UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION
Box 359470
Seattle, WA 98195-9470
Phone: 206-543-0098
Fax: 206-543-9218

APPLICATION: Modification, Approved Project

DO NOT SUBMIT THIS PAGE TO HSD

PURPOSE

Use this form to request modifications to an already approved IRB application, provide new information, add or remove research team members in specific roles, and safety monitor or DSMB reports. Use the REPORT CHANGE: Confidentiality Agreement, Personnel form instead of this form if the only change you are making is to add or remove names from an existing Confidentiality Agreement.

INSTRUCTIONS

- Please see the SOP Modifications for more information.
- When preparing double-sided copies, please make sure that each item (e.g. Modification Form, consent forms, study instruments, etc.) begins on the front of a new piece of paper.
- We will not accept handwritten forms.
- NUMBER OF COMPLETE PACKETS: Three(3). (Two packets for minimal risk).
- For users of the UW Clinical Research Center (CRC) in the UW Medical Center of 7 South: modifications that impact resource utilization on the CRC MUST ALSO be submitted to ITHS for review and approval prior to implementation. Email to: iths-crc@uw.edu.

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APPLICATION: Modification, Approved Project

FOR HSD OFFICE USE ONLY

DATE RECEIVED STAMP:

- ☐ MASTER COPY
- ☐ IRB WORKING COPY
- ☐ RESEARCHER COPY
- ☐ FULL IRB REVIEW REQUIRED
- ☐ EXPEDITED REVIEW
- ☐ APPROVED
- ☐ CONDITIONAL APPROVAL
- ☐ NOTED
- ☐ DISAPPROVED
- ☐ WITHDRAWN

DORA MOD #:

DATE OF IRB ACTION: PRINTED NAME:

IRB CHAIR OR DESIGNEE SIGNATURE:

NOTES:

1. Research Study & Contact Information

Full Application Title:	IRB #:	Committee:

Lead Researcher Information (change of lead researcher requires a modification)

Name:	Title:	Position (e.g. Assistant Professor or Director):

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

University of Washington

UW Department:	UW Division (Department of Medicine):

UW Position or Appointment of Lead Researcher (choose the most appropriate one):

- ◯ Faculty
- ◯ Student
- ◯ UW Resident or Fellow
- ◯ UW Administration or Staff
- ◯ None

Phone #:	Campus Box #:	Email:	Other address if not at UW:

Contact Person for the IRB (Change of contact person requires a modification)

Name:	Title:	Position (e.g. Assistant Professor or Director):

Home Institution (or source of paycheck):

University of Washington

UW Department:	UW Division (Department of Medicine):

UW Position or Appointment of IRB Contact Person (choose the most appropriate one):

- ◯ Faculty

Student

UW Resident or Fellow | UW Administration or Staff | None

Phone #:	Campus Box#:	Email:	Other address if not at UW:

Name and Mailing Address for all paper-based correspondence
(If blank, correspondence will be directed to contact person or lead researcher if no contact person.)

Name:	Campus Box #:	Other address if not at UW:

Name of person completing this form (if not Lead Researcher or IRB Contact)

Name:	Email:	Phone:

END PART ONE

2. Reason(s) Submitted

☐ Researcher or Sponsor Initiated Modification *(Check all the types of modifications you are requesting. The requested sections will then be available in the form.)*:

- ☐ Part 3: Purpose
- ☐ Part 4: Procedures
- ☐ Part 5: Populations
- ☐ Part 6: Recruitment
- ☐ Part 7: Consent/Assent
- ☐ Part 8: Waiver of Documentation of Consent
- ☐ Part 9: Waiver of Consent or Waiver/Alteration of Elements of Consent
- ☐ Part 10: Confidentiality of Research Data
- ☐ Part 11: HIPAA Authorization or Waiver of HIPAA Authorization
- ☐ Part 12: UW Confidentiality Agreement
- ☐ Part 13: Researchers and Research Staff
- ☐ Part 14: Individuals Performing Research Procedures
- ☐ Part 15: Non-UW Individuals, Organizations and Locations
- ☐ Part 16: Investigator Brochure and/or Protocol Amendments
- ☐ Part 17: Funding
- ☐ Part 18: Other Compliance Approval Letters/ Reports (Radiation Safety Approval, Data Safety Monitoring Reports)

END PART TWO

3. Purpose

3.1. Describe the change(s) to the purpose of the study:

3.2. Explain the reason for this change:

3.3. Do the changes affect the consent form(s)?

- **YES** — Complete Part 7 and include 3 clean copies of the consent form(s) and 3 copies of the consent form(s) with the revisions in tracked changes. (2 copies for Minimal Risk.)
- **NO** — Explain why not:

END PART THREE

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4. Procedures

PURPOSE OF THIS SECTION: Complete this section if you intend to change any research procedures. Procedures include (but are not limited to) developing research study instruments, changing your recruitment process, changing your consent process, requesting review of medical or other records for pre-screening or requesting records review as part of your research, changing the amount of compensation offered to subjects, adding additional surveys, questionnaires or interventions.

NOTE: You may also need to complete other sections of the Modification Form if you are changing recruitment materials, consent materials, and/or are requesting approval to review health care records.

4.1. Summarize the proposed changes or new procedures:

4.2. Explain why the changes are being made:

4.3. Do the changes affect any of the following processes and/or documents?

4.3.a. Recruitment process and documents, including advertisements?

- ○ **YES** Complete Part 6
- ○ **NO**

4.3.b. Consent process and documents?

