**APPLICATION: Human Subjects Review, Full Board or Subcommittee**

**DO NOT SUBMIT THIS PAGE TO HSD**

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**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](http://www.cancerconsortium.org/en.html) or contact Cancer Consortium Clinical Research Support at 206-667-4520, or [CRScustomer.service@fhcrc.org](mailto:CRScustomer.service@fhcrc.org). For a list of Cancer Consortium members, see [http://is-ext.fhcrc.org/sites/consortium/ccdb/members.php](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 [https://www.dshs.wa.gov/SESA/research-and-data-analysis/human-research-review-section](https://www.dshs.wa.gov/SESA/research-and-data-analysis/human-research-review-section) or contact their office at: 360-902-8075, or [wsirb@dshs.wa.gov](mailto: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/](http://www.washington.edu/research/hsd/) or call (206) 543-0098.
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: Patricia Kritek
Title: M.D., Ed. M.
Position: Associate Professor
Home Institution (or source of paycheck): University of Washington
Home UW Department (if applicable): Department of Medicine
Division: Pulmonary and Critical Care
UW Position or appointment (choose the most appropriate one):
[ ] Regular Faculty Appointment
[ ] Research Faculty Appointment
[ ] Clinical Faculty Appointment
[ ] Visiting Faculty Appointment
[ ] Dual Appointment with PNNL
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 #: 356522
Other Address if not at UW
Telephone: (206) 543-8660
Fax: 
E-mail: pkritek@uw.edu

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: Angela M. Wilson
Title: Research Coordinator
Home Institution (or source of paycheck): University of Washington
Home UW Department (if applicable): Surgery
Division: General Surgery
UW Position or appointment (choose the most appropriate one):
[ ] Regular Faculty Appointment
[ ] Research Faculty Appointment
[ ] Clinical Faculty Appointment
[ ] Visiting Faculty Appointment
[ ] Dual Appointment with PNNL
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 #: 356522
Other Address if not at UW
Telephone: ?
Fax: 
E-mail: angela30@uw.edu

III. TITLE OF PROJECT: Standardized Verbal Handoff in the ICU: Decreasing Patient Care Errors through Communication Optimization

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: Patricia Kritek, MD, Ed. M.
   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.
   Robb Glenny
   TYPED NAME PLUS SIGNATURE
   DATE
<table>
<thead>
<tr>
<th>IRB COMMITTEE SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
</table>

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.

*VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED*
V. TYPE OF NEW SUBMISSION

[X] 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.)

[X] 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)

[X] METHODS:

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

[ ] Social-Behavioral Procedures/Considerations

[ ] Observational

[ ] Behavioral Interventions

[ ] Interview/Focus Groups

[ ] Medical Procedures/Considerations

[ ] Bio-hazardous Substances

[ ] Controlled Substances

[ ] Emergency Treatment

[ ] Gene Transfer Study

[ ] Stem Cell Research

[ ] Magnetic Resonance imaging (MRI)

[ ] 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

Confirm by checking this box that you are listing on Section VIII all direct and indirect funding that supports this research. Indirect funding is generic (i.e., not tied to this specific study) federal salary support for the time that any key personnel spend on the research. Examples: many training grants, fellowships, scholarships, and career development awards.
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  [x] IRB Contact Person

   If one of these boxes is checked, you do not need to complete the rest of this table.

   Name __________________________ Title __________________________ Position Research __________________________

   Home Institution (or source of paycheck) __________________________ Title __________________________ Position Research __________________________

   UW Student? Home institution is UW. __________________________ Title __________________________ Position Research __________________________

   UW Student? Home institution is UW. __________________________ Title __________________________ Position Research __________________________

   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 # 356410 __________________________ Other Address if not at UW __________________________

   Telephone __________________________ Fax __________________________ e-mail __________________________

   Study Coordinator

   Check here if the same as: [ ] Lead Researcher  [x] 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) __________________________ Title __________________________ Position Research __________________________

   UW Student? Home institution is UW. __________________________ Title __________________________ Position Research __________________________

   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.

