IRB APPROVAL OF APPLICATION

January 4, 2019

Dear Dr. Bridges:

On 1/4/2019, University of Washington IRB Committee D reviewed the following application:

Type of Review:	Initial Study
Title of Study:	Prevention of Pressure Injuries During Aeromedical Evacuation or Prolonged Field Care
Investigator:	Elizabeth Bridges
IRB ID:	STUDY00006022
Funding:	Name: Triservice Nursing Research Program, Grant Office ID: A132067, Funding Source ID: 6057994690000
IND, IDE, or HDE:	None

The modification required to secure approval was reviewed and the application fully approved on 1/4/2019.

IRB Approval
Under FWA #00006878, the IRB approved your activity **from 1/4/2019 to 1/3/2020**.

- Your application qualified for expedited review (minimal risk; Category 9).
- This approval applies only to the activities described in your application (including any references to specific grant sections). It does not include other activities that may be described in your grant or contract.
- **Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data or specimens (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to approach possible subjects or conduct research procedures in the facilities (e.g., Seattle School District; the Harborview Emergency Department).**

Determinations, waivers, and regulations
The IRB made the determinations and waivers listed in the table below. Note that any granted waivers of consent do not override a subject's refusal to provide broad consent.

Requirement	Determination or Waiver
Documentation of consent	Waived – for phone screening

Location of documents
Use the consent form approved and stamped by the IRB. It can be downloaded from the Final column under the **Documents tab** in Zipline.

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,
Ariana

Ariana Chantée, CIP
Human Subjects Review Administrator
achantee@uw.edu | 206-616-9690

zipline

Date: Friday, December 3, 2021 11:56:10 AM

Print Close

STUDY00006022

View: SF: Basic Study Information

Basic Study Information

1. * Title of study:

Prevention of Pressure Injuries During Aeromedical Evacuation or Prolonged Field Care

2. * Short title:

This will be used to identify your study in Zipline

Pressure Injury Prevention in AE & PFC

3. * Brief description:

Randomized controlled trial to evaluate the effects of two interventions (Mepilex dressing) and LiquiCell Pad on risk factors for skin pressure injury under conditions similar to military long distance aeromedical transport or prolonged field care.

4. * What kind of study is this?

Single-site study

5. * Are you requesting authorization for an external IRB to review the study instead of the UW IRB?

○ Yes ● **No**

6. * Local principal investigator:

Can't find your PI? Make sure they have self-registered.

Elizabeth Bridges

7. * Does the local principal investigator have a Financial Conflict of Interest (FCOI) related to this research?

○ Yes ● **No**

8. * Attach the IRB Protocol:

	Document	Category	Date Modified	Document History
View	IRB Protocol(4)	IRB Protocol	1/4/2019	History

Use one of these templates:

- APPLICATION IRB Protocol
- APPLICATION IRB Protocol, No Contact with Subjects
- APPLICATION Status Report, Conversion Study

- *** Is this a conversion study?**
  ○ Yes ● **No**

- *** Is the Principal Investigator for this study a student, resident, fellow, or post-doc?**
  ○ Yes ● **No**

Important: The Faculty Advisor must be added as an Ancillary Reviewer prior to submitting your study.

STUDY00006022

View: SF: Study Funding Sources (not integrated with Grants)

Study Funding Sources

1. Identify each organization supplying funding for the study:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
Triservice Nursing Research Program	6057994690000	A132067	Grant Award Stipulation Response Grant Application

STUDY00006022 View: SF: Local Study Team Members

Local Study Team Members

1. Identify each additional UW person who needs to be able to edit the study or serve as a PI Proxy. Students: do not list your faculty advisor here.

Name	E-mail	Phone
There are no items to display		

2. External team member information:

Name	Description
Study Roles Addendum (Bridges) (0.01)	

STUDY00006022 View: SF: Study Scope

Study Scope

1. * **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
   ○ Yes ● **No**

2. * **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**
   ● **Yes** ○ No

3. * **Is this study intended to develop information about a drug, device or biologic through its prospective use and assignment to subjects, which will then be submitted by you or someone else to or held for inspection by the Food and Drug Administration (FDA)?**
   ○ Yes ● **No**

4. * **Are any federal institutions (not already listed as a funding source) involved in your research because their employees are performing one or more of the following activities?**
   ○ Yes ● **No**

   - Obtaining informed consent for subjects in your study
   - Conducting research procedures that involve interacting or intervening with the subjects or manipulating the subjects' environment
   - Obtaining private identifiable data about or identifiable specimens from the subjects in the research

5. * **Will your research require access to, or obtaining of any identifiable health care information from, any records maintained in the State of**

Washington, without first obtaining the consent of the subjects?

○ Yes ● **No**

6. * **Will your project involve any type of interaction (in-person or virtually) with individuals known or likely to be under the age of 18 years old?**

○ Yes ○ No

7. * **This question is only about UW Medicine facilities. Will the study require any services, items or tests that are:**
- Performed in a clinical facility that bills through UW Patient Financial Services (PFS), Northwest Hospital PFS, or UW Clinical Research Budget and Billing office (CRBB); and/or
- Furnished by a provider who bills through UW Physicians (UWP)?

○ Yes ● **No**

8. * **Does this research involve giving the subject any of the following? Check all that apply:**

None of the above

9. * **Does this research involve exposing subjects to radiation through any of the following? Check all that apply:**

None of the above

10. * **When do you estimate you will start enrolling subjects in your research? Select one.**

Within 3 months after receiving IRB approval

11. * **Does this project have any participant groups focused on employees/staff at any of the following organizations? Examples: residents; laboratory staff; nurses; physicians; custodians. Check all that apply:**

There are no items to display

12. * **This question is only about UW School of Medicine employed faculty. As part of this research, will the faculty member be practicing their licensed healthcare profession at a non-UW Medicine approved site of practice?**

STUDY00006022 View: SF: Local Research Locations

Local Research Locations

1. **Identify whether any of the following locations will be (1) where study procedures with participants will occur, or (2) places from which participants will be deliberately recruited.**

Location	Contact	Phone	Email
There are no items to display			

STUDY00006022 View: SF: Devices

Devices

1. * **Select each device the study will use as an HUD or evaluate for safety or effectiveness:**

Device	Humanitarian Use Device	Attachment Name
TcPO2 Monitor	no	TcPO2

2. * **Device exemptions applicable to this study:** Exempt from IDE requirements OR data will not be submitted to FDA

3. **Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device)

Document	Category	Date Modified	Document History
There are no items to display			

STUDY00006022 View: SF: Local Site Documents

Local Site Documents

1. Consent forms: (include all site-specific consent, assent, and parent permission materials, if applicable)

These should always be the forms that will be used by the site investigators. They may be based on one of the UW consent templates available on the HSD website, a template from another institution (such as a lead site), or no template (as long as the required elements are included).

	Document	Category	Date Modified	Document History
View	Consent Form (3)	Consent Form	12/27/2018	History

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

	Document	Category	Date Modified	Document History
View	Screening Form(2)	Recruitment Materials	12/27/2018	History
View	Recruitment Flyier(2)	Recruitment Materials	12/27/2018	History

3. Other attachments:

	Document	Category	Date Modified	Document History
View	Response - Deferral(1)	Other	12/20/2018	History
View	Responses - PreReview(1)	Other	11/16/2018	History
View	Devices - Liquicell(1)	Supplement	11/16/2018	History
View	Devices - Mepilex(1)	Supplement	11/16/2018	History
View	DoD Supplement(1.01)	Supplement	11/16/2018	History
View	DSMP(1.01)	Supplement	11/16/2018	History

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

- Curriculum vitae (CV) or biosketch for the local principal investigator
- Other documents specific to this site that are not already provided

STUDY00006022 View: Add / Edit

1. * Funding organization:
Triservice Nursing Research Program

2. * Sponsor's funding ID: (assigned by external sponsor)
6057994690000

3. * Grants office ID: (eGC1)
A132067

4. Attach files: (include any grant applications)

	Document	Category	Date Modified	Document History
View	Grant Application(1)	Sponsor Attachment	10/25/2018	History
View	Stipulation Response(1)	Sponsor Attachment	10/25/2018	History
View	Grant Award(1)	Sponsor Attachment	10/25/2018	History

5. * Name of the local Principal Investigator listed on the grant:
Elizabeth Bridges

6. Funding Title:

7. * What is being funded?
This specific study

8. * Identify the organizational location of the office that is receiving and administering the funds for the local PI (e.g., UW):
UW: OSP **If Other:**

9. * Identify the route of funding:
Directly from sponsor

10. * Will any of this funding be subcontracted from the UW out to any other institution?

◯ Yes ◯ No

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ◯. For example **1.1** must be answered.
- **Answer all questions**. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: Prevention of Pressure Injuries During Aeromedical Evacuation or Prolonged Field Care

1.1 Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **POLICY: Use of the UW IRB.***

University of Washington School of Nursing

1.2 Consultation history. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

[X] **No**
[ ] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[ ] **No**
[x] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

UW IRB 49693 – Mitigation of Pressure Ulcer Development during Combat Evacuation. PI Elizabeth Bridges. Previous research that used study methods similar to those outlined in this proposal. Specific methods that are similar are interface pressure measurements, transcutaneous tissue oxygen and skin temperature measurements. We will use the same recruitment screening process for the consent process. We are also using the same interventions – Mepilex and LiquiCell (both FDA approved). The previous study was characterized as minimal risk.

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

[x] **No**

[ ] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

We anticipate the funds will be available after 1 October – pending receipt of IRB approval.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If your application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

The purpose of this study is to explore the effectiveness of interventions that may be useful during aeromedical evacuation (AE) or prolonged filed care (PFC).

Skin cellular injury, skin perfusion, and skin microclimate will be tested with and without Mepilex sacral dressing or LiquiCell pads on 3 transport surfaces. Note: A litter is a stretcher.

Aeromedical Evacuation (AE) conditions

- Mepilex: Litter + AE mattress + 30° backrest
- Without Mepilex: Litter + AE mattress + 30° backrest
- Mepilex: Vacuum Spine Board (VSB) placed on AE mattress
- Without Mepilex: Vacuum Spine Board (VSB) placed on AE mattress

Prolonged Field Care (PFC) conditions

- LiquiCell: Talon Litter
- Without LiquiCell: Talon Litter

Aim 1. Under conditions simulating aeromedical evacuation (stretcher + mattress or stretcher + mattress + vacuum spine board) compare the effects of with/without Mepilex (multilayered dressing) on the buttocks/lower back (sacrum) on indicators of skin injury, skin blood flow and oxygenation, skin temperature and moisture and pressure between the support surface and the skin (interface pressure).

Aim 2. Under conditions simulating prolonged field care (field stretcher without a mattress pad) evaluate the effect of with/without LiquiCell (a pad with fluid-filled pocked of liquid) placed under the back and bottom on indictors of skin injury, blood flow, oxygenation, temperature, moisture and interface pressure.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

Stratified randomized control trial with subjects assigned to either the AE or Prolonged Field Care arms with or without the intervention. Stratification will be based on body fat percentage.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
☐	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	2. Part of an institution, organization, or program's own internal operational monitoring.
☐	3. Improve the quality of service provided by a specific institution, organization, or program.
☒	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☐	6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
☐	7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.
☐	8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
☐	9. Expanded access use of a drug or device not yet approved for this purpose
☐	10. Use of a Humanitarian Use Device

☐ 11. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if your proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

This military unique proposal seeks to identify a feasible strategy to augment pressure injury prevention during AE or prolonged field care.

Between 2001 and 2014, 137,433 patients were moved on 210,863 flights in the US Air Force Aeromedical Evacuation (AE) system. On average, 19% of these patients were immobile on a litter, placing them at high risk for a skin pressure injury. A very high-risk group are casualties who require spinal immobilization using the vacuum spine board (VSB - a beanbag type stretcher). A military unique aspect of nursing care for these critically ill/injured patients is pressure injury prevention during the 8 to 16- hour transports from the battlefield to Germany and the US. A skin pressure injury is defined as localized damage to the skin and underlying soft tissue due to intense or prolonged pressure or shear on bony prominences (e.g., heels, sacrum/buttocks). Other factors that increase the risk of pressure injuries are changes in skin temperature, moisture, and perfusion (blood flow and oxygen delivery). During aeromedical evacuation, patients are transported on a 23 x 72-inch mesh litter, with or without a 30° removable backrest. If possible, a 2.5-inch mattress (AE mattress) is placed on the litter. The only care recommendations for pressure injury prevention during AE are to use the AE mattress and to reposition the patient and elevate their heels. For patients transported in the VSB, additional care instructions include log rolling the patient (rolling with flexing the body) and releasing pressure in the VSB. However, these interventions are only partially effective in preventing pressure injuries. Between 2009-2012, 141 (4.9%) of critically injured patients transported from the combat zone developed a pressure injury, and in casualties transported on the VSB, the incidence was 10%. In addition to directly affecting their treatment and recovery, a conservative cost estimate for these 141 pressure injuries is $1.1 million dollars. In civilian high-risk intensive care patients, recent studies document a decrease in pressure injuries related to the use of a multilayered dressing placed on the buttocks/sacrum dressing (Mepilex, Mölnlycke Healthcare). The use of the Mepilex dressing offers an intervention that is potentially relevant and feasible for use during AE. Existing studies have not addressed the effects of this dressing on factors associated with tissue injury or how the dressing performs under AE conditions.

A second area where combat casualties are at increased risk for pressure injuries is under the setting of prolonged field care (PFC). Prolonged field care is defined broadly as care for a combat casualty under field conditions for longer than four hours. A recent review of 54 cases found a median time before transport to a medical facility of 10 hours (range 4-120 hours). Among these 54 cases, 52 were in remote or austere locations (mountains, desert, maritime). Care was provided outdoors (37%), in a hardened non-medical structure (37%), on a ship/boat (18.5%), rotary wing aircraft (16.7%), fixed wing aircraft (16.7%), or ground vehicle (14.8%). Only 1.9% were in a tent. These patients were at high-risk for pressure injuries, with 36/54 (67%) with life-threatening injuries or illnesses. General nursing care was identified as important in the care of these patients, but no documentation was provided specific to pressure injury prevention. Although not reported in this paper, the support surface for PFC would generally be an unpadded litter or possibly the ground. An additional risk is that the litter used by the US military under PFC conditions (is the Talon II Model 90C Collapsible Handle Litter). The surface of this stretcher is ridged, which may cause areas of increased pressure. A recent review paper[3] on nursing care in PFC recommended that the best possible care would involve padding and positioning the patient with pillows, blankets or towels if available. Of note, previous research conducted by the PI found no benefit from using blankets or towels as padding and lateral rotation to offload the sacrum and buttocks was associated with increased pressure on the hip. No research has been conducted on strategies for pressure injury prevention under PFC conditions.

