA [ ] UW Administration or Staff [ ] None

Campus Box # _____ Other Address if not at UW _____

Telephone _____ Fax _____ e-mail _____

2. Information for **research staff who will perform procedures that involve risk to subjects:**

The individuals below do not need to be identified by name, rather, by qualifications. As long as the qualifications of the individuals and the procedures performed remain the same, a modification is not needed.

The individuals below do not need to be identified by name, rather, by qualifications. As long as the qualifications of the individuals and the procedures performed remain the same, a modification is not needed.

If an individual is **not** an agent of the UW, indicate his/her institution or organization. Should an individual not be associated with an institution or organization, state so. For all non-UW individuals, it will be necessary for this individual to receive IRB review. There are a number of mechanisms by which this may occur.

- If the non-UW individual is associated with Pacific Northwest National Laboratories, Puget Sound Blood Center, King County-Seattle Public Health, or Northwest Kidney Center: the UW has an institutional **Authorization Agreement** with these institutions by which it provides the IRB review (as long as any funding is administered through the UW).
- If the non-UW individual is associated with the Fred Hutchinson Cancer Research Center, Group Health, Seattle children's, Swedish Medical Center, or Benaroya Research Institute at Virginia Mason: the terms of the UW's **Cooperative IRB Agreement** with these institutions may or may not allow the UW IRB to do the review. The individual should contact their institution's IRB for guidance.
- If the non-UW individual is associated with an institution or organization in which the UW **does not** have a Cooperative IRB Agreement, it will be necessary for the non-UW individual to provide their own IRB review. If the non-UW individual's institution or organization does not have their own IRB or does not use an IRB for review of their research and the non-UW individual's institution or organization has a Federalwide Assurance (FWA), the non-UW individual's institution or organization may enter into an **IRB Authorization Agreement** with the UW. This means that the UW will provide IRB review for the non-UW individual. The non-UW Individual's institution or organization may also wish to enter into an IRB Authorization Agreement even if they have their own IRB to prevent duplication of effort. However, entering into an IRB Authorization Agreement with a non-UW individual's institution or organization is at the discretion of the HSD.
- If the non-UW individual is not associated with an institution or organization or if the non-UW individual is associated with an institution or organization that does not have a FWA and does not routinely conduct research, an **Individual Investigator Agreement** may be entered into with the UW. The Individual Investigator Agreement extends the applicability of the UW's FWA to cover the non-UW individual, institution or organization. However, entering into an Individual Investigator Agreement with a non-UW individual, institution or organization is at the discretion of the HSD.

Please see SOP Authorization Agreements for information on how to obtain an Agreement for your research.

Study Procedures that involve risk to subjects

[ ] Phlebotomy (blood draw)

Who will perform this procedure?

[ ] Licensed Practitioner

Describe the qualifications for the Licensed Practitioner below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Study Nurse

Describe the qualifications for the Study Nurse below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Other:

Describe the qualifications for the Other Professional below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] MRI Scan

Who will perform this procedure?

[ ] Licensed Practitioner

Describe the qualifications for the Licensed Practitioner below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Study Nurse

Describe the qualifications for the Study Nurse below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Other:

Describe the qualifications for the Other Professional below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Surgical or Physically Invasive Procedure

Who will perform this procedure?

[ ] Licensed Practitioner

Describe the qualifications for the Licensed Practitioner below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Study Nurse

Describe the qualifications for the Study Nurse below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Other:

Describe the qualifications for the Other Professional below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Other Procedures Involving Risk to Subjects [name the procedure(s)]:

Examples: behavioral therapy; dietary counseling; assessments and/or interpretations of test reults that require specific expertise (e.g. physical exam; fitness assessment; cognitive state; suicidality; mental health; interpretation of imaging tests, genetic tests, cognitive tests, etc.)

For more than one "Other" procedures, copy and paste this portion of the table as many times as necessary.

Who will perform this procedure?

[ ] Licensed Practitioner

Describe the qualifications of the Licensed Practitioner below, including whether they are affiliated with the UW, what is their professional license, and their experience in performing this procedure:

[ ] Study Nurse

Describe the qualifications of the Study Nurse below, including whether they are affiliated with the UW, what is their professional license, and their experience in performing this procedure:

[ ] Other:

Describe the qualifications of the Other Professional below, including whether they are affiliated with the UW, what is their professional license, and their experience in performing this procedure:

3.a. **Non-UW Individuals, Institutions or Organizations.** It will be necessary for each non-UW individual, institution or organization listed below to receive IRB review of its involvement in this research. There are a number of mechanisms by which this may occur.