- ○ **YES** Complete Part 7
- ○ **NO**

4.3.c. Records and/or research data?

- ○ **YES** Complete Parts 10, 11 and/or 12, as appropriate

  If you will be submitting data to the federal GWAS dbGaP data repository, complete and attach the SUPPLEMENT: GWAS dbGaP
- ○ **NO**

4.3.d. Radiation exposure?

- ○ **YES** Contact Radiation Safety
- ○ **NO**
- ○ **N/A**

4.3.e. Administrative/Other?

- ○ **YES** Describe:
- ○ **NO**

4.4. Describe the effects of these changes on the risks and/or benefits to subjects. If there are no changes in the risks or benefits, state: "None".

4.5. Are you adding the use of a drug, medical device, biologic, botanical, or dietary supplement? For more information see the SOP FDA-Regulated Research.

- ○ **YES** Complete and attach the SUPPLEMENT: Devices, or SUPPLEMENT: Drugs, Biologics, Botanicals
- ○ **NO**

4.6. Are you adding any procedures that involve genetic research?

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.

○ **YES** Complete and attach the SUPPLEMENT: Genetics Research

○ **NO**

4.7. Are you adding any procedures that involve any component of the federal Department of Defense (DOD)? For more information see the SOP Department of Defense.

NOTE: "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.

○ **YES** Complete and attach the SUPPLEMENT: Department of Defense Involvement

○ **NO**

4.8. Are you adding any procedures that involves 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)? For more information see the SOP Department of Justice Research.

NOTE: "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.

○ **YES** Complete and attach the SUPPLEMENT: Department of Justice

○ **NO**

4.9. Are you adding any procedures that take place under, or otherwise involve, general anesthesia?

○ **YES** 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.

4.9.a. If you checked any box in question 4.9. except "None of the above", answer the following questions:

4.9.a.i. 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 procedure will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

4..9.a.ii. 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 modification without this consultation. If UW Department of Anesthesiology approval has been obtained, please attach the Department's letter of support.

○ **NO**

END PART FOUR BACK TO TOP

5. Populations

5.1. Identify the changes you are requesting in subject population(s).

☐ 5.1.a. Add new subject population(s).

☐ 5.1.b. Change eligibility criteria of already-approved study population(s).

☐ 5.1.c. Change number of subjects approved to complete the study for an already-approved study population.

NOTE: If changing the number of subjects is the only population change you are making, answer questions 5.2. and 5.3., the rest of the questions in this part will be hidden. Reset by deselecting this box.

☐ 5.1.d. Remove existing study population(s).

5.2. Briefly describe the proposed changes in subjects population(s), and explain the reasons for this change:

5.2.a. Describe changes (if any) to the following for each already-approved study population, and describe the following for any new study populations being added:

Inclusion Criteria:

Exclusion Criteria:

Age Range:

Number of Subjects:

5.3. Do the changes affect the consent form(s)?

○ **YES** Complete Part 7 and include 3 clean copies of the consent form(s) and 3 copies of consent form(s) with the revisions in tracked changes. (2 copies for Minimal Risk.)

○ **NO** Explain why not:

5.4. Do your changes in subject population(s) involve adding any of the following federally protected populations?	YES	NO
a. Pregnant women and/or fetuses	○	○
b. Neonates (newborns)	○	○
c. Minors	○	○
d. Prisoners	○	○
e. Are you removing any of the protected study populations listed above?	○	○

State which study population is being removed from the research:

If you checked "YES" to any of the protected populations listed above, **you are required to complete the** Supplemental Form: Protected and/or Vulnerable Populations **and attach it to this Modification Form.**

5.5. Do your changes in subject populations(s) 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 education records (current or past) 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?

○ **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

○ **NO**

5.6. Do the changes involve adding a population of subjects (or records) from the Bureau of Prisons (BOP)? For more information see the SOP Department of Justice Research.

○ **YES** Complete and attach the SUPPLEMENT: Department of Justice

○ **NO**

5.7. Do the changes involve adding a population of subjects (or records) from the Department of Defense (DOD)? For more information see the SOP Department of Defense.

○ **YES** Complete and attach the SUPPLEMENT: Department of Defense Involvement

○ **NO**

5.8. Do the changes involve other vulnerable group(s)?

*NOTE: "**Other vulnerable groups**" means groups of subjects who are not federally protected populations, but who may be more vulnerable to specific risks and/or less able to understand the consenting process. Examples include: individuals who are decisionally impaired due to illness, injury or other conditions; students; employees; illiterate individuals; terminally ill individuals; Native Americans/Alaskan natives; and individuals who do not speak English or who speak it as a second language.*

○ **YES** **You are required to complete the SUPPLEMENT: Protected and/or Vulnerable Populations and attach it to this Modification Form.**

○ **NO**

END PART FIVE

BACK TO TOP

6. Recruitment

6.1. Provide a general overview and context for the changes you are making to recruitment:

6.2. Describe the proposed changes to your recruitment process:
- If there are multiple recruitment strategies, describe each one individually;
- If there are multiple subject groups and your recruitment differs for each, describe the recruitment for each group.

6.3. Explain who will approach subjects and how this will be done to protect subjects' privacy:

6.4. Describe how you will minimize potential coercion or undue influence during recruitment:

6.5. Describe any changes to subjects gifts, payments, services without charge, or extra course credit, and include the value/ dollar amount, if applicable:

6.6. Complete the table below for each new or revised recruitment document.
- Identify the documents that are being revised and the documents that are new.
- Attach all of the materials in the same order that you listed the documents.
- Submit 3 clean copies and 3 copies with the revisions in tracked changes (2 copies for Minimal Risk).