Rationale for proposed interventions. In our previous study, LiquiCell pads were evaluated with the subjects on a litter plus AE mattress. There was no significant difference in skin interface pressure or tissue perfusion between the groups with/without LiquiCell. However, the sacral interface pressure was relatively low under all conditions. We do not know if LiquiCell might offer some relief from pressure or friction/shear under conditions consistent with PFC (Talon litter only; no mattress). Mepilex was also studied in our previous research. Although there are studies demonstrating decrease incidence of pressure injuries in patients with sacral Mepilex, we did not find any difference in skin pressure or perfusion with/without Mepilex. These results suggest that its beneficial effects may be in the reduction of skin pressure injury related to friction and shear. Friction and shear occurs most often with backrest elevation. For our current study we will be using a 30-degree backrest and additional physiological indicators of tissue injury. No research has been on strategies to decrease sacral pressure injuries when an individual is transported on a VSB. In this case, Mepilex may provide protection without interfering with the stabilizing capabilities of the VSB.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.

In our previous study UW IRB 49693 – Mitigation of Pressure Ulcer Development during Combat Evacuation we studied subjects for 40-minutes (to simulate the median time for transport from a field hospital to a larger military hospital). Because the TcPO2 electrode is heated to 44°C, there is a minor risk for a thermal injury (skin burn). In our previous work the protocol specified that the temperature on the weighted electrode will decrease to 98.6 (37C) if skin blood flow under the electrode decreases to 0. We had no cases where skin blood flow decreased to zero and no cases where there was any alteration in skin integrity under the heated electrode. Additionally, there were no complaints related to remaining supine or issues regarding placement of the Mepilex dressing. We will use the same measures in this proposed study. The previous

research was considered minimal risk. See 1.8a for results of study that have informed our current protocol and rationale for the study.

1.9 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
[x]	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Defense
[ ]	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Energy
[ ]	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of your research	*ZIPLINE* SUPPLEMENT: Drugs
[ ]	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	*ZIPLINE* SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC)
[ ]	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and you are asking the UW to provide the required certification or to ensure that the consent forms can be certified	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing
[x]	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
[ ]	**Multi-site study** You are asking the UW IRB to review one or more sites in a multi-site study.	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
[ ]	**Participant results sharing** Individual research results will be shared with subjects.	*ZIPLINE* SUPPLEMENT: Participant Results Sharing
[ ]	None of the above	

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Up to 84 subjects (non-military) will be recruited at the University of Washington (goal 72 subjects 12/group). Subjects will be randomly assigned to one of the six study groups. Characteristics described below.

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

Men and women aged 18 to 55 who meet the physical standards for military personnel and weigh less than 250 pounds (maximum allowable weight on the litter). Subjects must be able to remain in the study position for the duration of the study.

b. Exclusion criteria. Describe the specific criteria you will use to decide who will be excluded from your study from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

1) previous injuries to sacrum/buttocks with scarring, 2) history of pressure injuries, 3) cardiovascular disease, 4) neurological disease that would affect vascular response, 5) diabetes, 6) history of malignancy, 7) current skin condition (e.g., eczema or psoriasis) which may interfere with the skin cytokine levels, 8) current neck/back pain or history of chronic neck/back pain, 9) known vertebral/spinal cord disease/injury (scoliosis, kyphosis, or lordosis), 10) self-reported pregnancy or 11) concern about their ability to remain in the vacuum spine board for 120 minutes. All subjects will be asked to refrain from the use of nonsteroidal anti-inflammatory medications for seven days before the experiment, to abstain from sun bathing for 24-hours before the experiment, to abstain from ingesting caffeine or smoking for six hours before the experiment, to avoid eating for 2 hours before the study (to increase accuracy of body fat measurement) and to not use any skin care products on the day of testing. Subjects will be informed of these requirements at the time of screening.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will you recruit or obtain data from individuals that you know to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".

[x] **No**
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. What will you do to reduce the chances of this?

iii. Describe what you will do to make sure that (a) your recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

☐ **Confirmed**

b. Is your research likely to have subjects who become prisoners while participating in your study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

☐ **No**
☐ **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

☐ **No**
☐ **Yes** → If yes, describe the procedures and/or data collection you will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Population	Worksheet
☐ Fetuses in utero	WORKSHEET: Pregnant Women
☐ Neonates of uncertain viability	WORKSHEET: Neonates
☐ Non-viable neonates	WORKSHEET: Neonates
☐ Pregnant women	WORKSHEET: Pregnant Women

a. If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

2.5 Native Americans or non U.S. indigenous populations. Will you actively recruit from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[x] **No**
[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about *other individuals* from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

[x] **No**
[ ] **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need to complete your study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number will be considered non-compliance.

[ ] **No** → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.

Our goal is 12 subjects/group (N = 72). At the direction of the funding agency, we have added 12 additional subjects to account for any possible attrition. (Total recruitment = up to 84). Note: In our previous study, which used similar methods with subjects in supine position for 40 minutes, we did not have any subjects discontinue their participation.

[x] **Yes** → If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research **For clinical trials: provide numbers for your site and for the study-wide total number*
Group 1: Litter + mattress (no Mepilex)	12
Group 2: Litter + mattress (with Mepilex)	12
Group 3: Litter + mattress + vacuum spine board (with Mepilex)	12
Group 4: Litter + mattress + vacuum spine board (no Mepilex)	12
Group 5: Talon litter + LiquiCell	12
Group 6: Talon litter – no LiquiCell	12

3 NON-UW RESEARCH SETTING

Complete this section only if your research will take place outside of UW and Harborview

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

N/A – all research will be conducted at UW

3.2 Local context. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research or how it is conducted.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

No

3.3 Site-specific laws. Describe any local laws that may affect your research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

No site specific laws - subjects will be age 18 or older who will provide their own consent. No HIPAA laws apply to this study.

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.

No site-specific administrative or ethical requirements apply.

3.5 Students: Does your research involve traveling outside of the US?

[x] **No**

[ ] **Yes** → If yes, confirm by checking the box that (1) you will register with the **UW Office of Global Affairs** before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if your research involves travel to the list of countries requiring a UW Travel Waiver.

[ ] **Confirmed**

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how you will identify, recruit, and screen subjects. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Advertisements for participation will be placed throughout the Health Sciences Center with contact information provided. People interested in participating in the study will contact study staff. Study staff will discuss inclusion criteria allowing potential subjects to self-identify any criteria that would exclude them from the study.

4.2 Recruitment materials.

a. What materials (if any) will you use to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

Subjects will be recruited from the local community. A recruitment flyer (attached) with contact information will be placed in approved elevators and bulletin boards in common area of the Health Sciences Center. The content in these recruitment documents is similar to our previous study.

b. Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline***. If you will send letters to the subjects, the letter should include a statement about how you obtained the subject's name, contact information, and any other subject-specific information (such as a health condition) that is mentioned in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *You could provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, you might include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, you might include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

[x] **No**

[ ] **Yes** → If yes, describe the nature of the relationship.

4.4 Payment to participants. Describe any payment you will provide, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

Subjects will receive $50 for completion of all study procedures. They will be reimbursed $25 for completion of half and $10 if they complete only the placement of the sensors. Subjects will also be reimbursed up to $9 for parking at the University of Washington.

4.5 Non-monetary compensation. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

None

4.6 Will you access or obtain data or specimens for recruiting and screening procedures prior to enrollment?

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[x] **Yes** → If yes, describe any data and/or specimens (including PHI) you will access or obtain for recruiting and screening and whether you will retain it as part of the study data.

The potential subject will contact a study team member. We will not obtain any information prior to contact with the subject as a part of screening. During the screening process we will obtain information related to inclusion/exclusion criteria as specified in the Screening Call Form (see attached). PHI will include age, medical conditions as provided by the potential subject. We will also record name and contact information for study coordination.

4.7 Consent for recruiting and screening. Will you obtain consent for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[x] **Yes** → If yes, describe the consent process.

Study staff will discuss the purpose of the study and screening with subjects over the phone per the attached screening form. On the day of the study, subjects will be given the consent form for review, discussion with study staff and signature.

a. Documentation of consent. Will you obtain a written or verifiable electronic signature from the subject on a consent form to document consent for all of the **recruiting and screening procedures**?

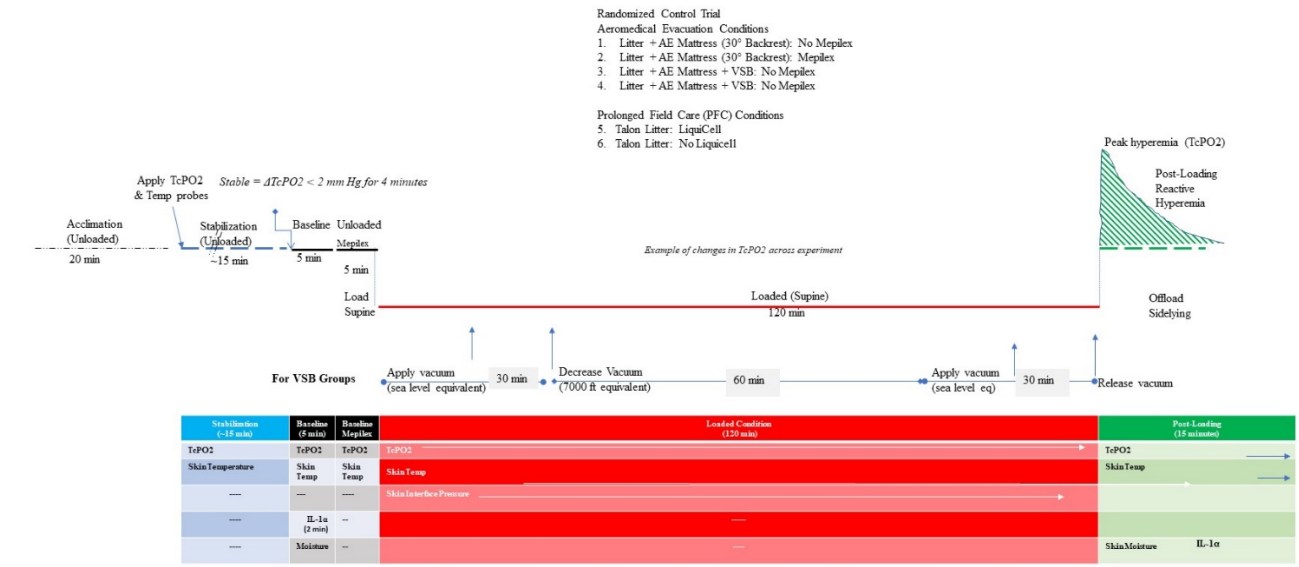
[ ] **No** → If no, describe the information you will provide during the consent process and for which procedures.

[x] **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of ***Zipline***.

5 PROCEDURES

5.1 **Study procedures**. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), use of records, time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY: Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.*



The study will take place in a temperature-controlled room (~72°F) at the University of Washington School of Nursing. Subjects will be assigned to one of six groups. Each subject will be clothed in a single layer of cotton like clothing (scrubs) and undergarments and socks. Height and weight will be obtained using a standup calibrated device and body fat will be measured using the InBody 570 Body Composition Analyzer. This device is used for medical research and in health clubs and involves standing on a scale.

Group Assignment: Subjects will first be stratified based on body fat percentage (< 10%, 10%-20%; > 20%). Using close block stratification, subjects will be randomly assigned to one of six groups to ensure distribution based on body composition.

Aeromedical Evacuation (AE) conditions

- Group 1: Mepilex: Litter + AE mattress + 30° backrest
- Group 2: Without Mepilex: Litter + AE mattress + 30° backrest
- Group 3: Mepilex: Vacuum Spine Board (VSB) placed on AE mattress
- Group 4: Without Mepilex: Vacuum Spine Board (VSB) placed on AE mattress

Prolonged Field Care (PFC) conditions

- Group 5: LiquiCell: Talon Litter
- Group 6: Without LiquiCell: Talon Litter

All Groups

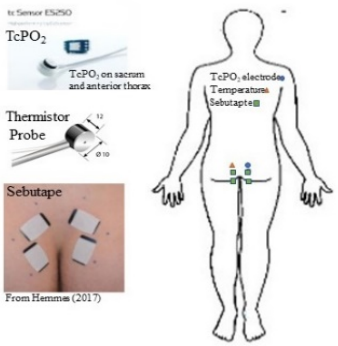
Acclimation: All subjects will complete a 20-minute acclimation period in the study room.

Placement of Sensors: After completion of the height, weight and body fat measurements, the subject will lie down on the study surface and the temperature/oxygen sensors will be placed on the lower aspect of their back and one oxygen sensor placed on their chest (approximately 2 inches below the collar bone on the left chest). The transcutaneous oxygen (TcPO2) probes will heat up to 111˚F, as recommended by the device manufacturer.

The subject will rest on their side for approximately 15 minutes while the measurements from the sensors to stabilize. These sensors allow for continuous measurement of skin tissue oxygenation and temperature.

Stabilization: Following acclimation, the subject will be assisted to a side lying position (unloaded) and the temperature and TcPO2 probes will be placed. Based on our previous research, it takes approximately 15 minutes for the sacral probe to stabilize ($TcPO_2$ < ± 2 mm Hg for 4 minutes).

Cytokine/Skin Moisture Measurements: After stabilization four small pieces of tape (Sebutape) will be placed on the lower back for 1 minute for the measurement of interleukin 1/Total protein. The Sebutape (size: 0.75 x 1.1 inches) will be placed in four quadrants (sacrum/buttocks). Sebutape has been used to measure IL-α in studies related to pressure and shear; including the evaluation of Mepilex under conditions of pressure and shear. Removal of the tape causes minimal stripping of the stratum corneum and discomfort to the subject. The Sebutape will be handled using blunt tweezers and gloved hands to avoid any cross contamination. Four patches will be applied (two on sacrum/two on buttocks) to intact, unblemished skin that is free of excessive hair,[55] which allows us to characterize potential injury on the buttocks and sacrum (areas of pressure injuries noted in Mok's study). After the one-minute sampling period the Sebutape will be removed using blunt tweezers and will be placed flat (avoid any crumpling or folding) into an individually labeled vial and immediately frozen on ice.



Position of sensors and Sebutape on posterior surface. TcPO2 also on anterior chest

Skin Moisture. We will also use a noninvasive probe to measure the amount of moisture in the skin on the lower back/sacrum. Two components of skin moisture will be measured: 1) Epidermal moisture, which reflects perspiration and 2) subepidermal moisture using a Delfin MoistureMeter D (Delfin Technologies, LTD, Grennwich, CT) dermal phase meter (http://www.delfintech.com/en/product_information/moisturemeterd/). Epidermal moisture (stratum corneum) will be measured at 0.5 mm below the skin surface and subepidermal moisture (i.e., below the epidermal stratum corneum layer) will be measured at a depth of 2.5 mm. The device consists of a control unit (signal producer) and a probe (open-ended coaxial transmission line), which is placed in contact with the skin The skin moisture will be measured at a standardized site, mid-sacrum, approximately 2 cm above the gluteal fold (avoiding the sites of the Sebutape). This location will be marked with ink pen to assure the same location for repeat measurement. For each depth, the probe will be placed on the skin surface and held for 5 seconds.

After these measurements are complete, subjects in the Mepilex dressing groups will have the dressing placed on their lower back/buttocks. All subjects will then complete an additional 5 minutes in the side-lying position, after which they will lie on their back on the designated surface. After positioning a sheet will be placed over the subject for comfort. A pillow may be placed under the head and heels at the subject's discretion.

The skin interface pressure will be measured continuously during the loaded period using the XSensor™ System (Crown Therapeutics, Belleville IL) with X3 Medical v6.0 software. This pad, which is similar to a sheet, will be positioned on the surface. *Peak skin-interface pressure,* which is the highest measured pressure for each body region and the *Peak Pressure Index* (PPI), which is the average of a 3 x 3 sensor area representing the highest pressure (including the peak pressure cell). The sacrum/buttocks will be divided into four quadrants based on the vertebral column and top of the gluteal cleft.[55] For the Mepilex groups, the pressure on the surface of the Mepilex will be recorded. Although this procedure does not directly measure skin interface pressure, which may be decreased by the Mepilex, it is not possible to place the pressure mat between the Mepilex and the skin.

Unique Procedures by Study Group

For all groups the stretcher is placed on the bedframe of a standard hospital bed. The stretcher is secured to the bed frame. This elevation on the bedframe is for ease of access for the subjects. The bedframe is in the low position, such that the subjects will be approximately 2-3 feet off the floor.

Aeromedical Evacuation (AE) conditions

Group 1: Mepilex: Litter + AE mattress + 30° backrest elevation. Subjects will be positioned supine on the litter plus AE mattress. Mepilex will be placed on sacrum/buttocks region. Subjects will be asked to lie supine with

limited motion for 120 minutes. After completion of the 120-minute supine period, subject will be positioned side-lying. After 5 minutes side-lying, the Mepilex will be removed and the skin moisture and skin cytokine measurements will be obtained. After completion of the 15-minute side-lying phase, the skin sensors will be removed, and the study will be complete

Group 2: Without Mepilex: Litter + AE mattress + 30° backrest. Subjects will be positioned supine on the litter plus AE mattress. Subjects will be asked to lie supine with limited motion for 120 minutes. No Mepilex will be used. After completion of the 120-minute supine period, subject will be positioned side-lying. After 5 minutes side-lying the skin moisture and skin cytokine measurements will be obtained. After completion of the 15-minute side-lying phase, the skin sensors will be removed, and the study will be complete

AE Conditions with Vacuum Spine Board

Subjects in Groups 3 and 4 will be positioned on the vacuum spine board (VSB), which will be place on top of the litter + AE mattress. The litter will be elevated to 30 degrees (consistent with current practice). The vacuum will be applied according to manufacturer's recommendations. After creation of the vacuum, the VSB will be loosened around the head and feet to allow for movement for comfort. These steps do not interfere with the thoracolumbar stabilization or the interface pressure over the sacrum/buttocks. To simulate en-route care the vacuum will be maintained for 30 minutes (simulate movement to the aircraft). At 30 minutes, the vacuum will be released with the straps in place (simulate current en route practice). At 90 minutes, the vacuum will be reapplied for 30 minutes to simulate descent and landing phase of flight (total time 120 minutes).

The VSB straps will be in place but loosened (the photo shows the straps tightened – as they would be during transport). The subject's arms will be free (the additional litter straps – seen as olive green in the photo across the upper legs and chest will not be used). The straps will remain clipped to enhance stability of the VSB, but the subject will be able to move their arms and legs and release the straps if so desired.

Group 3: Mepilex: Vacuum Spine Board (VSB) placed on litter + AE mattress. Subject will complete above procedure. Mepilex will be placed on sacrum/buttocks before positioning on VSB. After completion of the 120-minute supine period, the vacuum will be released, and the subject will be positioned side-lying. After 5 minutes side-lying, the Mepilex will be removed and the skin moisture and skin cytokine measurements will be obtained. After completion of the 15-minute side-lying phase, the skin sensors will be removed, and the study will be complete.

Group 4: Without Mepilex: Vacuum Spine Board (VSB) placed on litter + AE mattress: Subject will complete above procedure. No Mepilex. After completion of the 120-minute supine period, the vacuum will be released, and the subject will be positioned side-lying. After 5 minutes side-lying, the skin moisture and skin cytokine measurements will be obtained. After completion of the 15-minute side-lying phase, the skin sensors will be removed, and the study will be complete

Prolonged Field Care (PFC) conditions

Subjects in the prolonged field care groups (Groups 5 and 6) will lie on the Talon litter supine (no mattress/no head of bed elevation). Pillows may be placed under the head/heels for comfort. Subjects will be asked to remain as still as possible during the 120-minute supine period. Upon completion of the supine period, subjects will be positioned side-lying for 15 minutes. Skin moisture and skin cytokine measurements will be obtained 5 minutes after the subject is positioned side-lying. After completion of the 15-minute side-lying phase, the skin sensors will be removed, and the study will be complete

Group 5: LiquiCell: Talon Litter: Subjects will be positioned supine on the Talon litter plus a LiquiCell mat (see photo) will be positioned under the buttocks/sacrum. Subjects will be asked to lie supine with limited motion for 120 minutes. After completion of the 120-minute supine period, subject will be positioned side-lying. After 5 minutes side-lying the skin moisture and skin cytokine measurements will be obtained. After completion of the 15-minute side-lying phase, the skin sensors will be removed, and the study will be complete.

Group 6: Without LiquiCell: Talon Litter: Subjects will be positioned supine on the Talon litter. Subjects will be asked to lie supine with limited motion for 120 minutes. No LiquiCell pad will be used. After completion of the 120-minute supine period, subject will be positioned side-lying. After 5 minutes side-lying the skin moisture and skin cytokine measurements will be obtained. After completion of the 15-minute side-lying phase, the skin sensors will be removed, and the study will be complete

Pressure/Discomfort (All Groups): At Time 0 (supine) and every 30 minutes during the supine position, the subject will be asked to rate their discomfort using a standardized scale.

5.2 MRI scans. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

[x]	**No**	→ If no, go to question **5.3**.
[ ]	**Yes**	→ If yes, answer questions **a** through **c**.

a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive a MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

b. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

☐ **No**

☐ **Yes** → If yes, which agents will be used? *Check all that apply.*

	Brand Name	Generic Name	Chemical Structure
☐	Dotarem	Gadoterate meglumine	Macrocylic
☐	Eovist / Primovist	Gadoxetate disodium	Linear
☐	Gadavist	Gadobutro	Macrocyclic
☐	Magnevist	Gadpentetate dimeglumine	Linear
☐	MultiHance	Gadobenate dimeglumine	Linear
☐	Omniscan	Gadodiamide	Linear
☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic
☐	Other, provide name:		

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with your MRI scan(s). Describe the dose you will use and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If you plan to use a linear GBCA, explain why you cannot use a macrocyclic GBCA.

2.) Information for subjects. Confirm by checking this box that you will either provide subjects with the FDA-approved Patient Medication Guide for this GBCA you are using or that the same information will be inserted into the consent form.

☐ **Confirmed**

c. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)

	DISC Diagnostic Imaging Sciences Center (UWMC research facility)
	BMIC Biomolecular Imaging Center (South Lake Union research facility)
	Harborview Radiology/Imaging Services (the Harborview clinical facility)
	SCCA Imaging Services
	Northwest Diagnostic Imaging
	Other: identify in the text box below:

Personnel. For MRI scans that will be conducted at the DISC or BMIC research facilities: The role, qualifications, and training of individuals who will operate the scanner, administer the GBCA (if applicable), and/or insert and remove the IV catheter should be listed on the Study Team addendum.

5.3 Data variables. Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

As outlined in section 5.1 the following variables will be obtained: Height, weight, gender, percent body fat. Physiological variables that will be collected either continuously or intermittently include transcutaneous tissue oxygen on sacrum/chest, skin temperature on sacrum, skin moisture on sacrum, IL-1 (cytokine) obtained from epidermis of sacrum. We will also measure skin interface pressure on the buttocks/sacrum and subjects report of comfort/discomfort will be obtained every 30 minutes during the supine position.

5.4 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

Only the data outlined in the study procedures will be used in this study (height, weight, gender, body fat, skin oxygenation, skin temperature, skin moisture, cytokines from epidermis, skin interface pressure).

5.5 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: do all data and specimens to be used in the research exist (for example, in subjects' medical records) at the time this application is being submitted for initial review?

x	**No**
	Yes

Include any necessary comments or explanation below (Note that for most studies this can be left blank):

5.6 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

__Access__ means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".
__Identifiable__ means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.
__Direct identifiers__ are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.
__Indirect identifiers__ are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.
__Key__ refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.
__Obtain__ means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from __accessing__, which means to view or perceive data.

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

The subjects name will be recorded as a part of the consent/screening process. All study data will be coded using a unique identifier. The link between the study data and the identifiers will be broken upon completion of the study.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before you have access.
- [ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

  You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.
- [ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
- [ ] There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you obtain any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

Identifiers (name) will be collected during screening and consent. All study data will be coded using a unique identifier. The link between the study data and the identifiers will be broken upon completion of the study.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

[ ] There will be no identifiers.

[ ] Identifiers or the key have been (or will have been) destroyed before you have access.

[ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

[ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

[ ] There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe your data security plan here – we will ask for that information in section 9.6.

[ ] You will store the identifiers with the data. Describe the data to which this applies:

[ ] You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

[ ] You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

5.7 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015 **AND** will you obtain the bloodspots before January 21, 2019?

- [x] **No**
- [ ] **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?
  - [ ] **No**
  - [ ] **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.8 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***If you will use UW Medical Records, you must answer yes to this question.***

- [x] **No** → If no, skip the rest of this question; go to question **5.9**
- [ ] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

b. Is any of the PHI located in Washington State?

- [ ] **No**
- [ ] **Yes**

c. Describe how you will access or obtain the PHI. *Be specific.*

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

- [ ] **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

Provide the following assurances by checking the boxes.

☐ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☐ You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Compliance Policy #104. THIS IS ONLY FOR UW RECORDS.

☐ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.9 Genomic data sharing. Will you obtain or generate genomic data (as defined at http://osp.od.nih.gov/scientific-sharing/genomic-data-sharing-faqs/)?

☒ **No**
☐ **Yes** → If yes, answer the question below.

a. Do you plan to send genomic data from this research to a national database (for example, NIH's dbGaP database)?

☐ **No**
☐ **Yes** → If yes, complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

5.10 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

☒ **No**
☐ **Yes**

5.11 Data and specimen sharing/banking. Are you likely to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database for research purposes not related to this study, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **YES** even if you will only share information without identifiers. Answer **NO** if you are unlikely to do any sharing, or if your only sharing will be through the NIH Genomic Data Sharing described in question 5.9.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include: informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

☒ **No**

☐ **Yes** → If yes, answer all of the questions below.

a. Describe what will be stored, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

b. Describe what will be shared, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

c. Who will oversee and/or manage the sharing?

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

e. Consent. Will you obtain consent now from subjects for the banking and/or future sharing?

☐ **No**
☐ **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 8.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from banking or sharing?

☐ **No**
☐ **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

g. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach your template agreement forms; the IRB neither reviews nor approves them

☐ **Confirmed**

5.12 Communication with subjects during the study. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

The only contact with the subject will be for screening, scheduling the date/time for the study and during study participation. No additional communication is planned.

5.13 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

[x] **No**
[ ] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

5.14 Alternatives to participation. Are there any alternative procedures or treatments <u>that might be advantageous</u> to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

[x] **No**
[ ] **Yes** → If yes, describe the alternatives.

5.15 Upload to the Supporting Documents SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:*** *Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics you will cover and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you*

plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process you will use for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

5.16 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject's written consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

[x] **No** → If no, go to Section 8.

[ ] **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in your population(s). If there is more than one answer, explain.

[ ] **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will you obtain parental permission for:

☐ All of your research procedures → Go to question **6.2b.**

☐ None of your research procedures → Use the table below to provide your justification, and skip question 6.2b.

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written parental permission.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why you will not obtain parental permission	Will you inform them about the research?[3]	
			YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *If you plan to obtain identifiable information or biospecimens without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will you inform them about the research beforehand even though you are not obtaining active permission?*

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If you checked both boxes, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**
☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET: Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will you obtain assent for:

☐ All of your research procedures and child groups → Go to question **7.2.**

☐ None of your research procedures and child groups → Use the table below to provide your justification, then skip to question 7.5.

☐ Some of your research procedures and child groups → Use the table below to identify the procedures for which you will not obtain assent.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why you will not obtain assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

7.3 Dissent or resistance. Describe how you will identify a child's objection or resistance to participation (including non-verbal indications) during the research, and what you will do in response.

7.4 E-consent. Will you use any electronic processes (email, websites, electronic signatures, etc.) to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how you will do this.

7.5 Documentation of assent. Which of the following statements describes whether you will obtain documentation of assent?

☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then go to question **7.5.a**
☐ All of your research procedures and child groups	→ Go to question **7.5.a**, do not complete the table
☐ Some of your research procedures and/or child groups	→ Complete the table below and then to go question **7.5.a**

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

a. Describe how you will document assent. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

b. Upload all assent materials (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.6 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe your plans (if any) to re-obtain assent from children.

b. Describe your plans (if any) to obtain consent for children who reach the legal age of consent.

- If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.
- If you do not plan to obtain consent or think that you will be unable to do so, explain why.

7.7 Other regulatory requirements. (This is for your information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It usually (but not always) includes an opportunity for subjects to ask questions. It does not necessarily include the signing of a consent form. This question is about the consent process.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.

PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.
WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. **NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which your answers in this section apply.

[x] Adult subjects

[ ] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process. This series of questions is about whether you will obtain consent for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.6. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which you will not obtain consent?