Please only list the non-UW individual, institution or organization below if you are:

- **The direct recipient of an award or if you will be providing funding to the non-UW individual, institution or organization through a mechanism such as a sub-contract; and**
- **If the non-UW individual, institution or organization will be acting on behalf of the UW research study to do any of the following: 1) Obtain consent from subjects, 2) Perform procedures involving subject interaction or observation, 3) Obtain identifiable data/specimens, 4) Have access to, or receive coded or identifiable data/specimens, 5) Intervene by manipulating the environment.**
- If the non-UW individual is associated with Pacific Northwest National Laboratories, Puget Sound Blood Center, King County-Seattle Public Health, or Northwest Kidney Center: the UW has an institutional Authorization Agreement with these institutions by which it provides the IRB review (as long as any funding is administered through the UW).
- If the non-UW individual is associated with the Fred Hutchinson Cancer Research Center, Group Health, Seattle children's, Swedish Medical Center, or Benaroya Research Institute at Virginia Mason: the terms of the UW's **Cooperative IRB Agreement** with these institutions may or may not allow the UW IRB to do the review. The individual should contact their institution's IRB for guidance.
- If the non-UW individual, institution or organization is one in which the UW **does not** have a Cooperative IRB Agreement, it will be necessary for the non-UW individual, institution or organization to provide their own IRB review. If the non-UW individual, institution or organization does not have their own IRB or does not use an IRB for review of their research, and the non-UW individual, institution or organization has a Federal Wide Assurance (FWA), the non-UW individual, institution or organization may enter into an **IRB Authorization Agreement** with the UW. This means that the UW will provide IRB review for the non-UW individual, institution or organization. The non-UW individual, institution or organization may also wish to enter into an IRB authorization Agreement even if they have their own IRB to prevent duplication of effort. However, entering into an IRB Authorization Agreement with a non-UW individual, institution or organization is at the discretion of the HSD.

- If the non-UW individual is not associated with an institution or organization that has a Federal Wide Assurance (FWA) or if the institution or organization listed below does not have a FWA and does not routinely conduct research, an **Individual Investigator Agreement** may be entered into with the UW. The Individual Investigator Agreement extends the applicability of the UW's FWA to cover the non-UW individual, institution or organization. However, entering into an Individual Investigator Agreement with a non-UW individual, institution or organization is at the discretion of the HSD.

Please see SOP Authorization Agreements for information on how to obtain an Agreement for your research.

3b. Non-UW Individual, Organization or Location:

If there is more than one non-UW individual, organization, or location, copy and paste this table as many times as necessary.

Name of the non-UW Individual, Organization or Location:

Address of the non-UW Individual, Organization or Location:

Describe the activities that will be performed by/at the non-UW Individual, Organization or Location:	
Obtain consent from the subjects?	
Perform procedures involving subject interaction or observation?	
Obtain identifiable data/specimens?	
Have access to, or receive coded or identifiable data/specimens?	
Intervene by manipulating the environment?	

VII. SECTION 1 - LIST EACH PROPOSED AND FUNDED GRANT OR CONTRACT RELEVANT TO THIS APPLICATION, AND ATTACH A COMPLETE COPY OF EACH GRANT OR CONTRACT. THIS SHOULD INCLUDE GRANTS THAT SUPPORT FACULTY TIME FOR DATA ANALYSIS AND MANUSCRIPT PREPARATION, (I.E. SALARY SUPPORT). IF NONE, CHECK HERE ☐. FOR CENTER OR PROGRAM PROJECT GRANTS LIST P.I. AND TITLE FOR EACH SEPARATE PROJECT OR CORE. ADD SHEETS IF NECESSARY.

For Center, Program, and Institutional Training Grants (e.g., NIH "P" awards and "T" awards): Attach only the following components of the application. The terms used here are from the standard NIH applications for these types of grants. If the grant is from another agency, provide the equivalent application sections.

- Cover page(s)
- Project/Performance Site Location
- Other Project Information
- Research Plan (for Center or Program grants)
- Research Training Program Plan (for Institutional Training grants)
- Biosketch (profile) for the principal investigator on the grant

For Department of Defense (DOD) funding, complete and attach the SUPPLEMENT: Department of Defense
For Department of Justice (DOJ) funding, complete and attach the SUPPLEMENT: Department of Justice

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☐ Subcontract ☐ Other, specify

B. Name of principal investigator:

C. Name of funding agency:

D. Agency's number (if assigned):

E. Title of proposal:

F. Inclusive dates: from _____ through _____

G. Status: ☐ New ☐ Competing renewal ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☐ Yes ☐ No, (attach explanation)

This section asks for funding sources, which support the research activity. Include as many funding sources as are relevant to the activity. Explain what kind of funding mechanism is involved, the name of the Principal Investigator (this may be different from the first listed investigator on the Human Subjects application), the name of the agency to which the proposal was submitted, the number (if the agency has assigned one), the title of the proposal submitted (this may be different from the title of the Human Subjects application), the proposed dates of funding, the status of the proposal, and whether or not the proposal was submitted through the Office of Sponsored Programs (OSP). If the proposal was not submitted through OSP, explain why. One full copy of each new or competing renewal grant or contract should be appended to the Human Subjects application.

VIII. SUMMARY OF ACTIVITY. Answer in spaces provided (add numbered, referenced, single-sided sheets when necessary). Do not refer to an accompanying grant or contract proposal.

A. BACKGROUND AND PURPOSE OF RESEARCH. Provide relevant background information and explain **in lay language** why this research is important and what question(s) or hypotheses this activity is designed to answer.

This section should include a short description of the research goals and their significance. The description should provide IRB members with a context in which to review the research activity. Because the IRB includes non-scientists as members, please avoid technical terms and jargon. Do not reference the pages of an accompanying grant or contract proposal. A brief version of this section, written in language appropriate for the intended audience, should be included in the "Purpose" section of the consent form for subjects.