Examples for Row #1 - "Type of recruitment materials" can be:

- Advertisement
- Email
- Flyer
- Letter to subjects
- Letter to colleagues
- Magazine ad or article
- Newspaper ad or article
- Oral script
- Poster
- Radio ad
- Television ad
- Website text and layout

Examples for Row #2 - "Reason submitted" can be:

- Adding new recruitment flyer
- Deleting old recruitment letter to subjects, no longer in use
- Revising existing oral script
- Replacing existing oral script with new one

END PART SIX - Also complete the "recruitment materials" table(s)

BACK TO TOP

Recruitment materials		Table # 1
Row 1	Type of recruitment document or material:	
Row 2	Reason submitted:	
Row 3	IF APPLICABLE IRB Approval Date: (most recent approval date of recruiting material being revised or replaced.)	

Add Materials Table

Remove Materials Table

7. Consent/Assent

7.1. Provide a general overview and context for the changes you are making: (For more information on Consent and Consent Documentation, see the SOPs linked here.)

7.2. Describe the proposed changes to your consent process(es), and/or describe any new consent process(es) being added.
- If there are multiple new or revised consent processes, describe each one individually.
- Include information about who obtains consent, when, and how.

7.3. Do you plan to re-consent subjects?

○ **YES** Describe your re-consenting process:

○ **NO** Explain why not:

7.4. Provide a complete list of all new or revised consent materials by completing the table(s) below for each new or revised consent document:
- Identify the documents that are being revised and the documents that are new.
- If you are only submitting new consent documents, write “Not applicable” in the table below, where appropriate.
- Attach all of the consent materials in the same order that you listed the documents.
- Submit 3 clean copies and 3 copies with the revisions in tracked changes. (2 copies for Minimal Risk.)

Examples for Row #1 - "Type of consent materials" can be:

- Consent Form
- Parent Consent Form
- Parent Consent/Assent Form
- Assent Form for Age 0-6, Assent Form for Age 7-12, or Assent Form for Age 13-17
- Oral Consent Script
- Information Sheet
- Translated Consent Form
- Back-Translated Consent Form
- Consent Form approved by another IRB
- Sub-study Consent Form

Examples for Row #2 - "Reason submitted" can be:

- Adding new consent form
- Adding new addendum to consent form
- Deleting old consent form
- Revising existing consent form to update research staff
- Replacing existing consent form that is outdated

END PART SEVEN - Also complete the "consent materials" table(s) BACK TO TOP

Consent materials		Table # 1	
Row 1	Type of consent document or material:		
Row 2	Reason submitted:		
Row 3	Consent Form Title:	Old title, if applicable	New title
Row 4	Version number and/or revision date:	Old version number and/or revision date, if applicable	New version number and/or revision date
Row 5	IF APPLICABLE Consent Form Footer:	Old footer, if applicable	New footer
Row 6	IF APPLICABLE IRB Approval Date: (most recent approval date of consent form being revised or replaced)		

Add Materials Table

Remove Materials Table

8. Request for Waiver of Written Documentation of Consent

A request for the waiver of the requirement for written documentation of consent means that consent will be obtained from the subjects, but there will be no verifiable written documentation signed by subjects or by subjects' legally-authorized representatives. Examples:

- Obtaining consent with an oral process (face-to-face or over the phone).
- Obtaining consent by an electronic process that does not involve a verified electronic signature. Examples: subjects provide consent with a web-based form or by email.

(For more information on Consent and Consent Documentation, see the SOPs linked here.)

☐ Complete and attach the appropriate section of the form called SUPPLEMENT: Waiver Request, Consent Requirements.

END PART EIGHT BACK TO TOP

9. Request for Waiver of Consent or Waiver/Alteration of Elements of Consent

A request for a waiver of consent or waiver or alteration of elements of consent means that your consent process will alter, or not include, one or more of the required elements of consent, or that you will not obtain consent at all from the subjects. Example:

- For a study involving deception, you may wish to exclude the description of some aspects of the purpose and procedures.

(For more information on Consent and Consent Documentation, see the SOPs linked here.)

☐ Complete and attach the appropriate section of the form called SUPPLEMENT: Waiver Request, Consent Requirements.

END PART NINE BACK TO TOP

10. Confidentiality of Research Data (including records and specimens)

Examples of when to complete Part 10:

- Change the date when the link between data and subjects' identifiers is destroyed
- Change the means of data collection, data protection, and/or storage
- Change the variables abstracted from medical records

10.1. Are you changing the date by which you will destroy the link between data and the subject's identifiers?

◯ **YES** Provide the new date of destruction of the link, and rationale in the box below **AND**

- Revise the HIPAA Authorization Template and/or amend the Confidentiality Agreement as Appropriate **AND**
- Attach the HIPAA Authorization Template and/or signed Confidentiality Agreement to your Modification Form

◯ **NO**

10.2. Are you making any changes in how you protect the confidentiality of the research data?

◯ **YES** Describe the changes from the current IRB-approved data protection procedures:

◯ **NO**

10.3. Are you obtaining or using any new data (including records and specimens)?

○ **YES**

10.3.a. Describe:

10.3.b. For new records: Which institution maintains the new records that you plan to use?

10.3.c. For new records: What type of new records will be reviewed or used?

10.3.d. Are the data, records, or specimens (check all that apply):

- ☐ Identifiable (not coded)
- ☐ Coded
- ☐ Coded but code unknown to the researcher/do not have the link to subjects' identifiers
- ☐ Anonymous (there is no link of any kind to the subjects' identifiers)

10.3.e. For new records: Provide inclusive dates for the records you will review or use:

EXAMPLE: You want to review records that start on January 1, 2004, and end on December 31, 2007.

10.3.f. For new records: list the variables that you will record and attach your data collection form. These may be submitted on separate sheets if necessary. If this is not possible, explain why.

○ **NO**

10.4. Will you record any direct subject identifiers as part of your new data collection activities? "Identifiers" means anything that can readily identify a subject in the context of your study and your dataset. It does not refer to the 18 types of data in health care records that are considered by HIPAA regulations to be identifying.

EXAMPLES: Social security numbers, complete addresses, telephone numbers, locator information, etc.

○ **YES**

Explain why this is necessary:

Describe how you will protect identifiable data (and/or identifiers) against breach of confidentiality, and how long you plan to maintain the link between identifiers and data and/or specimens.

NOTE: This information should be consistent with what is provided in the Confidentiality Agreement (if you have one). See Part 12 to determine if a Confidentiality Agreement is needed.

Will you retain a link between any study codes and direct identifiers after the data collection is complete?

○ **YES** Explain why this is necessary and for how long you will retain the link/identifiers.

○ **NO**

○ **NO**

10.5. Who might have access to subjects' identifiable data besides the Lead Researcher (PI) and research staff?

EXAMPLES: Data Coordinating Centers, regulatory agencies (e.g. federal, state, and institutional compliance offices, study sponsors)

NOTE: Include in this list those who may have access to identifiable data in the consent forms or consent materials.

10.6. Are you now proposing to place a copy of the consent form or other study information in the subject's medical/health care record?

○ **YES** Explain why this is necessary:

○ **NO**

10.7. Do you anticipate using any data (information, specimens, subject contact information, etc.) from this research study for other studies in the future?

○ **YES** Describe the possible future uses. Include this description in the consent form.

○ **NO**

10.8. Are you proposing to review health care records from a health care provider, health plan, or health care clearinghouse for your research study?

DEFINITION: "Health Care Records" are medical records, dental records, psychiatric records, drug and alcohol treatment records, medical billing records, pharmacy records, all of which are created and maintained by an institution, clinic or private clinician providing clinical care to a person.

○ **YES** Complete Part 11: HIPAA Authorization or Waiver of HIPAA Authorization and Part 12: UW Confidentiality Agreement (if from a UW entity).

○ **NO**

END PART TEN BACK TO TOP

11. HIPAA Authorization or Waiver of HIPAA Authorization

Complete Part 11 when you are adding new records/data that are derived from a HIPAA covered entity.

11.1. If you are proposing to review health care records, check all of the following that apply:

☐ 11.1. a. Revise an existing HIPAA Authorization Form
Attach your revisions in copies using tracked changes. You are done with Part 11.

☐ 11.1.b. Add a HIPAA Authorization Form
Attach the HIPAA Authorization Form

☐ 11.1.c. Request a Waiver of HIPAA Authorization
Complete and attach the Waiver Request: HIPAA Authorization form

END PART ELEVEN BACK TO TOP

12. UW Confidentiality Agreement

DEFINITION: The Confidentiality Agreement is required if you are using personally identifiable official records of any kind (e.g., medical; personnel; student; etc.):

1. *From the University of Washington or any of its components, such as the UW Registrar's Office, UW Medicine, Harborview Medical Center, Seattle Cancer Care Alliance)* ***AND***
2. *The records are used without the written informed consent of the person to whom the records pertain or without the consent of the person's Legally Authorized Representative (LAR) (This means you will also need a waiver of consent.)*

NOTE: See the Confidentiality Agreement on the HSD Website for complete information.

REFERENCE: Washington State Law RCW 42.28 "Release of records for research"

12.1. Are you requesting a change to an existing Confidentiality Agreement?

○ **YES** Which of the following changes are you making to the Confidentiality Agreement?

☐ Adding new data or new UW records to the Confidentiality Agreement

Describe the records:

Complete and attach the TEMPLATE: Confidentiality Agreement with original ink signatures of all those research study staff that will access/use personally identifiable data. Incomplete or inaccurate Agreements will not be signed. You may also need a waiver of HIPAA authorization, or consent. Please see the Confidentiality Agreement on the HSD website for complete information.

☐ Changing the date by when the identifiers or data will be destroyed

What is the new date, and the reason for the new date?

Complete and attach the TEMPLATE: Confidentiality Agreement with original ink signatures of all those research study staff that will access/use personally identifiable data. Incomplete or inaccurate Agreements will not be signed.

☐ Adding or deleting individuals who will access/use these identifiable data.

Complete and attach the REPORT CHANGE: Confidentiality Agreement, Personnel. If this is the only change you are making to your study, complete and submit ONLY this form; you do not need to submit the Modification form.

○ **NO**

12.2. Are you adding the use of records that are:

- Official records that belong to any component of the University of Washington, including UW Medicine, Harborview Medical Center (HMC), Seattle Cancer Care Alliance (SCCA), and UW Registrar's Office **AND**
- Being accessed and used without obtaining the consent of subjects?

○ **YES** Complete and attach the TEMPLATE: Confidentiality Agreement with original ink signatures of all those research study staff that will access/use personally identifiable data. Incomplete or inaccurate Agreements will not be signed. You may also need a waiver of HIPAA authorization, or consent. Please see the Confidentiality Agreement on the HSD website for complete information.

○ **NO** A ***NEW*** Confidentiality Agreement is not needed.

END PART TWELVE BACK TO TOP

13. Researchers and Research Staff

Complete Part 13 when you are changing the lead researcher, study coordinator, IRB contact person, subject contact person, faculty advisor.

- Select "ADD" to add another study coordinator, IRB contact person, subject contact person to your project.
- Select "CHANGE" to replace the current lead researcher, study coordinator, IRB contact person, subject contact person, faculty advisor on your project.
- Select "REMOVE" to remove, without replacing, a study coordinator, IRB contact person, subject contact person from your project.

NOTE: Lead Researchers and Faculty Advisors can only be CHANGED.

FOR MORE INFORMATION ON WHO NEEDS TO BE LISTED ON THE IRB APPLICATION SEE: SOP Research Team

	ADD	CHANGE	REMOVE
13.1. Lead Researcher		○	

a. Name of the Lead Researcher being replaced:

b. Provide the following information for the new Lead Researcher:

Name:	Title:	Position (e.g. Asst. Prof. or Director):

Home Institution:	Other:
University of Washington	

UW Department:	UW Division (School of Medicine):

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

○ Faculty
- ○ Standard Faculty Appointment
- ○ Research Faculty Appointment
- ○ Clinical Faculty Appointment
- ○ Affiliate Faculty Appointment
- ○ Visiting Faculty Appointment
- ○ Dual Appt. with PNNL
- ○ Other - Describe:

○ Student
- ○ Graduate or Professional Student (Matriculated or approved "on leave")
- ○ Matriculated Undergraduate Student
- ○ WWAMI Student

○ UW Resident, Fellow, or Post-Doc at UW or Local VA

○ UW Administration or Staff

○ None

Phone	Campus Box #:	Email:	Other address if not at UW:

c. Reason why the Lead Researcher is being changed:

d. Confirm by checking the box that the new Lead Researcher on this study has ensured that all investigators (as defined by UW policy GIM 10) are aware of UW policy GIM 10 and their responsibility for complying with its relevant requirements.

☐ Confirmed

e. Does the individual who is the new Lead Researcher on (1) this research or (2) any grants or contract supporting this research have a financial conflict of interest with respect to this research?

○ **YES**

e.1. Has it been disclosed to the University? (since August 24, 1012, all disclosures are made through the University's online Financial Interest Disclosure System.) Final approval of this application cannot occur until the disclosure has been incorporated into the IRB's review

- ○ **YES**
- ○ **NO**

○ **NO**

f. Assurances by the new Lead Researcher.
By checking these boxes and signing this form I, the new lead researcher, acknowledge the following:

☐ The funding agency(s), if any, have been or will be informed of the new lead researcher.

☐ All other appropriate UW compliance offices have been or will be informed of the new lead researcher.

Signature of New Lead Researcher

Date

Signature of Current Lead Researcher | Date

If the signature of the Current Lead Researcher is not available, explain why:

g. Assurances by the Department Chair:

By signing below I, the Department or Division Chair, or Center Director of the New Lead Researcher certify that:

- The researcher is qualified to conduct the research, and that there are adequate resources (researcher time, personnel, financial support, equipment, facilities) available.
- This research has appropriate scientific merit, if it did not go through an extramural review process.

Typed Name | Department Chair Signature | Date

IMPORTANT: Be sure to revise any documents that mention the Lead Researcher's name, including consent forms and any Confidentiality Agreement. The revision should be submitted as part of this Modification. Any other aspects of the study (e.g. recruiting, study procedures) that will be affected by this change should also be submitted with this Modification.

Study Coordinator #:1

13.2. Study Coordinator	ADD	CHANGE	REMOVE
	○	○	○

a. Name of the Study Coordinator being changed:

a. Name of the Study Coordinator being removed:

b. Provide the following information for the new Study Coordinator:

Name:	Title:	Position (e.g. Asst. Prof. or Director):

Home Institution:	Other:
University of Washington	

UW Department:	UW Division (School of Medicine):

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

○ Faculty
- ○ Standard Faculty Appointment
- ○ Research Faculty Appointment
- ○ Clinical Faculty Appointment
- ○ Affiliate Faculty Appointment
- ○ Visiting Faculty Appointment
- ○ Dual Appt. with PNNL
- ○ Other - Describe:

○ Student
- ○ Graduate or Professional Student (Matriculated or approved "on leave")
- ○ Matriculated Undergraduate Student
- ○ WWAMI Student

○ UW Resident, Fellow, or Post-Doc at UW or Local VA

○ UW Administration or Staff

○ None

Phone	Campus Box #:	Email:	Other address if not at UW:

c. Reason why the Study Coordinator is being added:

b. Reason why the Study Coordinator is being removed:

c. Reason why the Study Coordinator is being changed:

IMPORTANT: Be sure to revise any documents that mention the Study Coordinator's name, including consent forms and any Confidentiality Agreement. The revision should be submitted as part of this Modification. Any other aspects of the study (e.g. recruiting, study procedures) that will be affected by this change should also be submitted with this Modification.

Add, change, or remove another study coordinator | Cancel

IRB Contact Person #:1

13.3. IRB Contact Person	ADD	CHANGE	REMOVE
	○	○	○

a. Name of the IRB Contact Person being changed:

a. Name of the IRB Contact Person being removed:

b. Provide the following information for the new IRB Contact Person:

Name:	Title:	Position (e.g. Asst. Prof. or Director):

Home Institution:	Other:
University of Washington	

UW Department:	UW Division (School of Medicine):

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

○ Faculty	○ Standard Faculty Appointment	○ Research Faculty Appointment	○ Clinical Faculty Appointment
	○ Affiliate Faculty Appointment	○ Visiting Faculty Appointment	○ Dual Appt. with PNNL
	○ Other - Describe:		
○ Student	○ Graduate or Professional Student (Matriculated or approved "on leave")	○ Matriculated Undergraduate Student	○ WWAMI Student
○ UW Resident, Fellow, or Post-Doc at UW or Local VA	○ UW Administration or Staff	○ None	

Phone	Campus Box #:	Email:	Other address if not at UW:

c. Reason why the IRB Contact Person is being added:

b. Reason why the IRB Contact Person is being removed:

c. Reason why the IRB Contact Person is being changed:

IMPORTANT: Be sure to revise any documents that mention the IRB Contact Person's name, including consent forms and any Confidentiality Agreement. The revision should be submitted as part of this Modification. Any other aspects of the study (e.g. recruiting, study procedures) that will be affected by this change should also be submitted with this Modification.

Add, change, or remove another IRB contact person | Cancel

Subject Contact Person #:1

13.4. Subject Contact Person	ADD ○	CHANGE ○	REMOVE ○

a. Name of the Subject Contact Person being changed:

a. Name of the Subject Contact Person being removed:

b. Provide the following information for the new Subject Contact Person:

Name:	Title:	Position (e.g. Asst. Prof. or Director):

Home Institution:	Other:
University of Washington	

UW Department:	UW Division (School of Medicine):

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

○ Faculty
- ○ Standard Faculty Appointment
- ○ Research Faculty Appointment
- ○ Clinical Faculty Appointment
- ○ Affiliate Faculty Appointment
- ○ Visiting Faculty Appointment
- ○ Dual Appt. with PNNL
- ○ Other - Describe:

○ Student
- ○ Graduate or Professional Student (Matriculated or approved "on leave")
- ○ Matriculated Undergraduate Student
- ○ WWAMI Student

○ UW Resident, Fellow, or Post-Doc at UW or Local VA

○ UW Administration or Staff

○ None

Phone	Campus Box #:	Email:	Other address if not at UW:

c. Reason why the Subject Contact Person is being added:

b. Reason why the Subject Contact Person is being removed:

c. Reason why the Subject Contact Person is being changed:

IMPORTANT: Be sure to revise any documents that mention the Subject Contact Person's name, including consent forms and any Confidentiality Agreement. The revision should be submitted as part of this Modification. Any other aspects of the study (e.g. recruiting, study procedures) that will be affected by this change should also be submitted with this Modification.

Add, change, or remove another subject contact person | Cancel

13.5. Faculty Advisor	ADD	CHANGE ○	REMOVE

a. Name of the Faculty Advisor being replaced:

b. Provide the following information for the new Faculty Advisor:

Name:	Title:	Position (e.g. Asst. Prof. or Director):

Home Institution:	Other:
University of Washington	

UW Department:	UW Division (School of Medicine):

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

- ○ Faculty
  - ○ Standard Faculty Appointment
  - ○ Research Faculty Appointment
  - ○ Clinical Faculty Appointment
  - ○ Affiliate Faculty Appointment
  - ○ Visiting Faculty Appointment
  - ○ Dual Appt. with PNNL
  - ○ Other - Describe:
- ○ UW Resident, Fellow, or Post-Doc at UW or Local VA
- ○ UW Administration or Staff
- ○ None

Phone	Campus Box #:	Email:	Other address if not at UW:

c. Reason why the Faculty Advisor is being changed:

By signing below, I, the new Faculty Advisor confirm that:

- I am responsible for working with the Student Lead Researcher to ensure that this research is performed in an ethical manner that complies with appropriate human subjects regulations and with the information provided in this Modification and the IRB Application.
- I have reviewed and concur with this research, including: purpose, design, methodology, procedures, subjects, and the provided description of risks and benefits.
- I will assist the student and the IRB as requested if any problems develop with the research.
- I will provide continued oversight and guidance to the student during the course of the research, as appropriate.
- If I will be unavailable (such as during a sabbatical leave or vacation), I will arrange for an alternate faculty advisor to assume responsibility during the absence, and I will (or the Student Lead researcher will) advise the IRB in advance.

Typed Name	Email	Faculty Advisor Signature	Date

IMPORTANT: Be sure to revise any documents that mention the Faculty Advisor's name, including consent forms and any Confidentiality Agreement. The revision should be submitted as part of this Modification. Any other aspects of the study (e.g. recruiting, study procedures) that will be affected by this change should also be submitted with this Modification.

END PART THIRTEEN

BACK TO TOP

14. Individuals Performing Study Procedures

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 preformed 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 Heath, 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 Agreements 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.

Individual #: 1	ADD	CHANGE	REMOVE
Added study procedures that involve risk to subjects (choose procedure(s))	○	○	○

☐ Person performing the 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:

☐ Person performing the 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:

☐ Person performing the surgical or physically invasive procedure

Who will perform this procedure?