   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).
**Study Procedures that involve risk to subjects**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Who will perform this procedure?</th>
<th>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:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlebotomy (blood draw)</td>
<td></td>
<td>[ ] Study Nurse \n</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[ ] Other: \n</td>
</tr>
<tr>
<td>[ ] MRI Scan</td>
<td></td>
<td>[ ] Study Nurse \n</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[ ] Other: \n</td>
</tr>
<tr>
<td>[ ] Surgical or Physically Invasive Procedure</td>
<td></td>
<td>[ ] Study Nurse \n</td>
</tr>
</tbody>
</table>

Please see [SOP Authorization Agreements](#) for information on how to obtain an Agreement for your research.

- 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.
APPLICATION: Human Subjects Review (13-11), Full Board or Subcommittee (Rev. 04/24/2015)

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.*

<table>
<thead>
<tr>
<th>Name of the non-UW Individual, Organization or Location:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address of the non-UW Individual, Organization or Location:</td>
</tr>
</tbody>
</table>

Describe the activities that will be performed by/at the non-UW Individual, Organization or Location (if the specified activities 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:

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 PROVIDE GENERAL SALARY SUPPORT TIME SPENT ON THE RESEARCH (E.G. A TRAINING GRANT OR CAREER DEVELOPMENT AWARD). 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  
X Other, specify: Quality Improvement Research

B. Name of principal investigator:  Patricia Kritek, M.D., Ed.M.

C. Name of funding agency:  Patient Safety Innovations Program (PSIP), University of Washington

D. Agency's number (if assigned):  

E. Title of proposal:  Standardized Verbal Handoff in the ICU: Decreasing patient care errors through communication optimization

F. Inclusive dates:  
- from May 2015  
- through October 2016

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

H. Submitted through UW Office of Sponsored  
- Yes  
- X No, this is an internal UW funded research  

APPLICATION: Human Subjects Review (13-11), Full Board or Subcommittee (Rev. 04/24/2015)
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)

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.

Background: Miscommunication is the leading cause for medical errors in the United States, and may account for up to 98,000 patient deaths annually. Miscommunication is common in the hospital, particularly between care providers who are handing over responsibility for patient care after a shift (during ‘hand-off’). ‘IPASS’ is a check-list tool for physician communication about patient information during hand-off. It is a way to standardize communication during the end of a work-shift and ensure that key information is conveyed. The name IPASS is a mnemonic, and each letter stands for a required element of sign-out between providers (standing for: “Illness severity”, “Patient summary”, “Action list”, “Situational awareness and contingency planning”, and “Synthesis by the receiver and feedback”). This tool was developed by a group of researchers in Boston in a pediatric hospital, and they showed a reduction in medical errors by 30% after implementation of the tool. This project is primarily a quality improvement project that will involve all providers in the intensive care units. This component of the project is simply implementation a teaching curriculum without any data collection for any research. Our intent is to teach this ‘IPASS’ tool to providers in our adult ICUs at Harborview Medical Center and the University of Washington. The IPASS curriculum includes provider education regarding the importance of quality handoffs, and education regarding the specific handoff mnemonic. The curriculum is executed in three primary ways. First, providers will be asked to complete a 5-10 minute
online module. Second, providers will receive a 5-10 minute didactic refresher. Third, providers will undergo observation by an IPASS “advocate” and receive a report card of their performance.

The secondary aspect of this project is a research study. We will solicit voluntary consent for enrollment and data collection from all providers. “Intervention subjects” are care providers that receive the IPASS tool and “control subjects” are providers who do not have the tool. We will then measure provider satisfaction and user experience with the IPASS curriculum, using a series of surveys. Finally, we will collect composite de-identified data related to patient complications before and after the IPASS tool is implemented.