B. RESEARCH PROCEDURES INVOLVED.

1. Provide a complete description of: a. the study design, and b. sequence and timing of all study procedures that will be performed, e.g., volume of blood, size of biopsy, drug administration, questionnaire, name of psychological test. Provide this information for each phase of the study (pilot, screening, intervention and follow-up). **Use lay language**. Attach study flow sheet, if available.

> The purpose of this section is to provide the reviewers with complete information on the research methods and sequence of activities. Because the IRB includes non-scientists as members, please avoid technical terms and jargon. Information should be specific, and include the size of samples to be taken, the names of all substances and devices to be used, and a description of instruments, questionnaires, interviews, and other relevant research methods. Appropriately referenced pages from the accompanying grant or contract proposal may be added, but do not simply refer to the proposal. A brief version of this section, written in language appropriate to the intended audiences should be included in the "Procedures" section of the consent form for subjects.

2. Would subjects undergo these or similar procedures (medical, psychological, educational, etc.) if they were not taking part in this research? ☐ No ☐ Yes If "Yes," describe how the study procedures differ from what subjects would otherwise undergo.

> The IRB wants to know how the study procedures compare with what would usually happen to a subject. This is most relevant when subjects are patients, but it could also be important when subjects are students or clients receiving a service. Identify the procedures that are experimental as well as those that are conducted in addition to what a patient, student, or client would undergo routinely.

3. Check all of the boxes below that apply to your research:

Drug administration

☐ Administration of a drug (either FDA-approved or investigational) for research purposes to a subject-patient during general or regional anesthesia.

☐ Administration of a drug (either FDA-approved or investigational) for research purposes to a subject-patient during the 1.5 hours preceding general or regional anesthesia.

Blood lines

☐ Inserting an intravenous (central or peripheral) or intra-arterial line for research purposes in a subject-patient **during** general or regional anesthesia.

Sample collection

☐ Obtaining samples of blood, urine, or cerebrospinal fluid for research purposes while a subject-patient is under general or regional anesthesia.

☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery, while the subject-patient is under general or regional anesthesia.

Radio-isotopes

☐ Administration of a radio-isotope for research purposes during the 3 hours prior to anesthesia or while a subject-patient is under general or regional anesthesia.

> If you checked this box, you are responsible for informing **in advance** all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.

Experimental devices

☐ Implantation of an experimental device while a subject-patient is under general or regional anesthesia.

Other experimental manipulations or procedures

☐ Other manipulations or procedures performed solely for research purposes while a subject-patient is under general or regional anesthesia (e.g., experimental liver dialysis, experimental brain stimulation)

None of the above

☐ None of the above apply to my research

4. If you checked any box in question #3 except "none of the above", answer the following questions:

a. Provide the name and institutional affiliation of the physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

b. If you have not yet consulted with an appropriately qualified person about this issue, describe in detail your plans to do so. The IRB will not approve your application without this consultation. If UW Department of Anesthesiology approval has been obtained, please provide the Department's letter of support.

These questions are intended for studies where anesthesia will be used on the subject.

5. Required application supplements. Complete and attach the indicated SUPPLEMENT, as appropriate

a. **SUPPLEMENT: Drugs, Biologics, Botanicals** – for research involving the use of any of the following:
   - Drugs regulated by the FDA (prescription, over-the-counter, approved, or investigational)
   - Biologics regulated by the FDA (prescription, over-the-counter, approved, or investigational)
   - Botanicals
   - Dietary Supplements

b. **SUPPLEMENT: Devices** – for research involving the use of any medical device (approved or investigational; including software used with a medical device, and including mobile medical applications).

c. **SUPPLEMENT: Genetic Research** – submit this supplement when your research involves genetics. **Genetic research** is defined as research involving the analysis of any of the following: DNA; RNA; chromosomes; mitochondria; any or all parts of the human genome; or biomarkers such as proteins or metabolites which may be implicated in, associated with, or cosegregated with a disorder, syndrome, condition, or predisposition to disease or behavior. Usually genetic research involves the collection and/or use of human biological specimens such as blood, skin, or other tissues, nail clippings, or hair. Genetic research may also include the construction of pedigrees ("maps" of the distribution of a particular trait or condition among related individuals) or family medical histories.

d. **SUPPLEMENT: Department of Defense** – for research involving any component of the federal Department of Defense (DOD). "Involvement" means funding; collaboration or cooperative arrangements; use of facilities, resources, or personnel; use of military or civilian members of the DOD (or their records/specimens) as subjects.

e. **SUPPLEMENT: Department of Justice** – for research involving the federal Department of Justice (DOJ) or any of its components (such as the National Institute of Justice, or any facilities/personnel of the Bureau of Prisons). "Involvement" means funding; collaboration or cooperative arrangements; use of facilities, resources, or personnel; use of records or specimens from DOJ employees or from prisoners in any Bureau of Prisons facility.

f. **SUPPLEMENT: GWAS dbGaP** – for research that will involve submitting data to the federal Database of Genotyped and Phenotyped (dbGaP) information.

g. For research involving the **Department of Energy (DOE)**, researchers should consult the **CHECKLIST Department of Energy** to ensure that they have addressed all DOE requirements. However, the Checklist does not need to be completed and submitted unless the researcher believes it would be a useful attachment.

Not all studies involve the above items, or agencies. HSD has separated the required questions into SUPPLEMENTS to the main application forms where appropriate.

C. DECEPTION: If any deception or withholding of complete information is required for this activity, explain why this is necessary and attach a protocol explaining if, how, when, and by whom subjects will be debriefed.

Provide an explanation of why deception is necessary as a part of the study. Explain who will debrief subjects, when the subjects will be debriefed, and what information you will provide to explain the deception and why it was necessary. Attach a copy of the debriefing statement you will use. For further information about deception, see the HSD website at: http://www.washington.edu/research/hsd/topics/Deception. The administration of placebo during a drug study is not considered deceptive as long as subjects are informed in the consent document that they may receive a placebo during the study.

D. SUBJECTS

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. If your research is approved for a specific number of subjects, the data from any "extra" subjects cannot be described as having been obtained with IRB approval.

See the HSD website for the definition of "human subject" http://www.washington.edu/research/hsd/docs/1253. Before answering the questions below, be sure that you are familiar with the definition.

1. **Subject groups/categories and numbers.** Complete this table by listing:

- Your groups or categories of subjects. "Group" should be defined as appropriate for your research.
  - "Units" within a group. For most research, a group will consist of individuals, such as children aged 8-12, or individuals with high blood pressure. However, this will not be true for all research. Examples of groups with "units" that are not individuals:
    - Dyads such as Alzheimer's-patient-and-caregiver, with one group of the dyads assigned to one intervention (e.g., behavioral modification) and another group of the dyads assigned to a comparison intervention(e.g., drug treatment).
    - Families. For example, a study of mental health interventions for homeless families might have one group of 30 families assigned to one intervention and another group of 30 families assigned to a different intervention.
    - Other. For example, the "units" in autism research might be an autistic individual and all his/her living blood relatives. The units in an academic excellence study might be a student-parents-teacher unit.
  - Types of groups. There are many ways in which subjects might be grouped. Examples:
    - By intervention. Example: research comparing two different drugs for high blood pressure.
    - By subject population. Example: research comparing the incidence of domestic violence in families living in urban settings versus families living in rural settings.
    - If you have only one group, fill in only one line in the table. Add more lines if needed.
- The age range of each group.
- The upper limit/number of **completed** subjects you need for each group. ***Completed*** *means that all research procedures involving the subjects or the obtaining of specimens/records/data have been completed as far as is possible for each subject, including any follow-up (such as follow-up access to medical records.) In some cases, such as an online survey, it is not possible to predict the number of subjects who will complete the research. If you cannot predict or describe the maximum number of subjects you need in each group, check the appropriate box and provide your rationale in the space provided below the table.*

Group name/description	Age range of subjects	Maximum desired number of individuals (or other group unit, such as families) who will complete the research.*	Cannot provide a number.**
			☐**
			☐**
			☐**
			☐**

***This is the number of subjects (individuals, dyads, families, etc., as appropriate) in each group that will be considered for approval by the IRB.**

****If you cannot predict or describe the maximum number of subjects you need in each group:**

Provide your rationale and description of research scope here. *Include any information or estimates you might have about the number of subjects, so that the IRB has a sense of the scope of your research. For example, your research might be a small pilot study of all patients presenting with a rare disease at UW Medicine in the next year. Or, it might involve a survey posted on Craig's List for two weeks that could result in thousands of responses.*

NOTE: In your periodic Status Report, you will be asked to complete the table below with your subject numbers. While developing your research protocol, please plan ahead so that you will have an accurate record of the subject numbers above.

This is for illustration only. Do not complete this table.

Group Name / Description	# Completions				# Ongoing (subjects still involved)	# Withdrawals, drops, lost		
	Total approved by IRB	A At time of last Status Report	B Since last Status Report	A + B Total to date		C At time of last Status Report	D Since last Status Report	C + D Total to date

2. Explain how you will achieve equitable subject representation in the following categories. If not applicable, justify exclusions.
   a. Age (minors, elderly):
   b. Gender:
   c. Ethnic and racial minority populations:

Subject representation by age, gender and minority is an important part of evaluating the equitable representation of ages, genders, and minority groups. This is especially important in large clinical trials, whether bio-medical or behavioral. If age, gender, and ethnicity are irrelevant to the study objectives, explain why this is so.

3. What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different.)

Provide a statement of the criteria that will be used to select subjects for the study (for example, females with osteoarthritis between the ages of 35 and 65). Information on inclusion and exclusion criteria is used to assess both equitability and safety of subject selection.

4. What characteristics (exclusion criteria) would exclude subjects who are otherwise eligible from this study? (Answer for each subject group, if different.)

Provide the criteria that will be used to exclude subjects (for example: pregnancy, allergy to specific medications, blood pressure over or under certain levels).

5. Describe the subject recruitment strategies you will use for each group of subjects.

Explain how you will recruit each group of subjects.