[x] **No**

[ ] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why you will not obtain consent	Will you provide subjects with info about the research after they finish? YES	NO
			☐	☐
			☐	☐

	☐	☐
	☐	☐
	☐	☐

Table footnotes

1. *If your answer is the same for all groups you can collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if you will obtain consent for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names).*
- *Whether/how you will provide an opportunity for questions*
- *How you will provide an adequate opportunity for the subjects to consider all options*

The PI or approved study team member will meet with the subject at the University of Washington School of Nursing lab where the study will occur. At this time, the subject will be provided the consent form for their review. The study team member will also review all of the procedures for the study and answer any questions the subject may have. The consent form will be completed and the study procedures will occur on the same day.

c. Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

The subject's comprehension of the study will be tested by asking them to describe the general study procedures, where the monitoring devices will be positioned and what they will be asked to do during the study.

d. Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

☒ **No**

☐ **Yes** → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

e. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) you will give subjects to ask questions or to change their minds about participating.

Not applicable

8.3 Electronic presentation of consent information. Will any part of the consent-related information be provided electronically for some or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. See GUIDANCE: Electronic Informed Consent for information.

x	**No**	→ If no, skip to question 8.4
	Yes	→ If yes, answer questions **a** through **e**

a. Describe your methodology and the information that will be provided.

All informational materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

b. Describe how the information can be navigated (if relevant). *For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?*

c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Will that be possible in your study? Also, describe what, if anything, you will do to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

d. What will you do if you encounter individuals who wish to participate but who do not have access to the methodology you are using or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, you cannot exclude these individuals from your study unless you have a compelling rationale. *For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.*

e. How will you provide additional information, including any significant new findings (such as new risk information) to subjects during the research? If this is not an issue, explain why.

8.4 Written documentation of consent. Which of the statements below describe whether you will obtain documentation of consent? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.6.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Are you obtaining written documentation of consent for:

☐ None of your research procedures	→ Use the table below to provide your justification then go to question **8.5.**
☒ All of your research procedures	→ Do not complete the table; go to question **8.5.**
☐ Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will you provide them with a written statement describing the research (optional)? YES	NO
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If your answer is the same for all adult groups or all procedures, you can collapse your answer across the groups and/or procedures.*

b. Electronic consent signature. For studies in which documentation of consent will be obtained: will subjects use an electronic method to provide their consent signature?

- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☒ **No**

☐ **Yes** → If yes, describe the methodology you will use.

See the GUIDANCE: Electronic Informed Consent for information about options (including the DocuSign system available through UW-IT) and requirements.

b.1 Is this method legally valid in the jurisdiction where the research will occur?

☐ **No**

☐ **Yes** → If yes, what did you use as your source of information about legal validity?

b.2 Will you obtain verification of the subject's identity if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

See the GUIDANCE: Electronic Informed Consent for information and examples

☐ **No** →If no, provide your rationale for why this is appropriate. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?

☐ **Yes** →If yes, how?

b.3 How will you meet the requirement to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

8.5 Non-English-speaking or -reading adult subjects. Will you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes** → If yes, describe the process you will use to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how you will provide interpretation and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how you will obtain translations of all study materials (not just consent forms) and how you will ensure that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.6 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe your plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if you are not obtaining written documentation of consent for any part of your research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

If a subject indicates they are functionally illiterate or do not read English well, the consent form will be read to them. Confirmation of understanding of the consent will be performed by asking the subject to explain what general procedures will happen during the study and what is required of them.

8.7 Deception. Will you deliberately withhold information or provide false information to any of the subjects? *Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception.*

- [x] **No**
- [ ] **Yes** → If yes, describe what information and why.

Example: you may wish to deceive subjects about the purpose of the study.

a. Will you debrief the subjects later? (Note: this is not required.)

- [ ] **No**
- [ ] **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***.

8.8 Cognitively impaired adults, and other adults unable to consent. Do you plan to include such individuals in your research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

x	**No**	→ If no, go to question **8.9**.
	Yes	→ If yes, answer the following questions.

a. Rationale. Provide your rationale for including this population in your research.

b. Capacity for consent / decision making capacity. Describe the process you will use to determine whether a cognitively impaired individual is capable of consent decision making with respect to your research protocol and setting.

b.1. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will reassess decision-making capacity and obtain consent during that time.

c. Permission (surrogate consent). If you will include adults who cannot consent for themselves, describe your process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **SOP: Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process you will use to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

8.9 Consent-related materials. Upload to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials you will use.

- *Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps you will take, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedures (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

All study data will be coded with a unique identifier. The link between identifiers (name) will be broken upon completion of the study. During the screening call, subjects will be asked about specific conditions that would exclude them from the study. A subject may choose to not answer a question. All study procedures will be performed in a controlled research area. The study room has an external door that will be closed during the placement of the study probes. To place the probes the subject will be required to expose the lower portion of their back. The subject will be draped during this procedure for privacy. A chaperone will be available.

9.2 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

- [x] **No**
- [ ] **Yes** → If yes, will you obtain subject consent for this use?
  - [ ] **Yes**
  - [ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[x] **No**
[ ] **Yes** → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

9.4 Retention of identifiers and data. Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/about/Documents/UWM-Records-Retention-Schedule.pdf***

[x] **Confirm**

9.5 Certificates of Confidentiality. Are you planning to obtain a federal Certificate of Confidentiality for your research data? *NOTE: Answer "No" if your study is NIH funded, because all NIH-funded studies automatically have a Certificate.*

[x] **No**
[ ] **Yes**

9.6 Data and specimen security protections. Identify your data classifications and the security protections you will provide, referring to the ***ZIPLINE* GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level. ***You cannot answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

The data being collected are Level 3 (e.g., weight, demographics – non-sensitive personal health information). We will follow all of the recommendations outlined in the Data Security Protection guidance.

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which you will *not* follow, list those here.

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

Because the TcPO2 (tissue oxygen) electrode is heated to 44°C (111°F), there is a minor risk for a thermal injury (skin redness or a minor skin burn) under a less than quarter size area. In our previous study, where the subjects were supine for 55 minutes with the electrode heated to 44°C (40-minutes loaded conditions/15 minutes unloaded condition), we had no alterations in skin integrity or subject reports of adverse events. In this current study, the electrode will be in contact with the subject at the maximum temperature for 135 minutes (120 minutes loaded condition and 15 minutes unloaded).

The TcPO2 electrode is used in clinical practice in both healthy and critically ill neonates and adults. Relevant to this proposal are studies that use TcPO2 under loaded conditions. In studies where the electrode is exposed to a pressure load, there have been no reports of thermal injuries. For example, in a study by Wong, nine patients in a long term care facility (age 85 ± 11 years) had TcPO2 electrodes placed on their sacrum (distal to the coccyx but proximal to the anus), trochanters (hip – 2 inches medial to the great trochanters) and on the plantar surface of the heels (note – the electrode will be on the sacrum for this proposed study). The subjects were 1) placed lateral for 30 minutes and 2) turned to supine position with the head of bed at 30° for 2 hours with both the sacrum and heels on the bed surface (low-air-loss), and 3) positioned lateral for 2 hours (unloading). *Total data collection was approximately 5 hours.* Although five subjects had a low TcPO2 (< 40 mm Hg), which indicates impaired perfusion, there were no reports of alteration in skin integrity associated with the electrodes. Two actions that have been successfully used in other protocols (including our previous study) will be taken to minimize the risk. The sacral electrode will be surrounded by a callus pad to offload any pressure directly on the electrode. If the TcPO2 on the weighted electrode decreases to 0 mm Hg, the temperature on the electrode will be decreased to 37°C for the remainder of the loaded period. At the completion of the study and removal of the TcPO2 sensor, the skin will be inspected. If there is redness that persists, the subject will be instructed to apply topical (such as aloe vera) if so desired. It they are concerned regarding skin condition, the study monitor (a nurse practitioner) will be asked to evaluate the subject and as appropriate refer for any treatment.