☐ Licensed Pracitioner

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:

Person performing Other Procedures Involving Risk to subjects (name the procedure(s)):

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

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:

☐ Person who performed the phlebotomy (blood draw)

Who performed this procedure?

☐ Licensed Practitioner

☐ Study Nurse

☐ Other:

☐ Person who performed the MRI scan

Who performed this procedure?

☐ Licensed Practitioner

☐ Study Nurse

☐ Other

☐ Person who performed the surgical or physically invasive procedure

Who performed this procedure?

☐ Licensed Pracitioner

☐ Study Nurse

☐ Other:

☐ Person who performed Other Procedures Involving Risk to subjects (name the procedure(s)):

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

Who performed this procedure?

☐ Licensed Practitioner

☐ Study Nurse

☐ Other:

Add, change or remove another procedure | Cancel

15. Non-UW Individuals, Organizations and Locations (Add or Remove)

Complete part 15 when adding or removing a non-UW individual, organization or location (site). 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, institution or organization is associated with **Pacific Northwest National Laboratories, Puget Sound Blood Center, King County-Seattle Public Health, or Northwest Kidney Center**: the UW IRB 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, institution or organization 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 Agreements 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.

	ADD	REMOVE
15.1. Non-UW Individual, Organization or Location	○	○

a. Name of the non-UW Individual, Organization or Location being added:

a. Name of the non-UW Individual, Organization or Location being removed:

b. Address of the non-UW Individual, Organization or Location being added:

b. Address of the non-UW Individual, Organization or Location being removed:

c. Describe the activities that will be performed by/at the non-UW Individual, Organization, or Location (if the specified activity will not be performed please enter N/A):

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:	

Add or remove another organization or location | Cancel

END PART FIFTEEN BACK TO TOP

16. Investigator Brochure, Protocol Amendments, and/or Package Inserts

16.1. Provide a summary of changes that are being made in the Protocol Amendment, Investigator Brochure and/or package insert.

NOTE: If you are adding a new drug or device to this study, you must submit a completed SUPPLEMENT: Drugs, Biologics, Botanicals, or SUPPLEMENT: Devices.

16.2. Submit one copy of the revised Protocol Amendment, Investigator Brochure, Package Insert or product information, with revisions marked in tracked changes. (If you are not able to indicate the "tracked changes" to the Investigator Brochure, Package Insert revision, or product information revision, please highlight them.)

16.3. Are there any changes in risks or benefits to subjects? Explain why or why not:

16.4. Do the consent forms or the consenting process need to be modified?

- ○ **YES** — Complete Part 7 in the Modification form and include 3 clean copies of the consent form(s) and 3 copies of the consent form(s) with the revisions in "tracked changes". (2 copies for Minimal Risk.)
- ○ **NO**

END PART SIXTEEN BACK TO TOP

17. Funding

17.1. Select from the following options. (A and/or B)

- ☐ **A** Delete Funding
- ☐ **B** Add Awarded Funding

PART SEVENTEEN INCLUDES TWO SECTIONS BACK TO TOP

Part 17 Section1: Deleting Funding or Support

17.1.1. Describe the funding you are deleting from the research study:

EXAMPLE: Title of the grant/contract/award, PI of the grant/contract/award, and funding agency.)

17.1.2. Provide an explanation of why this funding source is being deleted:

EXAMPLE: Grant expired, grant application was not funded.

END PART SEVENTEEN SECTION ONE

Part 17: Section 2: Adding Funding or Support

17.2.1. Do the consent forms or the consenting process need to be modified? (It is UW policy that external funding must be listed on the consent form.)

- ○ **YES** — Complete Part 7 in the Modification Form and include 3 clean copies of the consent form(s) and 3 copies of the consent form(s) with the revisions in tracked changes (2 copies for Minimal Risk.)
- ○ **NO** — Explain why not:

17.2.2. Does anyone on the research team now have a financial conflict of interest with respect to this research (as defined by UW Policy GIM 10) because of this new funding?

- ○ **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 modification cannot occur until the disclosure has been made and reviewed by the University, and the outcome has been incorporated into the IRB's review.

- ○ **YES**
- ○ **NO**

○ **NO**

17.2.3. Submit 1 copy of the grant application, contract, or other type of funding proposal with the pages pertaining to the research study flagged.

- Include the title page of the grant proposal, if applicable

NOTE: If your funding is not a grant application/proposal, then you must provide some other kind of documentation of funding (award letter, contract agreement, etc.).

- If there are multiple aims associated with this new funding (e.g. a new grant, contract, subcontract, etc.), please specify which aim(s) are relevant to this specific IRB application below:

17.2.4. If adding funding or support will also change any of your research procedures, please also complete Part 4: Procedures

Complete the information in the "Funding or Support" box below for each new or revised (updated) funding source.

END PART SEVENTEEN SECTION TWO - Also complete the "funding or support" table(s)

Funding or Support	Table #1

Type of Support:

☐ Grant ☐ Center Grant ☐ Training Grant ☐ University Funds

☐ Gift ☐ Fellowship ☐ Department Funds ☐ Contract

☐ Other, describe:

☐ Subcontract — Provide the following information about the prime/parent grant, contract, or award in the fields directly below:

Name of PI:	
Title of grant, contract or award:	
Agency/sponsor granting award:	
Title of Grant, Contract or Award:	
PI on Grant, Contract or Award:	
Funding Agency or Sponsor:	

If you are adding funding from the federal Department of Justice (DOJ) or any component (such as the National Institute of Justice): complete and attach the SUPPLEMENT: Department of Justice.