6. Explain who will approach subjects to take part in the study and how this will be done to protect subjects' privacy. (You should obtain letters of cooperation from agencies, institutions, or others involved in subject recruitment for your research records. Do not send these to HSD or the IRB.)

Explain who will be recruiting subjects and how subjects will be approached to participate in the study. For example, the investigator's nurse may approach patient-subjects in his or her clinic to ask if they are interested in the study, or a club president may ask club members if they are interested in participating and if they would allow their names to be given to the investigator.

7. Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.

Include an explanation of how the investigator will insure that subjects will feel free to decline participation and are not coerced nor feel undue influence to participate in the study.

8. Will you give subjects gifts, payments, services without charge, or extra course credit? ☐ No ☐ Yes If yes, explain:

If subjects will receive payments, service, extra course credit, or any other inducement for participating, explain what subjects will receive, how it doesn't present undue influence, how it will be delivered to the subjects (for example, pro-rated by length of participation, at the end of the study, at the beginning of the study). A clear description of inducements for participation should be included in the "Other Information" section of the consent form for subjects.

9. Will any of the subjects or their third-party payers be charged for any study procedures? ☐ No ☐ Yes If yes, explain:

Explain what charges, if any, subjects or their third-party insurers (including government agencies) will be asked to bear. If the study is of no benefit to subjects, include a justification of why subjects should be asked to bear these costs.

10. **UW Locations and research sites.** Provide the following information in list or table format for all UW locations at which any research procedures will occur. Be sure to consider: screening, recruiting, consenting, observation, intervention, data collection, data analysis, specimen analysis, and location of any consultants and collaborators.

- Geographical location and/or address
- Name of organization, agency, group, site, institution
- What procedures will occur at each location (how the location is involved in the research)
- Whether subject contact or interaction will occur at each site
- Whether consenting of subjects will occur at each site
- Whether each site, or individuals at the site, will obtain, use, or have access to coded or individually identifiable private information about subjects for research purposes

E. RISKS AND BENEFITS

In order to approve the research the IRB must find that risks are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

1. Describe nature and degree of risk of possible injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks of withholding standard care or procedures if this is the case. Do not reference the consent form.

Describe the risks, stress, discomforts, or invasion of privacy, which may occur to the subject as a result of participating in the study, including procedures which might be performed for patient care. For example, describe the possible side effects of substances being administered, the stress of responding to personal questions, the risk of disclosure of sensitive information, or the discomfort of psychological and physiological research techniques. A clear description of the likely risks involved in the study should be included in the "Risks, Stress, or Discomfort" section of the consent form. Do not reference the consent form in response to this question.

2. Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare. (If you will include protected groups of subjects (minors; fetuses in utero; prisoners; pregnant women; unviable neonates; neonates of uncertain viability; decisionally impaired or economically or educationally disadvantaged subjects) please identify the group(s) and answer this question for each group. Please also complete the SUPPLEMENT: Protected and/or Vulnerable Populations.)

The IRB's charge is to make sure that the researcher has minimized the risks of harm (physical, emotional, economic, etc.) and taken steps to protect the rights and welfare of subjects. For vulnerable groups of subjects (i.e., minors, prisoners, decisionally impaired subjects, etc.) the IRB would like to see evidence that the researcher recognizes the special needs of these groups and has taken steps to reduce the possibility of damage to their rights and welfare.

3. Is it possible that you will discover a subject's previously unknown condition (disease, suicidal intentions, genetic predisposition, etc.) as a result of study procedures? ☐ No ☐ Yes If yes, explain how you will handle this situation.

> If you will perform tests or administer instruments that might reveal a previously unknown condition, explain what the testing is and what the conditions are that might be revealed. For example, if you will perform genetic testing, explain the status of the test and the clinical implications of the results. Explain if you will involve a genetic counselor in providing information about the testing to the subject. If you will ask questions of subjects that might reveal an intention to commit suicide or that a subject is severely depressed, explain what steps you will take to protect the subjects. If your study procedures might reveal a previously undiscovered disease or condition, explain if you will provide additional diagnosis and treatment or if you will refer the subject to other care providers.

4. Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."

> Describe concisely and realistically the benefits of the proposed study for subjects (if none, so state), and for society. This information should be included in the "Benefits" section of the consent form for subjects.

5. Describe the anticipated benefits of this research for society.

> Describe concisely and realistically the benefits of the proposed study for society. The IRB must determine that the risk of harm to individual subjects is outweighed by the potential benefit for society, especially if there is little or no potential benefit for the subjects themselves. This information should be included in the "Benefits" section of the consent form for subjects.

F. ADVERSE EVENTS OR EFFECTS

1. Who will handle adverse events? ☐ Investigator ☐ Referral ☐ Other, explain:

> Provide an explanation of how the investigator will handle adverse events that might result from the study both immediately and in the future, if relevant. If the investigator will handle all possible adverse events, the IRB must determine that the investigator has these capabilities. If the research team will handle some adverse events, and refer others, this should be explained. This information should be included in the "Risks, Stress, or Discomfort" section of the consent form for subjects.

2. Are your facilities and equipment adequate to handle possible adverse events? ☐ Yes ☐ No, explain:

> If your facilities are not adequate to handle adverse events you have described, explain what steps will be taken if an adverse effect/event occurs.

G. CONFIDENTIALITY OF RESEARCH DATA

1. Will you record any direct subject identifiers (names, Social Security numbers, patient, hospital, laboratory or claim numbers, addresses, telephone numbers, locator information, etc.) ☐ No ☐ Yes If yes, explain why this is necessary and describe the coding system you will use to protect against disclosure.

> Sometimes it is necessary for researchers to retain identifiers. If this is necessary, provide an explanation, and describe the methods you will use to code the information, i.e., all identifiers are assigned a random letter/number code, and the code is kept separate from the actual information. Information about what identifiers will be kept should be included in the consent form for subjects.

2. Will you retain a link between study code numbers and direct identifiers after the data collection is complete? ☐ No ☐ Yes If yes, explain why this is necessary and for how long you will keep this link.

> Data should be coded using a unique study code. Social Security numbers, hospital or patient numbers, and clinic numbers are not sufficient to protect the identity of a subject. If data are coded, a master list linking the data to individual subjects should be maintained securely and separately from the data. All data should be identified only with the code number, and not with the identifier.

3. Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who (other than members of the research team) will have access to data (e.g., sponsors, advisers, government agencies, etc.).

> Describe the data protection procedures (encryption, password protected computers confidentiality agreements with members of the research team, etc.) that you will put in place to protect the study data from inadvertent disclosure. Identify any group (school, funding agency, drug company, manufacturer) which will have access to identifiable data, and explain why the group has such access. This information should be included in the "Other Information" section of the consent form.

4. Will you place a copy of the consent form or other study information in the subject's medical or other personal record?
☐ No ☐ Yes. If yes, explain why this is necessary.

5. Do you anticipate using any data (information, specimens, etc.) from this study for other studies in the future? ☐ No ☐ Yes
If "Yes," explain and include this information in the consent form.

> If you anticipate using the data collected for this study in the future, include a description of the possible future uses in the consent form. Depending on the specificity with which you are able to describe future uses, the degree of similarity between the current and future use, and whether the data will be linkable to subject identifiers, the IRB may allow the consent obtained for this study to apply to future studies.

H. ADDITIONAL INFORMATION

1. If the study will involve radiation exposure to subjects, e.g., X-rays, radioisotopes, what is status of review by the UW Radiation Safety Committee (RSC): ☐ Pending ☐ Approved (Attach one copy of approval.) ☐ NA

> Approval from the Radiation Safety Committee (RSC) must be obtained for any use of radiation in studies involving human subjects (for example, chest or dental X-rays, fluoroscopy, radioactive tracers or markers). Lack of completed review by the RSC will not impede the Human Subjects review process, but final approval will be contingent on submission to the IRB of the RSC letter of approval.

2. Does this research require approval from the UW Institutional Biosafety Committee (IBC) for recombinant/synthetic DNA human Gene transfer or vaccines?

☐ No ☐ Yes. If yes, what is the status of review by IBC? ☐ Pending ☐ Approved (Attach one copy of approval.) ☐ NA

3. Protected Health Information (PHI). Will you or any member of your research team obtain, access, or use a subject's protected health information by any method, and for any purpose including "pre-screening"?

"Methods" may include but are not limited to: directly looking at a medical record (electronic or paper), requesting medical record information from a service such as the UW Center for Health Excellence, or viewing surgery schedules, clinic records, appointment books, etc.

Examples of where PHI may be located include: medical records, dental records, clinical lab tests that you will have performed on subject samples, pharmacy records, medical billing records, clinical databases, etc.

☐ No ☐ Yes. If "yes":

a. Describe the type of records/data, location and how you will obtain the information:

b. Will you obtain any of the information without HIPAA authorization from each subject?

☐ No ☐ Yes. If "yes": Complete and attach the SUPPLEMENT: Waiver Request, HIPAA Authorization, and the SUPPLEMENT: Waiver Request, Consent Requirements. If the records are owned by the University of Washington or a state agency, complete and attach a UW Confidentiality Agreement.

c. Will you obtain HIPAA authorization from subjects for any of the information?

☐ No ☐ Yes. If "yes", attach the HIPAA Authorization form you propose to use

d. Will you be obtaining any of the data as a Limited Data Set?

☐ No ☐ Yes

4. Other Records. Will you or any member of your research team obtain, access, or use academic, employment, or any other type of records about subjects, by any method, and for any purpose including "pre-screening"?

"Methods" may include but are not limited to: directly looking at a record (electronic or paper), requesting records from offices such as Payroll or the UW Registrar's Office, obtaining records from the state Department of Health, etc.

☐ No ☐ Yes. If "yes":

a. Describe the type of records/data, location, and how you will obtain the information.

b. Will you obtain any of the information without the subject's consent?

☐ No ☐ Yes.

If the records are owned by the University of Washington, complete and attach a UW Confidentiality Agreement.

5. Will you use the Clinical Research Center (CRC) at the UW or Seattle Children's for any of your research activities?

☐ No ☐ Yes.

If you answered "yes":

A medical record will be created for your subjects at UW Medicine and CRC staff may need to access those medical records for you. This may be because they are performing procedures or collecting data for you. It may also be required if an event happens on the CRC that requires treatment (such as fainting during a blood draw). This means that you must obtain a signed HIPAA Authorization form from each subject and give a copy of it to the CRC. ***Complete and attach the UW research HIPAA Authorization template, available on the HSD Forms webpage. There is guidance in the template about how to describe the information that the CRC staff may access and disclose to you.***

6. Does your research involve any of the following:

- Students age 21 or younger who may be participants in your research?
- Access to, or use of, personally identifiable information from student (current or past) education records from any institution or agency of education (including, but not limited to, pre-elementary, secondary, post-secondary, job training, adult education, career and technical education, special education)?
- Conducting any research procedures in an educational setting?

☐ No ☐ Yes.

If you answered "yes":

Your research may be subject to the requirements of the **Protection of Pupil Rights Amendment (PPRA)** and/or the **Family Education Rights and Privacy Act (FERPA).**

Consult with the SOP Research Involving Students to determine whether PPRA or FERPA regulations apply to your research.

Check the appropriate box.

☐ PPRA regulations apply to my research

☐ FERPA regulations apply to my research

☐ Both PPRA and FERPA regulations apply to my research

☐ Neither set of regulations apply to my research

7. Will you make audio-visual or tape recordings or photographs of subjects? ☐ No ☐ Yes. If yes, explain what type of recordings you will make, how long you will keep them, and if anyone other than the members of the research team will be able to see them.

If audio-visual, tape or digital recordings (videos, photographs, movies, or voice recordings) are study procedures, check "yes." This information should be included in the consent form for subjects. If the recordings will be shared in any way (through publications, presentations, or classroom use) with anyone who is not a member of the investigating team, subjects may be offered the opportunity to review the recordings, and if possible, to delete any portions. .

8. Will your study involve use of equipment involving energy input to the subjects (EMG, EKG, MRI, ultrasound, etc.)?
☐ No ☐ Yes. If yes, attach documentation that all equipment will be tested regularly by the Scientific Instrument Division (call (206) 543-5580 for information) or describe safety testing procedures you will use.

The Scientific Instrument Division or its equivalent at other institutions must routinely inspect all instruments, standard and investigational, that use electricity. If this is not being done, investigators must describe their own methods for insuring that electrical equipment is safe for use with human subjects.

9. Confirm by checking the box that the principal investigator on this IRB application has ensured that all investigators (as defined by UW policy GIM 10) are aware of policy GIM 10 and their responsibility for complying with its relevant requirements.

   ☐ Confirmed

10. Does the individual who is the principal investigator on (1) this IRB application or (2) any grants or contracts supporting this research have a financial conflict of interest with respect to this research? ☐ No ☐ Yes.

    If yes, has it been disclosed to the University? (Since August 24, 2012, all disclosures are made through the University's online Financial Interest Disclosure System.) Final review of this application cannot occur until the disclosure has been made and reviewed by the University, and the outcome has been incorporated into the IRB's review. ☐ No ☐ Yes ☐ Not applicable, because there is no financial conflict of interest.

    A **Financial Interest** means any interest of economic or monetary value of a researcher/inventor and/or member of that person's immediate family (spouse, parent, child, grandparent, grandchild, or sibling) that could reasonably appear to affect or to be affected by the particular research or technology transfer transaction under consideration. See UW policy GIM 10 for a more complete definition and description.

11. Is your research:

    - Clinical research that will bill subjects or their health insurance for UW Medicine professional or facility services, items, or tests*, **AND/OR**
    - An "applicable clinical trial" as defined below" **

      ☐ No ☐ Yes

      If you selected "yes", you must register your research at the federal site ClinicalTrials.gov

      See the HSD document titled: ClinicalTrials.gov – Instructions for Registering Your Trials for step-by-step instructions about how to register your research.

***New Requirement**

As of January 1, 2014, a new federal requirement will require you to provide the clinical trials registration number assigned to your research in order to bill most UW medicine professional or facility services, items, or tests to research participants or their health insurance. This new billing requirement applies to some clinical research, such as Phase I studies, that don't meet the federal registration definition of "applicable clinical trials". *See also*: Clinical Research Budget & Billing Support (CRBB)

***Applicable clinical trial is defined as:*

*(1) a pediatric postmarket surveillance study required by the FDA **OR***

(2) an interventional study (with one or more arm) of an FDA-regulated drug, biological product, or device that involves health outcomes and meets one or more of the following conditions:

- *The trial has at least one site in the United states; or*
- *The trial is conducted under an FDA investigational new drug application or investigational device exemption; or*
- *The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research*

The source of funding (e.g., industry, federal, nonprofit) is irrelevant.

See this website for additional information: http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf

I. CONSENT

Obtaining informed consent is a process that involves more than obtaining a signature on a form. It is a process of information exchange that may include subject recruitment materials, verbal instructions, question-and-answer sessions, and measures of participant understanding. Obtaining voluntary informed consent is one of the central protections required by all human subjects regulations and ethical principles. The key features of the consent process include:

- Disclosure of the information needed to make an informed decision about participation
- Facilitation of comprehension by the potential participant
- Promotion of the voluntariness of the potential participant's decision

Refer to the **SOP Consent** and **SOP Consent Documentation** for more information.