Purpose statements:
a. The purpose of the quality improvement component of this project is to enhance physician communication, and improve patient safety and outcomes. 
b. The purpose of the research component of the project is several-fold, and aims to answer the following questions:

First, the research is designed to assess providers’ perceptions of the quality and completeness of handoff in the intensive care units at Harborview and University of Washington Medical Centers. Second, this research will investigate whether implementation of a standardized verbal handoff curriculum (IPASS) will result in improved provider perception of the quality and completeness of handoff. Third, this research will investigate whether implementation of a standardized verbal handoff curriculum will result in improved patient outcomes as measured by de-identified aggregate patient data from the Center for Clinical Excellence indicators.

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.

A. Quality improvement intervention: implementation of the IPASS curriculum

The IPASS curriculum will be introduced to care providers in the ICUs at Harborview and UW. Providers include resident physicians, attending physicians, fellows, and advanced-practice providers. The three components of the curriculum are as follows:

1. Two weeks before the care provider begins to work in the designated ICU, an email will be sent to them with a link to an online teaching module. This module will take 5-10 min to complete and will educate providers on the mnemonic IPASS and how to use it in their handoffs.
2. Within the first 5 days of starting to work in the ICU, the provider will receive an in-person refresher course that lasts 5 minutes. During this, they will be reminded of the mnemonic and given a pocket card for reference. The refresher course will be taught by a team leader from the IPASS project.
3. At least once during the month, the provider will be observed during handoff, and verbal and written feedback will be given by a leader from the IPASS project.

These three components of the curriculum will be implemented across all ICUs at Harborview and UW, but this will be accomplished gradually and in two phases. 4 ICUs will be randomly assigned to receive the curriculum in Sept 2015, and the remaining 5 ICUs will receive the curriculum 3-4 months later. This will facilitate a before-after comparison for the research component of this study.

B. Research: recruitment, enrollment and consent

Consent forms for intervention subjects and control subjects will be emailed to using conglomerate list-servs (group emails for each residency). The email will contain an untraceable link (catalyst survey). The survey will ask the viewer to review the consent form (attached) and indicate their choice for voluntary participation with an electronic signature (click button ‘yes’ or ‘no’). The survey will also ask for a cell phone number and individual email for data collection from the research subject. Cell phone numbers and emails will not be shared outside of the secure platform (data security details under “Research: Data Collection” section below).

The subject population is comprised of faculty, fellows, resident physicians, nurses, advanced practice providers, and nurses at University of Washington Medical Center or Harborview Medical Center providing care in the intensive care unit (ICU) between Sept 20, 2015 and Sept 20, 2018.

C. Research: Data collection

1. Surveys:

Brief 1-4 question surveys will be administered to subjects via email and via cell phone text messaging. These specific surveys are attached to this application.

Qualtrics is the company which will be managing our text messaging to ask survey questions. These questions do not request any personally identifiable or sensitive information. Although Qualtrics uses cell phone numbers to collect data, the company has assured us that cell numbers and all data collected are strictly confidential and will not be shared with a third party. All data is firewall protected and is compliant with UW data security standards. (see attached security document).
Moreover, Qualtrics has worked with the UW family medicine department to administer surveys previously, and have maintained data security throughout this project. All data from our study will be destroyed by Qualtrics by 7/1/2019. All data from the surveys sent via this platform will be stored in a password-protected database, on a secure server, behind locked doors in a research office at Harborview Medical Center. The research subjects will incur no cost for any of the text-message surveys sent by Qualtrics, nor will these be counted by cellphone plans. Qualtrics was paid in a lump sum for all of these text messages by study funding.

Please see the company's attached security document for more details.

2. Aggregate patient data:

De-identified aggregate patient data from the Center for Clinical Excellence will be collected. Variables include Intensive Care Unit (ICU) length of stay, days of ventilator support, quantity blood products received, readmission to the ICU within 48 hours of discharge (“bounce-back”), incidence of ventilator-associated pneumonia, catheter associated urinary tract infection, central line associated blood stream infection and mortality. For full details of data collection forms, please see attached documents.

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

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.

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.

**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.

**No deception or withholding of complete information is required for this activity.**

**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](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.

<table>
<thead>
<tr>
<th>Group name/description</th>
<th>Age range of subjects</th>
<th>Maximum desired number of individuals (or other group unit, such as families) who will complete the research.*</th>
<th>Cannot provide a number.**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care providers – Resident or Fellow Physicians</td>
<td>Adults</td>
<td>700</td>
<td>**</td>
</tr>
<tr>
<td>Care providers – Faculty</td>
<td>Adults</td>
<td>100</td>
<td>**</td>
</tr>
<tr>
<td>Care providers – Registered Nurses</td>
<td>Adults</td>
<td>500</td>
<td>**</td>
</tr>
<tr>
<td>Care providers – Advanced Practice Providers</td>
<td>Adults</td>
<td>100</td>
<td>**</td>
</tr>
</tbody>
</table>

*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.
<table>
<thead>
<tr>
<th>Group Name / Description</th>
<th>Total approved by IRB</th>
<th># Compleitions</th>
<th># Withdrawals, drops, lost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A At time of last Status Report</td>
<td>B Since last Status Report</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

2. Explain how you will achieve equitable subject representation in the following categories. If not applicable, justify exclusions.

   a. Age (minors, elderly): Adults only (greater than or equal to 19 years of age)

   b. Gender: male and female

   c. Ethnic and racial minority populations: diverse races and ethnicities

The subject sample will be comprehensive and representative of the diversity (age, gender, race, ethnicity) that exists amongst all faculty, fellows, resident physicians, advanced practice providers, and registered nurses in the study units under investigation.

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

   Faculty, fellows, resident physicians, Advanced Practice Providers, and registered nurses providing care in an intensive care unit (ICU) at Harborview or University of Washington Medical Centers between Sept 20, 2015 and Sept 20, 2018.

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

   Those that are not faculty, fellows, resident physicians, Advanced Practice Provideres, or registered nurses in the ICU.5. Describe the subject recruitment strategies you will use for each group of subjects. (When applicable, 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.)

Faculty, fellows, resident physicians, advanced practice providers and registered nurses will be contacted via e-mail prior to initiation of the study to inform them of the research project. Faculty, fellow, Advanced Practice Providers, and resident physicians rotating through a study ICU will be identified via academic administrative resources such as MedHub and individual service director’s records. Registered Nurses providing care in study units will be identified through accessing employment records of the University. All providers’ involvement in the research will be voluntary and anonymous.

In order to participate in the study, providers will need to respond positively to an e-mail, providing their contact information. Providers can opt out by not responding to the e-mail, or responding negatively. Study participation will consist primarily of providing subjective feedback via e-mail and text message survey. Participation is therefore a private rather than public endeavor, and the identity of study participants will not be disclosed outside of the research team. Faculty, fellows, and others in a position of authority or supervision will not know the identity of providers who opt in or out. Thus, risk of coercion is minimal, and the risk to the provider of not participating is zero.

6. Explain who will approach subjects to take part in the study and how this will be done to protect subjects’ privacy.

Subjects will initially be contacted by e-mail asking for voluntary participation. If the subject wishes to participate he/she will fill out an electronic survey and consent form. Providers who choose to participate will be contacted at the end of their shifts, sometimes daily, by text message to their cell phone via secure electronic data collection platform. Data collected from this survey is anonymous and will not be associated with the resident’s name, phone number, or e-mail. The names, phone numbers, and e-mails of subjects participating in the study will be destroyed at the conclusion of the study.

7. Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.
All participating providers will be informed regarding the design and purpose of the research. They will be informed that their involvement in the study, and thus their responses to the questionnaires are optional and anonymous.

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

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

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.

<table>
<thead>
<tr>
<th>Name of organization, agency, group, site, or institution</th>
<th>Location Address</th>
<th>Procedure</th>
<th>Will subject contact or interaction occur at this location?</th>
<th>Will subject consent occur at this location?</th>
<th>Will there be access to identifiable private information about subjects at this location?</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Washington Medical Center</td>
<td>1959 NE Pacific St, Seattle, WA 98195</td>
<td>Data collection</td>
<td>Subject contact will occur electronically and could be accessed at this location.</td>
<td>Subject consent will occur electronically and could be accessed at this location.</td>
<td>No.</td>
</tr>
<tr>
<td>Harborview Medical Center</td>
<td>325 9th Ave, Seattle, WA 98104</td>
<td>Data collection</td>
<td>Subject contact will occur electronically and could be accessed at this location.</td>
<td>Subject consent will occur electronically and could be accessed at this location.</td>
<td>No.</td>
</tr>
</tbody>
</table>

**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.

   The research will include optional, anonymous written surveys of providers. There is a theoretical minimal risk of harm to reputation if a participant commented on inadequate sign-out skills on the self-assessment portion of the written questionnaire. However, this risk is eliminated by the anonymous nature of the questionnaire.

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 risk of harm is eliminated by making sure the written surveys are anonymous.

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? X 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.”

   Subjects will learn a standardized verbal handoff curriculum developed by Boston Children’s Hospital that has been shown to decrease medical error due to communication error between medical providers.

5. Describe the anticipated benefits of this research for society.
An estimated 44,000 – 98,000 inpatients die each year as a result of preventable medical errors. The Joint Commission sentinel event statistics estimate that communication errors contribute to two thirds of these events, and that one half of communication errors are a direct result of handoff failures. Implementing a standardized verbal handoff curriculum could significantly reduce such errors, improving patient outcomes and healthcare efficiency.
F. ADVERSE EVENTS OR EFFECTS

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

2. Are your facilities and equipment adequate to handle possible adverse events? X Yes □ No, 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 X Yes If yes, explain why this is necessary and describe the coding system you will use to protect against disclosure.

Subject phone numbers will be recorded in order to text message subjects the link to a daily survey. These phone numbers will not be associated with a name. They will be stored in a locked electronic file accessible only by the research staff. This file will be destroyed at the completion of the data collection.

2. Will you retain a link between study code numbers and direct identifiers after the data collection is complete? X 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.).

Data will be stored in a locked electronic file, only accessible on two computers. Access to these computers is encrypted and only designated members of the research team will have access to these computers.

4. Will you place a copy of the consent form or other study information in the subject’s medical or other personal record? X 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? X 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.) X NA

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

X 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.

   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”?

APPLICATION: Human Subjects Review (13-11), Full Board or Subcommittee (Rev. 04/24/2015)
“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  X Yes. If “yes”:

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

The research team will access employee records from both University of Washington Medical Center and Harborview Medical Center. These records are necessary to identify faculty, fellows, resident physicians, Advanced Practice Providers, and registered nurses, in the various units where data collection will occur.

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

☐ No  X Yes. It is necessary to know names of residents rotating through the units before the residents are consented.

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?

xNo  ☐ 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.

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  X 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

X Neither set of regulations apply to my research

7. Will you make audio-visual or tape recordings or photographs of subjects? X 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.

8. Will your study involve use of equipment involving energy input to the subjects (EMG, EKG, MRI, ultrasound, etc.)?

X 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.

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.

X 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? X 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

APPLICATION: Human Subjects Review (13-11), Full Board or Subcommittee (Rev. 04/24/2015)
reviewed by the University, and the outcome has been incorporated into the IRB’s review.  □ No  □ Yes  X Not applicable, because there is no financial conflict of interest.

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” **

   X 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.

Providers will receive an e-mail with a description of the research along with a statement clarifying that participation is voluntary. Interested providers will follow a link where they will be informed of all methods, procedures, and possible risks of the research. Those who wish to consent and participate will be asked to provide their name and phone number.
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

   **Not Applicable**

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.*

   To ensure that subject participation is truly voluntary, the research team will offer no reward or recognition for participation. Persons in positions of authority, whether on the research team or not, will not be involved in recruiting participants.

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.

   The initial e-mail containing a description of the research will state that participation is voluntary. Future communication with subjects will re-confirm that participation is voluntary and will not be compensated.

6. Do you expect that all of your participants will be fluent in spoken and/or written English? ☐ No  X 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?
7. 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.

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