If you are adding funding from the federal Department of Defense (DOD) complete and attach the SUPPLEMENT: Department of Defense Involvement.

Award Number:					
Funding dates:	☐ N/A	Start:		End:	

What institution or agency processed the funding proposal?

☐	UW Office of Sponsored Programs (OSP)	☐	UW Royalty Research Fund	☐	Seattle Institute for Biomedical and Clinical Research	☐	VA Boise
☐	Fred Hutchinson Cancer Research Center	☐	UW Development Office	☐	Puget Sound Blood Center	☐	VA Seattle/American Lake
☐	Public Health Seattle/ King County	☐	Other, describe:				

18. Other Compliance Approvals/Considerations

18.1. Check the boxes below to indicate the type of compliance approval or report that you are submitting:

- ☐ Data and safety monitoring report(s)
- ☐ Data Use Agreement(s)
- ☐ Embryonic Stem Cell Research Oversight Committee (ESCRO)
- ☐ Federal Certificate of Confidentiality or Privacy Certificate
- ☐ Institutional Biosafety Committee (IBC)
- ☐ Implant and Investigational Device Committee (IIDC)
- ☐ Material Transfer Agreement(s)
- ☐ Radiation Safety Applications or Radiation Safety Approval Letters (RS)
- ☐ Other IRB approval letters/notifications
- ☐ Other, describe:

18.2. Are there any changes in risks or benefits to subjects associated with these compliance considerations? If not, state "None":

18.3. Do the consent forms or the consenting process need to be modified?

- ○ **YES** Complete Part 7 in the Modification Form and include 3 clean copies of the consent form(s) and 3 copies of consent form(s) with the revisions in tracked changes. (2 copies for Minimal Risk.)
- ○ **NO** Explain why not:

18.4. Other sections of the modification form may need to be completed and submitted if the compliance approvals or reports affect other aspects of your research.

END PART EIGHTEEN BACK TO TOP

19. Attachments

- Check to make sure that all of the required attachments are included with this submission.
- Collate all of your attachments.
- Use clips, not staples, with at least one packet, so that HSD staff may easily distribute your materials to additional IRB reviewers as needed.
- If you are attaching **consent forms and materials and/or recruitment materials, provide a total of 3 clean copies of each document and a total of 3 copies of each document with the revisions in "tracked changes". (2 copies for minimal risk)**
- Unless otherwise instructed below, include 3 copies of each document. (2 copies for minimal risk)
- When possible, please order your documents as listed below.
- You should have a total of 3 complete submission "packets" with attachments included. (2 copies for minimal risk)

Explanation of Attachments (if necessary):

- [ ] Assent form(s)
- [ ] Confidentiality Agreement ***(1 original ink-signed copy ONLY)***
- [ ] Consent form(s)
- [ ] Consent materials translated into a language other than English
- [ ] Consent Materials: addendum consent, information sheets, oral consent scripts
- [ ] Data collection instruments/forms
- [ ] Data safety and monitoring charter and/or report(s)
- [ ] Data Safety Monitoring Plan
- [ ] Data Use Agreement(s)
- [ ] Department of Anesthesiology Approval
- [ ] Embryonic Stem Cell Research Oversight Committee (ESCRO) approvals/letters/report
- [ ] Engagement Worksheet
- [ ] Environmental Health and Safety (EHS) approvals/letters/report
- [ ] Federal Certificate of Confidentiality or Privacy Certificate
- [ ] Grant application and title page of grant application ***(1 copy ONLY)***
- [ ] HIPAA Authorization Form
- [ ] Implant and Investigational Device Committee (IIDC) approvals/letters/report
- [ ] Individual Investigator Agreements
- [ ] Institutional Biosafety Committee (IBC) approvals/letters/report
- [ ] Investigator brochure ***(1 copy ONLY)***
- [ ] IRB Authorization Agreements
- [ ] Literature or abstracts supporting the purpose of your research
- [ ] Material Transfer Agreement(s) (MTA)
- [ ] Oral scripts
- [ ] Other funding documentation, only if you have funding that is not a grant application/proposal
- [ ] Non-UW IRB approval letters/notifications
- [ ] Non-UW IRB approved applications
- [ ] Protocol ***(1 copy ONLY)***
- [ ] Radiation Safety Applications or Radiation Safety Approval Letters (RS)
- [ ] Radioactive Drug Research Committee (RDRC) approvals/letters/report
- [ ] Recruitment - electronic materials: scripts for emails, and/or copies of web pages
- [ ] Recruitment - oral materials: scripts, radio ads
- [ ] Recruitment - written materials: flyers, brochures, newspaper ads, and/or letters
- [ ] Study instruments: surveys, questionnaires, assessment tools, tracking forms, web surveys
- [ ] SUPPLEMENT: Department of Defense Involvement
- [ ] SUPPLEMENT: Department of Justice
- [ ] SUPPLEMENT: Devices
- [ ] SUPPLEMENT: Drugs, Biologics, Botanicals
- [ ] SUPPLEMENT: Genetic Research
- [ ] SUPPLEMENT: GWAS dbGaP
- [ ] SUPPLEMENT: Protected/Vulnerable Populations
- [ ] SUPPLEMENT: Waiver Request, Consent Requirements
- [ ] SUPPLEMENT: Waiver Request, HIPAA Authorization
- [ ] Other, specify:

END ATTACHMENTS BACK TO TOP

Print Form