1. Description of consent process for adult subjects. How are you going to obtain informed consent from your adult subjects? Describe in detail your consent methods, process, and settings. Identify who will provide the information to subjects and who will interact with them during the consent process. If there is more than one consent process, describe each one separately. For subjects who do not speak English: Describe the process that will be used, and whether anyone on the research team will speak the subjects' language. **Complete this section if you will obtain consent from any subjects for any aspect of the research.**

2. Description of assent process for children subjects. Describe in detail how you will obtain assent from children subjects, following the instructions provided in the question above. Also, describe how these processes will differ based on age/cognitive ability. Finally, describe how you will determine whether a child is assenting or dissenting throughout the research (if applicable). **Assent means a child's affirmative agreement to participate in the research. Mere failure to object should not be interpreted as assent.*

3. Special issues or considerations. The standard concept of consent is based on the Western ethical tradition of individual autonomy and privacy. This may not apply well to your research. Your research may be subject to specific cultural or other contextual issues that affect the consent process. Describe any special issues and considerations about obtaining consent for your research. If none, state: "Not Applicable".

   Example issues:

   - Who is the appropriate person(s) for providing consent?
   - The desirability of a group consent process, or a surrogate consent process
   - Research that occurs in a setting with a blurred sense of what is public versus private
   - The cultural acceptability of the consent process (or documentation)
   - Cultures or groups in which it is considered impolite to refuse a request and/or in which people are fearful of refusing requests that they regard as coming from authorities

4. Undue influence. Describe how you will minimize any undue influence on your subjects' decision about participating in your research. If this is not an issue for your research, describe why. *This is an important consideration when persons recruiting or consenting subjects are in a position of authority or influence – for example, the subject's teacher, doctor, or employer.*

5. Subject comprehension. Describe anything that you will do to facilitate or verify your subjects' comprehension of the information you provide them during the consent process.

6. Do you expect that all of your participants will be **fluent** in spoken and/or written English? ☐ No ☐ Yes.

   If "No", please answer the following questions.

   6.1. In what language(s) will they be fluent?

   6.2. Translation of documents into another language. Federal regulations require that consent, assent, and authorization documents must be presented to participants in a language that is understandable to them. The UW IRB expects that translated documents will be:

   - Linguistically accurate;
   - At an appropriate reading level for the subject population; and
   - Culturally sensitive for the locale in which they will be used.

Describe how you will obtain translations of relevant documents, and how you will ensure that the translations meet these requirements.

6.3. Interpretation. Describe how you will provide interpretation, and when. Specifically:

a. For what situations will you provide interpretation? (At a minimum, an interpreter should be available for the consent process, unless the IRB has waived consent.)

b. Who will be the interpreter?

c. Describe the qualifications of the interpreter – for example, background, experience, language proficiency in English and in the other language, native language fluency, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

d. How will you ensure that the subjects will understand ongoing study-related communication? If the subject has questions, complaints, or adverse events, how will that be communicated to the researchers?

Check all that apply:

☐ **Written** *Attach copies of all consent forms for each subject group. Include a footer identifying the version date of each form and a header or title that identifies each different form. If you propose to delete one or more of the required elements of consent from a consent form, attach and complete the form called SUPPLEMENT: Waiver Request, Consent Requirements.*

☐ **Waiver of written documentation of consent** *This means that you are requesting a waiver of the requirement to obtain written documentation of consent. Complete and attach the form called SUPPLEMENT: Waiver Request, Consent Requirements. . Also, attach the Information Statement, oral consent or assent protocol and script, or other materials you will use to communicate the necessary elements of consent to the subjects.*

☐ **Waiver of consent** *This means that you are requesting a waiver of the requirement to obtain consent. Complete and attach the form called SUPPLEMENT: Waiver Request, Consent Requirements. .*

☐ **Assent** *Attach copies of any written materials or scripts you will use with minor subjects (individuals under the age of 18) to obtain their assent to being in your research.*

☐ **Parental permission** *Attach copies of any written materials or scripts you will use with parents, to obtain their permission to enroll their minor children in your research. See also SUPPLEMENT: Protected and/or Vulnerable Populations for waivers or alterations of consent requirements.*

Standard procedure is that subjects of research should provide documentation of informed consent through a written and signed consent form. If there is good reason why this approach should be different in your study, provide the relevant information and include an example of how consent will be obtained. For instance if you are requesting that consent be obtained orally, provide an explanation of why oral consent is appropriate and include an example of the statement, which will be read to subjects. In most cases in which consent is obtained orally, subjects should be provided with a written information statement, which includes all of the elements of informed consent except the signature of the subject. If you are requesting that informed consent be waived, attach an explanation of why this is appropriate.

Consent documents should be prepared for each group of subjects participating in the study. Assent forms should be prepared for minor subjects appropriate to their ages, and consent form(s) for parents or legal guardians should also be prepared. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted regarding assent, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Consent forms should be prepared for the parents.

Language used in the consent form should be appropriate for the intended group. Avoid medical or scientific jargon. Use short words and short sentences.