UNIVERSITY OF WASHINGTON

Human Subjects Division
Box 359470

HUMAN SUBJECTS REVIEW COMMITTEE APPLICATION

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

APPLICATION NO.

Send three one-sided copies of this form (including one copy with original inked signatures) and three one-sided copies of all relevant materials (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statement, advertisements, etc.) to the Human Subjects Division, Box 359470. Do not leave blanks. Attach one one-sided copy of each research proposal, grant or contract, and/or one one-sided copy of the protocol and investigator's brochure for clinical trials. Students should attach one one-sided copy of thesis or dissertation proposals. For information and assistance, visit our web site at http://www.washington.edu/research/hsd/index.php or call (206) 543-0098. We will not accept handwritten forms, incomplete forms, or forms printed on both sides of the paper. Use 10 point type or larger throughout application. The contents of this application and attachments will be kept confidential within the limits of the law.

☐ **Check this box if your project falls into one or more of the minimal risk ("expedited") categories of research (see web site for listing of categories) and send us only two copies of all your materials.**

I. PRINCIPAL INVESTIGATOR (Provide all the information requested. Correspondence will be directed to this person. You may designate a contact person other than yourself in section II., below.)

Name _____ Title _____ Position _____
Department _____ Division _____
Mail box or address _____
Telephone _____ Fax _____ e-mail _____

II. CONTACT PERSON (Provide all the information requested. This person does NOT have signatory authority with regard to this application.)

Name _____ Title _____ Position _____
Mail box or address _____
Telephone _____ Fax _____ e-mail _____

III. TITLE OF PROJECT:

IV. SIGNATURES: The undersigned acknowledge that: 1. this application represents 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 Human Subjects Review Committee (HSRC). The principal investigator is responsible for reporting any serious adverse events or problems to the HSRC, for requesting prior HSRC approval for modifications, and for requesting continuing review and approval.

A. Investigator:

_____
TYPED NAME PLUS SIGNATURE **DATE**

B. Faculty sponsor (for student):

_____
TYPED NAME PLUS SIGNATURE **DATE**

C. The Chair, Dean, or Director signing below acknowledges that this proposed activity has received intra-mural review and approval of scientific merit and investigator qualification.

_____
TYPED NAME PLUS SIGNATURE **DATE**

_____ _____ APPROVE ☐ DISAPPROVE ☐
HUMAN SUBJECTS REVIEW COMMITTEE SIGNATURE DATE

Subject to the following conditions: _____

_____

Period of approval is one year, from _____ through _____

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED

V. CO-INVESTIGATORS (Provide all the information requested for each co-investigator. Add sheets if necessary.)

Name ______________________ Title ________________ Position ________________
Department ____________________________ Division ____________________________
Mail box or address ____
Telephone ______________ Fax ________________ e-mail ______________________

Name ______________________ Title ________________ Position ________________
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Department ____________________________ Division ____________________________
Mail box or address ____
Telephone ______________ Fax ________________ e-mail ______________________

VI. LIST EACH PROPOSED AND FUNDED GRANT OR CONTRACT RELEVANT TO THIS APPLICATION. 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.

☐ **American Recovery and Reinvestment Act (ARRA) – also known as the Stimulus Package or Recovery Act**
If you checked this box, please attach the ARRA cover sheet to your submission. (http://www.washington.edu/research/link.php?id=9)

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)

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 ______________

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B. Name of principal investigator:

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D. Agency's number (if assigned):

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F. Inclusive dates: from ______________ through ______________

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☐ Other, specify

B. Name of principal investigator:

C. Name of funding agency:

D. Agency's number (if assigned):

E. Title of proposal:

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

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

VII. 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.

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.

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.

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.

D. SUBJECTS

1. How many subjects will you need to **complete** this study? Number _____ Age range
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:
3. What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different.)
4. What characteristics (exclusion criteria) would exclude subjects who are otherwise eligible from this study? (Answer for each subject group, if different.)
5. Describe the subject recruitment strategies you will use for each group of subjects. (Attach advertisements, flyers, contact letters, telephone contact protocols, Health Sciences recruitment web site template, etc.)
6. Explain who will approach subjects to take part in the study and how this will be done to protect subjects' privacy. (Attach letters of cooperation from agencies, institutions or others involved in subject recruitment.)
7. Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.
8. Will you give subjects gifts, payments, services without charge, or extra course credit? ☐ No ☐ Yes If yes, explain:
9. Will any of the subjects or their third-party payers be charged for any study procedures? ☐ No ☐ Yes If yes, explain:
10. Where will the study procedures be carried out? (Attach copies of IRB approvals or letters of cooperation from non-UW research sites, if necessary.)

