PROPOSAL FOR HUMAN RESEARCH

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APPROVED
OCT 23 2019
60 MDG IRB
TRAVIS AFB CA

CLINICAL INVESTIGATION FACILITY
60th Medical Group (AMC)
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FWA00003321, DoD 50004, IRB000011217

For assistance, call the Chief, Research Oversight and Compliance at (707) 423-7206

1. Title of Investigation:

NATO Litter: Fluid Immersion System (FIS) versus Traditional Mattress for Pressure Dispersion

2. Investigator and Investigation Staff:

Name	Rank	Study Role	Date of Investigator Training	Staff/ Resident/ Fellow	Dept/ Office Symbol	Phone	DoD Assurance Number	E-mail
	Col	PI	13 Jul 17	Staff	59 MDW/ST		50004	
	Lt Col	Co-PI	29 Jan 19	Staff	SGSE		50004	Contact information redacted 23 Jan 20
	CTR	CRN	19 Jun 17	CTR	SGSE		50004	
	CTR	CRN	1 Nov 17	CTR	SGSE		50004	

- The **PI** must complete an Institutional Review Board (IRB) approved investigator training course prior to submitting the study.
- All **AIs, CIs** and **SCs** must complete investigator training prior to the study receiving final approval.
- Only qualified, IRB-approved investigators and study coordinators may perform, administer, and countersign/witness informed consent.

Research Monitor (RM): N/A this is not a greater than minimal risk study. All procedures are non-invasive and no medication/drug use is involved. All equipment used is commercially available and FDA approved as required.

3. Facility and/or Contractor:

All subject enrollment, data collection and data analysis will be conducted at David Grant USAF Medical Center, Travis Air Force Base, California.

4. Purpose of Investigation:

Clearing the battlefield quickly and providing the best care possible for the wounded is a priority for military medics. The primary mode of patient transport whether by land, sea or air is on a litter (NATO litter for USAF aircraft) [3,6,7]. Litter stands provide the support necessary to transform a litter into an operating room (OR) table or hospital bed. Patients can spend several hours and/or days resting on a litter in a field hospital, or in transit to the next level of care [6-7]. Injuries or illness that prevents patients from normal movement and repositioning place them at increased risk of pressure ulcer development [8]. Specialty beds and mattresses are available in most hospitals to help prevent pressure ulcer development in patients. Unfortunately, these products are not currently available for contingency or aeromedical evacuation (AE) operations. The purpose of this study is to measure peak skin interface pressures and the total area of the body exposed to skin interface pressure above 30 mm Hg at different areas of the body in the supine position on two different support surfaces applied to a standard North Atlantic Treaty Organization (NATO) litter (NSN: 6530-01-380-7309) and a Raven 90C Litter (NSN6530-01-432-5114). The Raven 90C is the official litter for the U.S. Navy. It is approved for flight on USAF aircraft. It can be easily folded for storage and transport to remote settings. The support surfaces are the Warrior Evacuation Litter Pad (WELP) and the Dolphin Fluid Immersion Simulation Stretcher System (FIS). In theory, mattresses that reduce and/or minimize pressure on the capillary bed's perfusion can help reduce pressure related injury such as pressure or decubitus ulcer development. Skin interface pressure measurements using a pressure mapping system along with transcutaneous oxygenation readings will allow us to determine these differences between support surfaces. A better understanding of skin interface pressure associated with the litter support surfaces is vital for military nurses to develop and implement preventative interventions to reduce pressure ulcer development in our patients. In addition, this study will provide information to help determine the usefulness and feasibility of incorporating the fluid immersion system (FIS) as a litter support surface.

5. Category of Study and Risk Assessment:

5.1. Category of Study:

☐ **Medical Utilization** ☒ **Prevention** ☐ **Medical Readiness** ☐ **Diagnosis/Treatment/Other**

5.2. Proposed Risk:

☒ Minimal Risk
☐ Greater Than Minimal Risk

6. Proposed Research:

6.1. Background and Review of Literature:

Background

Each year, 2.5 million people in the United States (U.S.) develop pressure ulcers [1, 11], while approximately 60,000 die of pressure ulcer (PU) related complications each year [9]. The Centers for Medicare & Medicaid estimate that each pressure ulcer adds $43,000 in costs to a hospital stay [26, 31], as much as $70,000 for management of a single full thickness pressure ulcer, and an annual financial burden estimate of $11 billion per year [25]. Medicare considers Stage III and IV pressure ulcers a health care-associated condition and will not pay for the additional treatment of patients who acquire them in the hospital [9]. The incidence of pressure ulcers has increased in combat casualties returning from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) from 2003 to the present [7]. Inter-theater patient movement can have injured and or/ill patients resting on litters for >8 to 10 hours [6]. Research conducted by Lt Col Susan Dukes using the Joint Theater Trauma Registry (JTTR) from 2008-2012 found 164 patients developed pressure ulcers (PU) within three days after enroute care (ERC) transport and 142 (87%) were Critical Care Air Transport Team (CCATT) patients [43]. The number of CCATT patients with PUs was only 5% of the total number of patients transported; however, it was still relatively close to the 7% of hospital acquired pressure ulcers reported for acute care facilities in the U. S. [6, 24]. Prevention of hospital-acquired pressure ulcers (HAPU) is a nursing quality outcome measure used to evaluate the effectiveness of nursing care and optimal patient outcomes [1,7,9,10,11,18, 23, 28-30]. In October 2008, the Centers for Medicare & Medicaid Services added prevention of HAPU to the National Patient Safety Initiatives [31]. Preventing HAPU is also a priority for improving the quality care in the current Healthy People 2020 objectives [26].

Pressure Ulcers

Pressure ulcers (PU) are defined by the United States National Pressure Ulcer Advisory Panel (NPUAP) and the European Pressure Ulcer Advisory Panel (EPUAP) as "localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear" [8-9]. Pressure ulcers develop when soft tissue is compressed between a bony prominence and a hard surface for an extended period of time. In an alert person with normal motor and sensory function, nociceptors sense increased pressure and signal the brain. As a result of the signal, the person naturally repositions. But if a patient is anesthetized, has a condition that impairs their ability to reposition (such as decreased level of consciousness or paralysis), or is taking opioids that decrease the pain messages, this protective mechanism is blunted or completely disappears raising the risk of pressure ulcer development [9, 18, 39-40]. While PUs can appear in as little as 24 hours, it can take as long as five days before they appear [10,13, 20,35]. Prevention of PU development is extremely important as they lead to decreased quality of life, increased length of hospital stay, pain, increased morbidity and decreased mortality [1]. Pressure ulcers are both high cost and high volume adverse events. Although

multiple factors contribute to ulceration such as nutritional status, level of bladder/bowel control (continence), physical condition, level of consciousness, immobility, exposure to pressure, shear and friction forces, the key factor in tissue damage is unrelieved pressure [2, 5, 9, 18, 20, 27]. Therefore, surfaces that can redistribute pressure across the body are important [19].

Mattress Surfaces

In the past, purchasing hospital mattresses was a simple task carried out by housekeeping staff or supply custodians. Now with advanced clinical understanding of how a mattress can effect skin/wound development and healing, mattress selection has increased in importance [14, 17, 19-22, 32,36]. The choice of a medical mattress must be made with a clinical focus on therapy and treatment. A variety of support surfaces are on the market. Many manufacturers claim that their product relieves or reduces the external forces that contribute to pressure ulcer development.

Fluid Immersion System (FIS)

The U.S. Navy trained dolphins for military exercises to use their sophisticated sonar abilities. However, the transport of dolphins outside of water subjects them to the vertical shear forces of gravity causing internal organ trauma and circulatory distress. An Auto Vector surface was created in response to minimize the effects of the gravity's shearing forces. Biologics Inc. began development of a Fluid Immersion Simulation (FIS) software technology to mimic the fluid buoyancy of a body in salt water. This new technology was further developed for medical patients. Joerns Healthcare now offers the health care industry hospital beds, operating room tables, stretchers and wheelchairs with this FIS technology. Dolphin FIS software uses complex algorithms, a microprocessor and sophisticated dynamic pressure waveform analysis to precisely adjust the density of the surface for the unique anatomical features of the patient. It is reported to continuously monitor the patient's weight, three dimensional (3D) surface area and movements to automatically calculate the exact settings to effectively manage the pressure of the patient's body in the medium. The result is that the patient is truly floating, cradled in a simulated fluid environment and suspended in a near neutrally buoyant state (according to the manufacturer/product developer). Distortion to the body is minimized and orientation of bone, muscle and subcutaneous tissue is normalized (using volumetric pressure redistribution). Dolphin FIS technology is easy to use. There's virtually no programming, no manual data input, and no need for caregiver/staff intervention. Simply plug it into the wall and place the patient on the Auto Vector (mattress) surface. Auto Vector "Dolphin" Stretcher Mattress with FIS is customizable to any stretcher regardless of make or model [41-42]. Therefore, this technology could be designed to fit a NATO litter with or without the Special Medical Emergency Evacuation Device (SMEED) commonly used to support equipment with critical care aeromedical transport team (CCATT) patients. It also remains inflated up to eight hours with full operation under its own internal battery supply. This is a FDA approved commercially available product.

A Cochrane systematic review and meta-analysis of studies focusing on the effectiveness of pressure redistribution support surfaces in the prevention of pressure ulcers found good evidence that higher specification foam mattresses, sheepskin and some overlays are effective in preventing pressure ulcers. However, the benefits of high-tech constant low pressure and alternating pressure for pressure ulcer prevention are still unclear. Further research is recommended[19, 21].

Limited data exists on blood flow perfusion using the Dolphin FIS technology [32,33]. Kohanzadeh et al. (2009). [33] investigated the effect of the FIS stretcher system on the body's cutaneous microcirculation using laser doppler flow instrumentation in10 healthy subjects on a hospital gurney. Skin perfusion was measured at pressure points of the bilateral shoulders of each subject. This technique allowed investigators to monitor the dynamic changes in the microcirculation in real time. A significant difference was observed in perfusion of 90.52% vs. 22.31% on a regular gurney mattress and Dolphin FIS, respectively. This significant improvement in microcirculation using the Dolphin FIS technology when compared to regular gurney foam support mattress may result in reduced pressure sores and greater patient comfort. These results are supported from observations by Evers et al. (2009)[32]. Researchers found significantly improved blood flow on the Dolphin FIS when compared to the standard gurney/bed despite such encouraging results, the studies were small scale with limited sample sizes. Therefore, further study with this new FIS technology is recommended [33].

NATO Litter

Very little literature is published on the use of NATO litters and/or litter padding and pressure ulcer development[37,38]. The interface pressure areas were compared in two subjects on the screw and plate strip NATO litter and tacked canvas NATO litter (NATO 6530-99-138-8737). Both litter versions were evaluated without mattresses. Pressure varied greatly on the screw and plate litter than the tacked litter. Pressure was highest when the subject's sacrum rested over a ridge on the screw and plate stretcher (138 mmHg and 104 mmHg) compared with 38 and 43 mmHg on the tacked litter. The authors concluded that the tacked litter might possibly be better than the screw and plate version [38].

In a larger study, investigators explored the differences in skin interface pressures of subjects on the NATO litter (the standard canvas NATO litter with wooden poles, NSN 6530-00-783-7905) [3]. Thirty-two subjects (18 women/14 men, ages 18-55) underwent skin interface pressure measurements on multiple locations over the body (bilateral heels, calves, buttocks, scapula, elbows, occiput and sacrum) using the X Sensor pressure mapping system. The measurements were taken with subjects on various litter configurations: the litter without any padding, with a military wool blanket for padding, with the standard aeromedical evacuation (AE) litter pad and with the Baxter Maxifloat Mattress. Pressure measurements were taken with the subjects in various physical positions (supine, 30° degree lateral position with 0° degree backrest elevation and supine with 40° degree backrest elevation) for each litter iteration (with and without the padding). There was a significant and progressive decrease in peak pressures between the

litter with no padding and the litter with the AE mattress. The greatest pressure decrease was found with the Maxifloat mattress. The wool blanket added the least amount of pressure reduction (mainly in the region of the buttocks). The AE mattress reduced pressures in all areas measures when compared to the litter with no padding and the litter with the wool blanket. The Maxifloat mattress reduced pressure areas on an average of 20 mmHg more than the AE mattress. However, peak pressures over the high risk body areas (e.g. occiput, heels and sacrum) were all higher than the critical closing pressure (30 mmHg). This finding indicated a potential risk for pressure ulcer development. These peak pressures were also higher than those on the Maxifloat mattress. Elevating heels, turning or repositioning are recommended for patients at risk for pressure ulcer development. Unfortunately on an AE mission with critically injured and/or ventilated patient, turning and repositioning may not be possible. The investigators recommended further study using litter stanchions, the Raven litter and a mesh decontamination litter. They also recommended that transcutaneous oxygenation and blood flow be measured[3].

Pressure Mapping

Pressure mapping systems determine the actual pressure between the body surface and the resting platform (mattress, bed, seat cushion, etc.). The mapping system consists of a thin, sensor-filled mat with monitoring capabilities placed between the patient and the surface he's lying, sitting, or standing on. The sensors convey interface pressures to a computer, which produces a color-coded image of the pressure distribution on a computer screen. Different colors represent different pressure ranges. Typically, the colors blue and green represent lower pressure ranges while yellow, orange, and red indicate progressively higher pressure levels[15]. Although the amount of pressure and/or duration of pressure causing skin damage remain equivocal, evidence suggests that 30 mm Hg be considered the threshold for pressure measurement. Pressures ≥30 mmHg is believed to exceed capillary filling pressure, causing ischemia and skin damage [35].

6.2. Relevance/Significance:

The war wounded are not immune to pressure ulcer development and unfortunately, as a result of the severity of their injuries and the process of medical evacuation, the risk for pressure ulcer development in wounded personnel returning from Iraq and Afghanistan has increased. Furthermore, the risk for pressure ulcers was identified, with one of the major military treatment centers noting an increase in the incidence of pressure ulcers among the returning wounded [7, 43]. Pressure ulcers are characteristically more prevalent in adults ≥65 years of age due to changes associated with advanced age and failing health. They are also associated in individuals with limited or no mobility such as spinal cord injuries. The Global War on Terror has created a new population of young polytrauma patients with new challenges for the military health care system, one of which is preventing pressure ulcer development. Their injuries were most likely sustained

in a hostile and austere environment where care was focused primarily on immediate life-threatening interventions and medical evacuation to a higher level of care. Medical evacuation most likely occurred on a NATO field litter, which can produce peak interface pressures greater than 30 mm Hg over bony prominences[3] and limit tissue perfusion [35]. The combination of poly-trauma, traumatic brain injury, hypoperfusion, sedation, cervical collars, and medical evacuation places injured individuals at high risk for pressure ulcer development early in the care continuum. Finding ways to reduce or eliminate pressure ulcer development is a patient safety/quality of care issue. Interventions to help reduce/eliminate this problem as early in the continuum of care as possible would improve patient safety outcomes and raise quality of care. In the operational setting, that starts with the transport litter.

Purpose:
The purpose of this study is to measure peak skin interface pressures and the total area of the body exposed to skin interface pressures above 30 mm Hg while subjects are in the supine position. Two different support surfaces will be applied to a standard North Atlantic Treaty Organization (NATO) litter (NSN: 6530-01-380-7309) and a Raven 90C Litter (NSN6530-01-432-5114). The support surfaces are the Warrior Evacuation Litter Pad (WELP) and the Dolphin Fluid Immersion System (FIS). These pressure measurements along with transcutaneous oxygenation readings will allow us to determine differences between support surfaces.

This research protocol has one major aim:

To determine the difference in the pressure redistribution qualities between the WELP and the Dolphin FIS

There are also two secondary aims:

1. To determine the difference in the pressure redistribution qualities of the WELP when used as the mattress on the NATO litter and Raven litter.

2. To determine the difference in the pressure redistribution qualities of the Dolphin FIS when used as the mattress on the NATO litter and Raven litter.

6.3. Hypotheses or Research Questions or Objectives:

Research Questions:

1. Is there a significant difference in pressure redistribution qualities between the WELP and Dolphin FIS mattresses on the NATO Litter?

2. Is there a significant difference in the pressure redistribution qualities between the WELP and Dolphin FIS mattresses on the Raven Litter?

3. Is there a significant difference in the pressure redistribution qualities of the WELP between the NATO and Raven 90C litters?

4. Is there a significant difference in the pressure redistribution qualities of the Dolphin FIS mattress between the NATO and Raven litters?

Hypotheses:

1. Pressure redistribution qualities will be greater for subjects on the Dolphin FIS than the WELP in the supine position.

2. There is a difference in pressure distribution between men and women, given BMI level (high, ideal) for subjects on the WELP padded NATO with Raven litters.

3. There is a difference in pressure distribution between men and women, given BMI level (high, ideal) for subjects on the Dolphin FIS padded NATO with Raven litters.

4. There is a difference in pressure redistribution qualities of the WELP for subjects on the NATO and Raven litters.

5. There is a difference in pressure redistribution qualities of the Dolphin FIS for subjects on the NATO and Raven litters.

Outcome measures:

Pressure Redistribution: Peak Pressure Index & Total Surface Area (TSA)

Pressure redistribution qualities will be measured in mmHg using XSensor X3 pressure mapping technology. To minimize the risk of a faulty sensor or false reading over one sensor, the average of eight cells around the region will be recorded and referred to as the Peak Pressure Index (PPI). Peak interface pressure is the highest average pressure (mm Hg) measured over vulnerable bony prominences (occiput, sacrum, and bilateral scapula, buttocks, and heels).

TSA will be measured in centimeters squared (cm^2). Vulnerable bony prominences with skin interface pressures exceeding 30 mm Hg will be documented.

Tissue Perfusion: Transcutaneous Oxygenation:

Transcutaneous partial pressures of oxygen (tcpO2) in millimeters of mercury (mmHg) is non-invasive measurement/monitoring of the skin's surface partial pressure of oxygen. For purposes of this study, $tcpO_2$ measurements will be captured in the scapula region and expressed in mm Hg. Transcutaneous tissue perfusion has been used as the index of tissue viability by several groups [44,45,49]. From the early work of Seiler et al. (1997, 1983) [47,48], a baseline $tcpO_2$ value for

uncompressed soft tissue was established as 80 mmHg (10.7kPa). When tissue is subjected to pressure load, the $tcpO_2$ decreases dramatically due to occlusion of the blood flow underneath the pressure point. Bogie et al. (1992) [46] suggested a threshold value of $tcpO_2$ as 30 mmHg to indicate a significantly higher risk to tissue viability below this value. Bogie et al. (1995) [50] later suggested the threshold value for $tcpO_2$ as 44 mmHg.

Body Mass Index (BMI) will be obtained for men and women obtained using tools (BMI calculator and/or tables) from the U.S. Department of Health and Human Services, National Institutes of Health, Heart, Lung and Blood Institute. For the purposes of this study, BMIs will be categorized as high or ideal.

Ideal = Normal BMI of 18.5-24.9
High = Overweight BMI of 25 -29.9 and Obese BMI of 30 and above

BMI Calculator can be found at
http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

BMI tables can be found at
http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmi_tbl.htm

Demographic characteristics will be obtained to describe the study sample.

6.4. Research Design and Methods:

Research Design

This protocol is a Quasi Experimental Cross Factor study. The subject sample is nonrandomized. Subjects will be their own control and have repeated measurements to compare baseline and supine transcutaneous oxygenation levels on four different surface combinations. Interface pressure will be measured using the XSensor X3 Pressure Mapping System 32x 80 medical mattress, ½" resolution, 10,240 sensing points, 5-50 &10-200mmHg pressure range. The XSensor system uses force transducer arrays, which consist of a grid of transducers with half inch square resolution aligned in a matrix which is embedded in a 32 x 80 thin mat which is placed under the subject to map the entire body. Calibration of the pressure mapping system will be performed before and after each participant and the amount of drift evaluated. Mattress will be sanitized with disinfectant wipes between each participant. The sequence of the four surface combinations will be randomly assigned using Research Randomizer at https://www.randomizer.org for each participant. A stratified sampling scheme will be used to ensure adequate representation of the following attributes: gender, normal weight and overweight or obese as determined by BMI.

Healthy adults with authorized access to Travis AFB will be offered the opportunity to participate in this study. After the consenting process is completed, subjects will be

scheduled for study participation. If time allows, the subject may be able to participate directly after completing the consent process. The subject will be assigned an identification (ID) number which will be annotated on the consent form and all of the data collection documents. The subject's name will only appear on the study consent form. All other study documents and data collection forms will only have the subject's ID number and no other personally identifiable information (PII). Subjects will be asked to wear a nonrestrictive single layer of garments for the study. They will be given a hospital gown to wear over the upper body. This will allow the study staff easy access to the subject's back for application of the transcutaneous oxygenation transducers. Females will not be required to remove their bra. Subjects will be asked their age and have their height and weight measured by a study team member. They will also be asked their litter and mattress preferences at the end of the study. The study portion should take approximately two hours to complete and can be broken into segments for multiple visits if necessary to accommodate a subjects schedule.

Prior to skin oximetry readings, subjects will be asked to refrain from exercising, smoking and drinking caffeinated beverages for at least two hours before data collection. These readings will be performed using specialized equipment from the DGMC hyperbaric clinic. Bilateral transcutaneous oxygenation will be obtained using a radiometer or Perimed™ instrument and by placing electrochemical transducers bilaterally in the region of the subject's scapula. The transducers and probes will be affixed to the skin after the site has been cleaned. To increase permeability of the skin to oxygen at the measuring sites, transducers will be heated to 44° C (111.2°F). After a calibration period of approximately 10-15 minutes, a constant transcutaneous partial pressure of oxygen will be obtained and recorded onto the patient data sheet. Baseline measurements will then be obtained (about five additional minutes) with the subject sitting upright and no pressure applied to the back.

Next, the subject will be asked to lay supine on the first of four randomly assigned litter mattress combinations. Because the litters will be resting on top of stands, special care will be taken by study team members to ensure subjects safely mount and dismount litters without injury. Subjects will be secured to the litters in accordance with Aeromedical Evacuation Equipment Standards (AFI10-2909, 23 July 2013 pages 73-74).

"5.4.4.1. The patient is placed on the litter, covered with the sheet and blanket as necessary, and secured to the litter with 2 ***litter straps****. The straps are placed mid-thigh and on the upper chest of the patient. Secure the litter straps so the buckles are on the aisle side of the litter, and lay the excess strap flat over the patient. DO NOT tie the excess strap in a knot. Litter straps will be visible for inspection.*
5.4.4.2. A mattress pad is recommended to prevent skin breakdown."

After the subject is positioned comfortably on the litter, the pressure mapping will begin. The peak interface pressure (the highest average pressure (mm Hg) measured over each

body region) will be measured for the occiput, sacrum, bilateral scapula, buttocks and heel areas. The total body surface area exposed to skin interface pressure greater than 30mm Hg will also be measured in centimeters squared (cm^2) for each body region. Measures of tissue perfusion using the $tcpO_2$ in mmHg will be measured for comparison to baseline data. This process will take approximately twenty minutes for each of the four iterations. An additional 30 minutes is required to change the litter and mattress configurations. After baseline data are captured and tcpO2 measurements are taken with the subject supine on all four litter/mattress combinations, the session is complete. Data from subjects who do not complete all four litter/mattress combinations will be excluded from the analysis. An estimated 25% attrition rate is factored into this study to ensure that 43 completed data sets are obtained.

6.5. Risks/Benefits:

- There is a potential risk of injury from falling off the litter while attempting to mount or dismount. This risk will be minimized by having a member of the research staff present whenever a subject is on the litter. Staff will be available to assist participants on and off the litter. A step stool will also be available to assist participants in safely mounting and dismounting the litter.

- There is also a potential risk of skin reaction to the adhesive which will hold the transcutaneous oxygenation transducers in place. If a participant shows signs and/or symptoms of skin irritation from the adhesive (redness, itching, rash or hives), the adhesive will be removed and the participant will be encouraged to see their primary care provider if the signs and/or symptoms do not quickly resolve or becomes worse after the adhesive is removed. If the participant's initial reaction to the adhesive pads is severe (difficulty breathing, face/lips, throat swelling, loss of consciousness) the subject will be taken to the DGMC Emergency Department for treatment.

- There is a potential risk of superficial burn from the $tcpO_2$ transducers. They are heated to 44 degrees Celsius which is 111.2 degrees Fahrenheit. If a participant shows signs and/or symptoms of skin irritation (redness) or complains of burning, stinging or discomfort in the area of the transducers, the transducers will be removed and the participant will be encouraged to see their primary care provider if the signs and or symptoms do not quickly resolve or become worse. If the participant needs immediate medical assistance, they will be taken to the DGMC emergency department for treatment.

- There is no anticipated individual benefit to subjects attributed to participation in this study. Given the economic and overall health impact of pressure ulcer development, a litter mattress system that can help reduce and/or eliminate pressure sore development will be beneficial to military patients in theater and during transport.

6.6. Subject Population

Age Range: ☒ ≥ 18 y/o ☐ Children (≤ 18)

Sex: ☒ Male ☒ Female

Vulnerable Population: ☒ No ☐ Yes (explain)

Number of Subjects:

- Total Number of Subjects (nation-wide/study-wide): 43
- Number of Subjects Planned for DGMC: 43
- Number of Subjects Planned for (Specify Institution): N/A

Statistical tests will be 2-tailed with a significance level of 0.05. A 25% attrition rate is expected. A total of 53 subjects will be recruited in order to obtain 43 evaluable subjects with complete data sets.

Inclusion/Exclusion Criteria:

Inclusion:

- Adults over the age of 18 years with lawful access to Travis AFB.

Exclusion:

- Orthopedic or neurological conditions that prevent a subject from lying flat (supine) without any pillows for head, neck, or lumbar support
- Medical conditions (such as an uncontrollable tremor or twitch) that prevent a subject from staying still for the required periods of time (20 minute increments).
- Pregnancy
- Inability to ambulate unassisted, unstable gate (presenting increased fall risk)
- Extremity prosthetics (hand/arm or foot/leg)
- Height greater than 72inches (6 feet) - exceeds length of the litter & mattress surfaces
- Body weight greater than 300 lbs

- Subjects who find it difficult, uncomfortable or impossible to remain still for the necessary study time durations (20 minute increments) on the relatively narrow litter surfaces will be removed from the study.

- Subject does not speak or understand the English language

Recruitment:

1. **Fliers** – Will be posted throughout DGMC in approved/authorized locations such as Heart, Lung & Vascular, Family Medicine, Family Health, Internal Medicine and Flight Medicine clinics, cafeteria, elevators and other public areas. Advertisement posters/fliers will also be posted and briefed in other public buildings on Travis AFB in order to ensure recruitment of a sample representative of the active duty population. Research coordinators may also sit near advertisement posters in the clinic waiting room, common areas and cafeteria to answer any potential participant's questions.

2. **Pamphlets** – Will be placed in the waiting rooms of primary care clinics, base gym, Base Exchange (BX), hospital cafeteria and Grant Central Station.

3. **E-mail/Newspaper** – The research team may elect to advertise the study via e-mail sent out by Wing public affairs office. The research team may also elect to advertise via Air Force newspaper publications or other military newspapers at surrounding bases.

4. **Marquee** – Base and MDG

Consent:

Subjects that have expressed interest in the study will be scheduled for an informed consent review/initial visit at the Clinical Investigation Facility (CIF). The subject will be brought to a private exam room or office where they will be individually consented by the research coordinator, PI or other qualified research team member. The study team member will explain the nature and scope of this study, discuss potential risks and benefits of participation, answer questions and ensure the subject fully understands the informed consent document. The study will be explained to the subject in lay terms. At least one hour of study staff time will be set aside for each participant to receive information, ask questions and consider participation in the study. The subject may elect to discuss the study with others if they so choose, prior to agreeing to participate. If the subject agrees to participate, the IRB approved informed consent document will be signed and dated by the subject and primary investigator or another delegated research team member. A copy of the signed consent form will be made and provided to the subject. The original signed consent form will be turned into the protocol office and a copy will be placed in the subject's study folder. The study folder will be stored in a locked filing cabinet in an office that is locked when the office owner is not in the room. Subjects will be assured that they may withdraw from the study at any time for any reason and their medical treatment will not be

compromised. Research procedures will not start until the IRB approved informed consent document has been signed and dated by the subject and research team member.

6.7. Safeguards for Protecting Subjects:

- All subjects will be treated in compliance with AFI 40-402 and applicable FDA and DHHS guidelines.
- Subjects will be monitored by study staff members at all times while on a litter to reduce the risk of falling off the litter.
- Study staff members will observe and assist subjects as needed when getting on and off of the litter to reduce the subject's fall risk.
- A step stool will be available to assist subjects in safely getting onto and off of the litter.
- Subjects will be assigned an ID number after they are consented. This ID number will be used to protect subject privacy and ensure confidentiality of recorded data. Subject's protected health information will not be accessed or recorded during this research protocol.

- **Data Entry:** Data will be entered by authorized study personnel only. Upon completion of data entry all hard copy documents will be stored as per the hard copy records policy outlined below. All electronic data will be housed on the DGMC computer drive and will only be accessible via a Common Access Card enabled computer accessible only to study personnel within a secured office. All electronic transmissions of data will be encrypted over a secured network.

- **Data security and transfer:** Study documents will reside in the Clinical Investigation Facility within the 60MDG SGSE Directory in a limited access password protected directory designated exclusively to the study. Access will be granted only to study personnel.

- **AES Encryption:** To be in compliance with Government regulations study personnel will utilize 128 bit AES encryption. AES is widely used across the government healthcare sector to secure data-at-rest, data-in-motion and data-in-transit. All data transfers will be made via (password protected CD, encrypted Electronic Mail, Secured FTP server, etc.). All data files will utilize the Advanced Encryption Standard approved cryptographic algorithm used to protect electronic data.

- **Hard Copy Records:** A copy of the IRB approved informed consent signed and dated by the study subject and designee will be provided to the subject. The original signed and dated IRB approved informed consent form will be placed with other study records, in a locked cabinet and secured area within the IRB Protocol Office at the Clinical Investigation Facility. A copy of the records will be in the coordinators offices located in the Internal Medicine Clinic. These records will be accessible only to study personnel, the IRB, and employees of authorized Federal departments and regulatory agencies. Duplicates will be provided to the volunteer upon written request.

6.8. Data Collection/Analysis:

A sample size of 43 subjects is required for this study. This is similar to the sample size used by Col Elizabeth Bridges and colleagues in a study of skin interface pressure on a NATO litter[3]. In their study, a stratified sample (n= 32) with four support surfaces using a single canvas style NATO litter was used. The surface effect was statistically significant for all peak pressure and surface area analyses (repeated-measures analysis of variance, $p < 0.01$, α 0.05, β 0.20). Interface pressure will be measured using XSensor X3 Pressure Mapping 32x 80 medical mattress, 5-50 &10-200mmHg pressure range. The XSensor system uses force transducer arrays, which consist of a grid of transducers with half inch square resolution aligned in a matrix which is embedded in a 32 x 80 inch thin mat. This mat is placed under the subject to map their entire body. Calibration will be performed before and after each participant and the amount of drift evaluated. Mattress will be sanitized with disinfectant wipes between each participant.

A stratified sampling scheme will be used to ensure adequate representation of the following attributes: gender, normal weight and overweight or obese as determined by BMI.

The dependent variables (pressure mapping index = mmHg, Total body surface area (TSA) greater than 30 mmHg = cm^2; transcutaneous oxygenation ($tcpO_2$) = mm Hg) will be measured on four different support surface combinations using the independent variables – litters/mattresses: (1) NATO litter with the WELP; (2) NATO litter with the Dolphin FIS; (3) Raven litter with the WELP and (4) Raven litter with the Dolphin FIS.

The subjects will service as their own controls. Baseline measures of $tcpO_2$ over bilateral scapular regions will be taken with the subjects sitting upright prior to having them lay supine on the support surfaces for pressure mapping with repeated $tcpO_2$ measurements.

Data collected will include the subject's age, race, gender, height and weight the weight will be measured on a calibrated scale.

Subject height and weight will used to determine their BMI.

BMI is an individual's weight (in kilograms) divided by their height squared (in centimeters). The BMI calculator or tables from the U.S. Department of Health and Human Services National Institutes of Health (NIH) web will be used to calculate BMI for this study.
http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmi_tbl.htm

NIH BMI Categories:	For the Purposes of this study: BMI
Underweight = <18.5	
Normal weight = 18.5–24.9	Ideal = 18.5-24.9
Overweight = 25–29.9	High = 25 or greater
Obesity = BMI of 30 or greater	

This is a cross-factor design that will use a Repeated Measures Analysis of Variance (ANOVA) model to examine the effects of within and between factors. Mean change in $tcpO_2$ (mmHg), LDP pressure units, surface area ($cm^{2)}$ will be computed. All analyses will be done using STATA v 13.0 (College Station, TX).

Source of Research Material per Participant:

Source of Research Material per Participant	Standard Care	Research Driven
Demographic Data	0	1
Age in years (89+ for anyone over 89 years of age)	0	1
Gender – Male or Female	0	1
Body Mass Index (BMI)	0	1
Height (centimeters/inches)	0	1
Weight (pounds/kilograms)	0	1
Pressure Mapping (mmHg) - NATO Litter (WELP)	0	1
Transcutaneous Oxygenation (TcpO2) mmHg	0	4
Pressure Mapping (mmHg) - NATO Litter (FIS)	0	1
Transcutaneous Oxygenation (TcpO2) mmHg	0	4
Pressure Mapping (mmHg) – Raven Litter (WELP)	0	1
Transcutaneous Oxygenation ($TcpO_2$) mmHg	0	4
Pressure Mapping (mmHg) - Raven Litter (FIS)	0	1
Transcutaneous Oxygenation ($TcpO_2$) mmHg	0	4

7. Conflict of Interest

None

8. Investigation Schedule

Estimated Timeline: IRB approval estimated for May 2016. PI PCS'd and alternate deployed, therefore, anticipated protocol start date Jan 2018 protocol start (need additional equipment, supplies, also requesting additional funding).

	Jan 2018 Y2Q2	Y2 Q3	Y2 Q3	Y2 Q4	Y3 Q1	Y3 Q2	Y3 Q3	Y3 Q4
Recruitment	X	X	X	X				
Enrollment	X	X	X	X	X	X		

Data Collection	X	X	X	X	X	X		
Statistical Analysis						X	X	
Publications/Reports						X	X	X

9. Use of Investigational Drug(s) ☒ No ☐ Yes

10. Use of Investigational Device(s) ☒ No ☐ Yes

11. Support Required

CIF Support:
Administrative, bio-statistician consultation and Clinical Research Coordinator to help with subject recruitment, informed consent process and data collection support is required. (See attachments for Letter of Support).

Other Support:

DGMC Hyperbaric Clinic: Staff and equipment for Transcutaneous Oximetry ($tcpO_2$) (see attachments for Letter of Support).

See attached Letters of Support

12. Budget, Equipment, and Supplies:
Requesting Funds: ☒Yes ☐No

☒R&D ☐O&M ☐HMJ ☐OTHER (explain source):

Study Year	Item Description	Unit of Issue (UOI)	Cost/UOI	Quantity	Total Cost
2015	Dolphin FIS	1	19,470.00	1	19,470.00
2015	X3 Sensor Sleeves	100	150.00	1	150.00
2015	NATO Litter NSN: 6530-01-380-7309	1	397.78	1	397.78
2015	Litter Raven 90C NSN: 6530-01-432-5114	1	391.25	1	391.25
2015	Litter Stands NSN: 6530-01-618-7419	1 pair	778.00	2	1556.00
2015	Mattress Litter	1	320.00	1	320.00

2016	Dell Laptop Computer	1	3,368.39	1	3,368.39
2016	XSENSOR X3 Pressure Mapping System	1	12,650.75	1	12,650.75
2016	Biopac® Laser Doppler package (includes: MP-160, LDF 100c, LDF Probe TSD 140)	1 - MP-160 2 - LDF 100c 2 – LDF Probe TSD	31,000	1	31,000
2016	TCOM probes	1	1,500	2	3,000
2016	TCOM Fixation rings	1 Box of 100	150.00	2	300.00
2016	TCOM membrane	1 Box of 12	132.31	10	1,323.10

☒ I understand that the funding is the responsibility of the PI, which includes; management, tracking, recording and must be reported to the IRB annually with your continuation report.

13. Manpower

Rank	AFSC	# hours duty time	# hours off-duty time
Col	46N3	80	40
Lt Col	46N3	240	40
CRC	Civ/CTR	80	0
CRC	Civ/CTR		0
CRN	CTR	40	0
CRN	CTR	40	0
RA	CTR	80	0
RA	CTR	80	0

14. Institutional Official (IO)

(name redacted 23 Jan 20), Col, USAF, MC
Commander, 60th Medical Group

David Grant USAF Medical Center, Travis AFB, CA
(contact information redacted 23 Jan 20)

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16. Attachments:

1. CIF Letter of Support
2. DGMC Hyperbarics Clinic Letter of Support

17. Commander's Acknowledgment of Review and Approval

Principal Investigator: I am aware that I am not authorized to accept any funds or other form of compensation for conducting research. All subjects will be treated in compliance with applicable Air Force, DOD and federal regulations, as well as applicable FDA and DHHS guidelines. I have read, understand, and signed the attached Certificate of Compliance. I understand I must complete a review of this protocol at least every 12 months to prevent expiration of the study's approval. I will notify the protocol office **prior** to relocations, separation actions, or closure.

☐ Initial Submission
(ALL signatures required)

☒ Amendment Submission
(PI signature ONLY)

information redacted 23 Jan 20

_____ 23 Oct 2019
Date