Another strategy to decrease the risk will be repeated assessment of the subject's perceptions of perceived pressure or discomfort using the Category Partitioning Scale (CP-50), which is a verbal scale that describes discomfort/pressure under each condition. Use of this scale may be more appropriate than a "pain scale" as a subject may or may not experience pain, but rather sense pressure or discomfort. Using the CP-50, the subject is first asked to describe using verbal terms the pressure intensity or discomfort associated with the stimulus (i.e., sacral/buttocks pressure or discomfort). The subject can then fine-tune their assessment using the numeric scores. The final score is the analog number. For purposes of this research, at baseline and every 30 minutes, we will ask the subject to limit their evaluation to the pressure/discomfort sensed on the sacrum/buttocks, but we will also ask the subjects to identify on their body where they are experiencing the most pressure/discomfort.

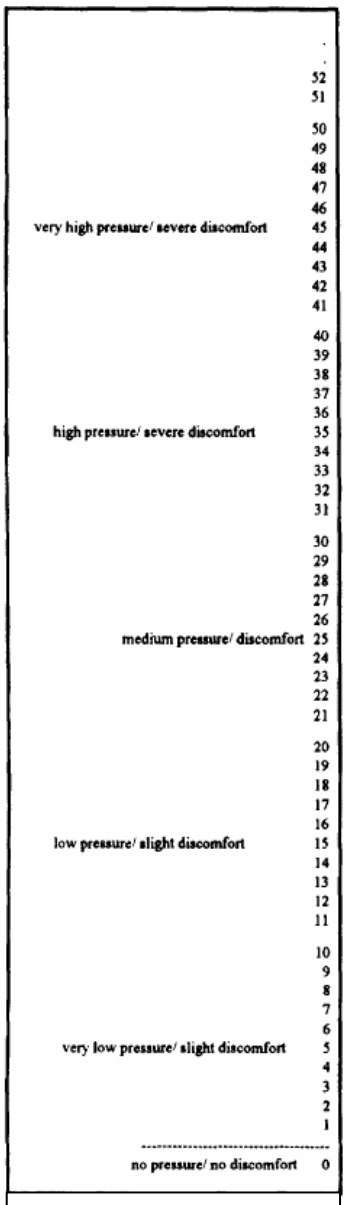


Figure 3. Category Partitioning Scale (CP-50).[7]

To protect the subject from undo perceived pressure or discomfort, a threshold of CP-50 score of 40 will be established as the maximum score. If the subject reports a CP-50 score greater than 40, the experiment will be stopped. The subjects will not be informed of this cutoff. (This threshold is consistent with Games study, where a threshold of 45 was used in a study of discomfort associated with prolonged sitting in an unpadded seat.

The CP-50 was used in two studies of Black Hawk UH-60 crewmembers exposed to four hours of sitting in a simulated cockpit on an unpadded seat.[9,10] The CP-50 score increased significantly at each time point (every 30 minutes), and at 240 minutes the score had increased an average of 30 points. In the second study,[10] healthy subjects were exposed to 36 kPA (270 mm Hg) and 44 kPA (330 mm Hg) on the ischial tuberosity and poster thigh for 10 minutes. Application of pressure was associated with increased discomfort on the posterior thigh (5.5 points at 36 kPA and 7.5 points at 44 kPA) and ischial tuberosity (3.1 points/4.2 points, respectively), with increased discomfort at higher pressures. Of importance, in this proposed study the skin interface pressure will be much lower, thus we anticipate lower levels of perceived pressure and discomfort. Based on our previous work, the average sacral/buttocks pressure on the litter plus mattress was 42 ± 12 mm Hg and 60-70 mm Hg on the vacuum spine board.[11]

Because the area of the body we are interested in is the lower back/buttocks, we will provide pillows for the head and to elevate the heels.

Placement of the Mepilex and performance of the monitoring will require the subject to expose the lower half of their back and upper aspect of their buttocks. The procedures will be conducted with the subject lying face-down. The subject will be appropriately draped to minimize exposure. All procedures will be performed in a screened area and the subject will be asked if they would like a chaperone present during these procedures.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[x] **No** → If no go to question 10.3

[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps you will take to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If you will require the use of contraception: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what you will do if a subject (or a subject's partner) becomes pregnant

For example; will you require the subject to immediately notify you, so that you can discontinue or modify the study procedures, discuss the risks, and/or provide referrals or counseling?

10.3 MRI risk management. *Answer this question only if your subjects will receive MRI scans*. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

a. Describe how you will assess the renal function of your subjects prior to MRI scans and how you will use that information to exclude subjects at risk for NSF.

Not applicable

b. Describe your protocol for handling a sever allergic reaction to the GBCA or any other medical event/memergency during the MRI scan, including who will be responsible for which actions.

Not applicable

10.4 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[x] **No**

[ ] **Yes** → If yes, identify the procedures.

10.5 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while subjects-patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[X] **No**
[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device
- [ ] Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If you checked any of the boxes:
You must provide the name and institutional affiliation of a 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, and you must consult with the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine for feasibility, safety and billing.

*** If you checked the box about radio-isotopes: 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.*

10.6 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for your research, upload your DSMP to the **Supporting Documents** SmartForm in ***Zipline***. If it is embedded in another document you are uploading (for example, a Study Protocol, use the text box below to name the document that has the DSMP.

In our previous research, which used similar methods, the IRB determined that the study was minimal risk and a medical monitor/DSMB was not required. DSMP v1 (Bridges) is attached.

10.7 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or you do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

Not applicable

10.8 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

The subject will be withdrawn in they report discomfort about the specified threshold. Although we do not anticipate a subject having intolerance to lying in the stiff vacuum spine board, if they indicate intolerance to the compression (e.g., a sense of claustrophobia), we will offer them the opportunity to discontinue their participation. We will obtain post-measures (skin cytokines and moisture) and record final tissue oxygen and skin temperature measurements at the time of withdrawal. All study data will be retained.

10.9 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

There is no direct benefit to participants.

10.10 Individual subjects findings.

a. Do you anticipate that the research will produce any urgent, clinically actionable results?

These may be results from screening procedures, results that are actively sought for purposes of the study or they may be results that are discovered unintentionally. Examples include high calcium levels, liver function test results, and a mass on an MRI that may indicate a tumor, a diagnostic discrepancy, and suicidal intentions.

[x] **No**
[ ] **Yes** → If yes, the results should be shared with the subject(s). Complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

b. Do you plan to share any other results of your study procedures or findings with the subjects – such as genetic test results, laboratory tests, etc.?

You should answer YES if your consent form says anything about sharing individual information with subjects.

[x] **No**
[ ] **Yes** → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

10.11 Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

[x] **No**
[ ] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

11.2 Costs to subjects. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

No costs to subject

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

Subjects will be reimbursed for parking (up to $9) or cost of public transportation on the day of the study

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

12.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

We will hold regular study team meetings. During these meetings we will ensure study team members are informed and have the opportunity to perform all required study procedures as appropriate. We used this same method in our previous study to ensure ongoing adherence with all study protocols.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Other regulatory approvals. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
☐ RDRC	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

13.2 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

13.3 Financial Conflict of Interest. Does any member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, has the Office of Research made a determination regarding this SFI as it pertains to your proposed research?

- ☐ **No** → If no, contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination
- ☐ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to the research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.