E. RISKS AND BENEFITS

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.
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, decisionally impaired or economically or educationally disadvantaged subjects) please identify the group(s) and answer this question for each group.)
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.
4. Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."
5. Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

F. ADVERSE EVENTS OR EFFECTS

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

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

3. Who will be financially responsible for treatment of **physical injuries** resulting from study procedures?
   ☐ Study sponsor ☐ Subject or subject's insurer ☐ UW compensation plan ☐ Veterans Affairs ☐ Other, explain:

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.

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.

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.).

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.

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

2. Will you need access to subjects' medical, academic, or other personal records for screening purposes or during this study?
   ☐ No ☐ Yes. If yes, specify types of records, what information you will take from the records and how you will use them.

3. Are you requesting permission to access, use or disclose subjects' protected health information (for example, medical or dental records) without written authorization from the subjects for research purposes?
   ☐ No ☐ Yes. *If yes, complete and attach the form called Waiver Request: HIPAA Authorization.*

4. 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.

5. 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.

6. Have all Investigators (i.e., all UW personnel responsible for the design, conduct or reporting of the proposed research) read and complied with GIM 10, the University's policy governing the disclosure of Significant Financial Interests? ☐ No ☐ Yes.
   (Note: This application can not be considered unless all Investigators have read and complied with GIM 10, which may be accessed at http://www.washington.edu/research/osp/gim/gim10.html.)

7. Does any Investigator have a Significant Financial Interest related to the proposed research that must be disclosed as provided in GIM 10? ☐ No ☐ Yes. If yes, each Investigator having a Significant Financial Interest must comply with GIM 10, including submission of a Significant Financial Interest Disclosure Form. Final review of this application cannot occur until the GIM 10 review is complete. Delays in complying with GIM 10 will result in delays in completing the final review of this application. Please list the name of each Investigator having a Significant Financial Interest below:

I. CONSENT FORMS

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 Waiver Request: Consent or Consent Requirements.*

☐ **Oral** *This means that you are requesting a waiver of the requirement to obtain written documentation of consent. Complete and attach the form called Waiver Request: Consent or Consent Requirements. Also, attach written scripts of oral consent and assent for each subject group.*

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

☐ **"Short Form" consent** *Attach copies of all materials you will use for the consent process. Complete and attach the form called Waiver Request: Consent or Consent Requirements.*

J. DRUGS, SUBSTANCES, AND DEVICES

1. List **all** non-investigational drugs or other substances used to conduct this research (analgesics, anesthetics, drugs used to treat side effects, etc.). Include products used for standard clinical care if they are used in this study for research purposes.

Name	Source	Dose	How administered

2. List **all** investigational new drugs or other investigational substances to be used in the study. Include marketed products used "off-label" (different formulation, dose, route of administration, or indication). Provide:

- **three** copies of a concise summary of information about the drug prepared by the investigator (including animal and human toxicity data, studies done in animals and humans to date);
- **one** copy of the Investigator's Brochure;
- **one** copy of the study protocol.

Important note: You must register an IND with the appropriate institutional pharmacy (**UWMC: 598-6054; HMC: 731-5448, VA: 764-2142**) before using the drug in research.

Name	Source	Dose	How administered	IND Number	Phase of testing

3. List all investigational devices you will use. Provide the information requested below and attach one copy of the company protocol. If there is no Investigational Device Exemption (IDE), explain why. Include a statement as to why the device qualifies as non-significant risk. Provide a copy of the FDA letter(s) which states the device classification (PMA, 510K, Class I, II, or II, or custom device) and categorization (Category A or B). "Category A" means that Medicare may **not** be billed for the device or for services related to its use. "Category B" means that Medicare may be billed for services related to its use **if** the U.S. Health Care Finance Administration (HCFA) grants authorization. **Important Note:** Register IDE devices with the UWMC Manager of Surgical Support Services (598-6538) or the HMC Business Manager of Surgical Services (731-8094) to obtain authorization for use.

   a. Name of the device:

   b. Name of the manufacturer:

   c. Description of its purpose and how you will use it in this study:

   d. Descriptions of previous studies in humans and animals:

   e. Investigational Device Exemption (IDE) number or FDA status: