Development of a Novel Cooling Vest to Prevent Heat-Induced Thermoregulatory Dysfunction in Persons with Spinal Cord Injury

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Subject Name:	**Informed Consent Date:**
Protocol #:1696610 **Principal Investigator: John P. Handrakis, PT, DPT, EdD, NCS**	**VAMC: James J Peters**
Title of Study: Development of a Novel Cooling Vest to Prevent Heat-Induced Thermoregulatory Dysfunction in Persons with Spinal Cord Injury	

1. Purpose of study and how long it will last:

You are being asked to participate in a research study to determine the safety and usefulness of using a cooling vest in warm conditions. To be eligible for this study, you must have a high-level spinal cord injury (Hi-SCI: C4-T2) rated as ASIA Impairment Scale A or B (unable to voluntarily move your legs) for more than one year or be an able-bodied (AB) control subject. You must also be between 18 and 68 years old.

If you are an AB control, the purpose of this 1-day study is to determine 1) the temperature of your skin underneath the vest and 2) how cool and comfortable the cooling vest feels to you. We will measure the temperature of your skin inside the vest, your inner ear temperature, blood flow of your skin at 2 areas on your arm and 2 on your leg, sweat rate of your arm and leg, your sensation of the temperature of the cool vest, and your comfort of the temperature of the vest when you are wearing it in a warm room for up to 2 hours.

If you are a person with Hi-SCI, the purpose of this 2-day study is to compare 1) your body's core temperature, measured by a disposable forehead skin temperature sensor (Bair Hugger™ Spot On™ Temperature Monitoring System, 3M, Maplewood, Minnesota). and 2) your general sensation of temperature and your comfort to the temperature of the room **during 2 different conditions**: ***one*** while wearing the wet cooling vest (*wet vest*) and ***two*** while wearing only shorts and a T-shirt (*no vest*), while in a warm room (95° F) for up to 2 hours. We will also measure your skin temperature, inner ear temperature, skin blood flow of your arm and leg, and sweat rate of your arm and leg.

You will not be able to participate if any of the following apply to you. You do not have to tell the investigators which statement applies, only that you cannot participate.

- **I have cardiovascular, kidney, or untreated thyroid disease**
- **I have a traumatic brain injury (TBI)**
- **I have diabetes mellitus**
- **I have an acute illness or infection**
- **I am dehydrated**
- **I smoke**
- **I am pregnant**
- **I have broken, inflamed, or otherwise fragile skin**
- **My Body Mass Index (BMI) is more than 30 kg/m^2**

This study will be 1 visit for AB control participants and 2 visits for participants with Hi-SCI. You will be 1 of 17 participants in this study. Funds for this research are provided by the VA Rehabilitation Research & Development (RR&D) Small Projects in Rehabilitation Research (SPiRE).

2. Description of the Study Including Procedures to be Used:

If you consent to participate in this research study, you will be asked to come to room 7A- 13 in the James J. Peters Veterans Affairs Medical Center (JJP VAMC). All procedures are done for research purposes.

If you are an AB control, we will measure your skin temperature, inner ear temperature, sweat rate, and skin blood flow, your heart rate, blood oxygen saturation, and blood pressure, your sensation of the temperature of your skin, and your comfort to the temperature of the vest you're wearing. Your participation will last for 3 hours and will involve 1 visit. This 1-day study is designed to determine the temperature of your skin when the cooling vest is turned on, how cool you feel the inside of the vest is when next to your skin, and your personal comfort to the temperature, while you are wearing the wet cooling vest and sitting in a warm (95° F) room for up to 2 hours.

If you are a person with Hi-SCI, we will measure your body's core temperature (with a disposable forehead skin temperature sensor (Bair Hugger™ Spot On™ Temperature Monitoring System, 3M, Maplewood, Minnesota).), your skin temperature, inner ear temperature, sweat rate and skin blood flow of your arm and leg, blood pressure, heart rate, and blood oxygen saturation. We will ask you how warm or cool you feel (thermal sensation), and your personal comfort to the temperature of the room (thermal comfort). Your participation in this study will involve 2 visits (4 hours per visit) over the course of 1-2 weeks. This 2-day study is designed to determine your body's ability to maintain a constant body temperature (typically about 98.6° F) and your thermal comfort while sitting in a warm (95° F) room for up to 2 hours. During one visit, you will wear the wet cooling vest and during the other visit, you will wear only shorts and a T-shirt (or sports bra for females). We will compare how much each condition (*wet cooling vest*, *no vest*) affects your core temperature and your thermal comfort (ability to stay comfortable).

Preparation for Study Visits: You will be asked to come to room 7A-13 of the JJP VA MC between 8:00-10:00 AM for each visit. You will be asked to eat a plain bagel or 2 pieces of toast 2 hours prior to your scheduled visit time. For each visit you will be asked to empty your bladder before your arrival and again upon arrival, if needed. You will be asked to avoid caffeinated and alcoholic beverages and heavy exertion for 24-hours before testing. During the study, you will be asked to wear shorts and a T-shirt.

Pre-Baseline Instrumentation:

If you are an AB control, skin temperature sensors will be taped to your skin at 12 different places on the front and back of your trunk (chest and stomach). A laser sensor will be used to measure the blood flow in the skin of your forearm and calf. Capsules will be strapped to your left upper arm, left forearm, left upper leg, and left calf to measure how much you sweat. A blood pressure cuff will be placed above one elbow to measure your blood pressure (BP) and your heart rate (HR). An oximeter will be placed on the index finger to measure the amount of oxygen in your blood (blood oxygen saturation).

If you are a person with Hi-SCI,a disposable forehead skin temperature sensor (Bair Hugger™ Spot On™ Temperature Monitoring System, 3M, Maplewood, Minnesota). and skin temperature sensors will be taped to your skin at 10 different places on the front and back of your trunk (chest and stomach) and on each hand and foot (total of 14 skin temperature sensors). Capsules will be strapped to your left upper arm, left forearm, left upper leg, and left calf to measure how much you sweat. A laser sensor will be used to measure blood flow in the skin of your forearm and calf. A blood pressure cuff will be placed above one elbow to measure your blood pressure (BP) and heart rate (HR).

Baseline Collection (15 minutes): After resting in the seated position in your wheelchair (wheelchair and seat cushion provided for AB controls) for 30 minutes (acclimation) in the set-up room at room temperature (77°F), we will start collecting baseline data for 15 minutes.

If you are an AB control, skin temperature will be measured continuously, skin blood flow will be measured for 5 minutes every 10 minutes. Inner ear temperature, BP, blood oxygen saturation and HR will be measured every 10 minutes. BP will be assessed right before and after skin blood flow measurement. Sweat rate will be measured for 15

minutes during baseline. You will be asked about the sensation of your skin temperature on a 9-point scale and your thermal comfort on a 6-point scale every 10 minutes.
If you are a person with Hi-SCI, Core body temperature with a disposable forehead skin temperature sensor (Bair Hugger™ Spot On™ Temperature Monitoring System, 3M, Maplewood, Minnesota). and skin temperature will be measured continuously. Skin blood flow will be measured for 5 minutes every 10 minutes. Inner ear temperature, BP, blood oxygen saturation, and HR will be measured every 10 minutes. BP will be measured before and after skin blood flow measurement. Sweat rate will be measured for 15 minutes. You will be asked about your general sensation of temperature that you feel (Thermal sensation) on a 9-point scale and personal thermal comfort on a 6-point scale every 10 minutes.

Thermal Challenge (120 minutes): Following the completion of Baseline, you will be wheeled into a warm (95°F) thermal room for a maximum of 2 hours.
If you are an AB control, you will be fitted with a wet cooling vest. Data collection will continue as it did in baseline. Skin temperature will be collected continuously, skin blood flow will be measured for 5 minutes at 20-minute intervals (5 times total), and inner ear temperature, BP, blood oxygen saturation, and HR will be measured every 10 minutes. BP will be measured right before and after skin blood flow measurements. Sweat rate will be measured for 15 minutes every 30 minutes (4 times total). You will be asked about the sensation of the vest's temperature on your skin on a 9-point scale (Thermal sensation) and your personal thermal comfort on a 6-point scale (Thermal comfort) every 10 minutes. If at any time you feel uncomfortably warm or wish to end the thermal challenge, the visit will stop and you will be transferred to a cool room (70°F), covered with cooling blankets, and given cold fluids. If your symptoms continue, the study physician will assess you and provide the appropriate care.
If you are a person with Hi-SCI, you will be fitted with a wet cooling vest or no vest (chosen randomly) during Visit 1. Core body temperature and skin temperature will be collected continuously, skin blood flow will be measured for 5 minutes at 20-minute intervals (6 times total), and inner ear temperature, BP, blood oxygen saturation and HR will be measured every 10 minutes. BP will be measured right before and after skin blood flow measurements. Sweat rate will be measured for 15 minutes, every 30

minutes (4 times total). You will be asked about the general sensation of temperature that you feel (Thermal sensation) on a 9-point scale and general feeling of comfort related to your general sensation of temperature (Thermal comfort) on a 6-point scale, every 10 minutes.

If at any time your core body temperature from the Bair Hugger™ Spot On™ Temperature Monitoring System sensor reaches 100.4°F, you feel uncomfortably warm, or uncomfortable for any reason, the visit will stop and you will be transferred to a cool room (70°F), covered with cooling blankets, and given cold fluids. If your symptoms continue, the study physician will assess you and provide the appropriate care.
During Visit 2, you will do the same thermal challenge with either the *wet cooling vest* or *no vest* (whichever condition you have not done yet). The same procedures performed during Visit 1 will be performed again on Visit 2.

Procedure Details:
Cooling Vest (all subjects): An appropriately sized cooling vest will be fitted for each subject. When turned on, it will circulate cool water through the vest to help remove heat from the body. The outer surface of the vest will be sprayed with water for evaporative cooling.
Skin Temperature (Tsk) (all subjects): Skin temperature will be measured by sensors taped to your skin at 12 areas for AB controls (6 sensors on each side of your trunk) and 14 areas for persons with tetraplegia (5 sensors on each side of your trunk and 1 on each hand and foot). Skin temperatures will be measured continuously for 15 minutes during Baseline and continuously throughout the Thermal Challenge period for every visit.
Inner Ear Temperature (all subjects): Inner ear temperature (tympanic temperature) will be measured using an infrared heat-sensing thermometer. It will be measured every 10 minutes during Baseline and every 10 minutes during the Thermal Challenge for every visit.
Blood Pressure (BP), Blood Oxygen Saturation and Heart Rate (HR) (all subjects): Blood Pressure will be measured at your upper arm. Baseline BP will be measured every 10 minutes during Baseline and every 10 minutes during the Thermal Challenge

for every visit. BP will be measured immediately before and after measurement of skin blood flow. Blood oxygen saturation will be measured at your index finger every 10 minutes during baseline and the thermal challenge.

Thermal Sensation (all subjects): You will be asked to rate how warm or cool your skin feels if you are an AB subject or, if you are a subject with Hi-SCI, how your temperature generally feels, on a 9-point scale: +4 (very hot), +3 (hot), +2 (warm), +1 (slightly warm), 0 (neutral), -1 (slightly cool), -2 (cool), -3 (cold), -4 (very cold). You will be asked about your thermal sensation and comfort every 10 minutes during Baseline and every 10 minutes during the Thermal Challenge for every visit.

Thermal Comfort (all subjects): You will be asked to rate how comfortable your body temperature feels on a 6-point scale: +3 (very comfortable), +2 (comfortable), +1 (just comfortable), -1 (just uncomfortable), -2 (uncomfortable), -3 (very uncomfortable). You will be asked every 10 minutes during Baseline and every 10 minutes during the Thermal Challenge for every visit.

Skin Blood Flow (all subjects): The blood flow to your skin will be measured by a laser light-emitting sensor taped to the skin of both your forearms and calves. Skin blood flow will be recorded for 5 minutes at 10-minute intervals during Baseline and for 5 minutes at 20-minute intervals during the Thermal Challenge for every visit.

Core Body Temperature (subjects with Hi-SCI only): Core temperature will be measured using the Bair Hugger™ Spot On™ Temperature Monitoring System, a disposable forehead skin temperature sensor. Your body's core temperature will be continuously measured and recorded during the 15 minutes of the baseline period (thermoneutral room) and throughout Thermal Challenge period (warm room) for both visits.

Sweat Rate and Volume: Your sweat rate will be measured by capsules that will be strapped to your right upper arm, right forearm, right upper leg, and right calf to measure how much you sweat. Sweat rate will be recorded for 15 minutes during the baseline period, and for 15 minutes, every 30 minutes during the Thermal Challenge Period for every visit.

During this study we may see something that should be checked by your primary care doctor. If that happens, we will call you within a week of the test to let you know. We will then send the findings to your primary care doctor. If you do not have a primary care doctor, we will refer you to one within the VA system. Please note that we are not specifically looking for any medical problems so it is unlikely that we will find any underlying issues. These tests are not the same as regular medical care.

Table 1: Schedule of Assessments and Procedures

Measures	Acclimation	BL	Thermal Challenge
Run Time (min)	30	15	120
Cumulative Time (min)	30	45	165
*Tcore		††	††
Skin Temperatures		††	††
Inner Ear Temperature		2x	12x
Sweat Rate and Volume		1x	4x
Thermal Sensation	1x	2x	12x
Thermal Comfort	1x	2x	12x
Laser Doppler Flow		2x	6x
Brachial BP, O2 sat		2x	12x

†† Tcore and skin temperature measurements will be monitored and collected simultaneously throughout the study. *Tcore in persons with Hi-SCI only.

3. Description of any Procedures that may Result in Discomfort or Inconvenience:

Cooling Vest (all subjects): You may feel cool or uncomfortable in the cooling vest, but we will make adjustments as needed to ensure comfort and safety at all times.
Inner Ear Temperature (all subjects): Inner ear temperature measurement is non-invasive and should not cause any discomfort.

Skin Temperature (Tsk) (all subjects): Skin temperature measurement is non-invasive and should not cause any discomfort. Removing the tape may be uncomfortable at the end of each visit.
Blood Pressure (BP) and Heart Rate (HR) (all subjects): BP and HR measurement is non-invasive and should not cause any discomfort. You may find the pressure of the cuff around your upper arm uncomfortable.
Thermal Sensation (all subjects): Measurement of how warm/cool you feel is non-invasive and should not cause any discomfort.
Thermal Comfort (all subjects): Measurement of how comfortable you feel is non-invasive and should not cause any discomfort.
Skin Blood Flow (all subjects): Measurement of blood flow in your skin is non-invasive and should not cause any discomfort.
Core Body Temperature (subjects with Hi-SCI only): The disposable forehead skin temperature sensor (Bair Hugger™ Spot On™ Temperature Monitoring System, 3M, Maplewood, Minnesota) is non-invasive and not associated with any risks. Removing of the adhesive disposable skin sensor may be uncomfortable at the end of each visit.
Sweat Rate and Volume: Your sweat rate and volume measurement is non-invasive and should not cause any discomfort. However, you may find the capsule fasteners to be uncomfortable. We will ensure the fasteners are fitted properly to minimize that discomfort.

Since this research may have unknown effects on an unborn child and should not be done during pregnancy, it is necessary for a pregnancy test to be done first. To your knowledge you are not pregnant at the present time. You also agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study. You should know that your female partner should not become pregnant, once you agree to participate in this study. Therefore, take all precautions to prevent pregnancy.

4. Expected Risks of Study:

Cooling Vest (all subjects): There is a slight risk your skin will get irritated while wearing the cooling vest. This risk will be minimized by instructing you to wear a T-shirt between the vest and your bare skin. We will carefully monitor your skin temperature

and turn the vest off or remove it if we notice unusually low temperatures or if you complain of discomfort. The risk of a skin injury is low because the main components of the vest are commercially available. We have added safety and additional cooling components to that vest. It has been fully lab-tested and fulfilled all safety requirements. There are safety measures built into the vest to either not cool as much or shut down cooling, if your skin temperature decreases too much.

Inner Ear Temperature (all subjects): Inner ear temperature measurement is non-invasive and is not associated with risks.

Skin Temperature (Tsk) (all subjects): Skin temperature measurement is non-invasive and is not associated with risks.

Blood Pressure (BP), Blood Oxygen Saturation, and Heart Rate (HR) (all subjects): BP, oxygen saturation, and HR measurement is non-invasive and not associated with risks.

Thermal Sensation (all subjects): Measurement of how warm/cool you feel is non-invasive and not associated with risks.

Thermal Comfort (all subjects): Measurement of how comfortable you feel is non-invasive and not associated with risks.

Skin Blood Flow (all subjects): Skin blood flow measurement is non-invasive and not associated with risks.

Core Body Temperature (subjects with Hi-SCI only): The disposable forehead skin temperature sensor (Bair Hugger™ Spot On™ Temperature Monitoring System, 3M, Maplewood, Minnesota) is non-invasive and not associated with any risks. Removing of the adhesive disposable skin sensor may be uncomfortable at the end of each visit.

Sweat Rate: The measurement of sweat rate and volume is noninvasive and is not associated with risks.

Thermal Challenge: There is a risk of hyperthermia with being in the warm (95°F) thermal room for 2 hours. To minimize this risk, your core temperature, skin temperature will be continuously monitored to ensure your safety throughout the visit, while your BP and HR will be measured every 10 minutes. If your core temperature increases to 100.4°F or if you feel discomfort (uncomfortably hot), the visit will be stopped and you will be transferred to a cool room (70°F), covered with cool, heat-absorbing blankets,

and given cool fluids. Your temperature will be monitored for a minimum of 30 minutes during the recovery period to ensure that it returns close to your baseline value.

Autonomic dysreflexia (AD): If you have a SCI above T6 (Hi-SCI), there is a potential risk of AD. We will check for the symptoms of AD (sudden high blood pressure, pounding headache, etc.) every 10 minutes. This risk is lowered because we check blood pressure every 10 minutes, and you are seated throughout the study.

Hypotension: There is a potential risk of hypotension. We will check for the symptoms of hypotension (sudden low blood pressure, dizziness, lightheaded, feeling faint, etc.) every 10 minutes. This risk is lowered because we check blood pressure every 10 minutes and have you report any symptoms immediately.

Subject modesty: You will wear a standard T-shirt and pair of shorts during the study. This may cause potential embarrassment, but we limit your exposure to the area of the study and to the few research team members.

There may be risks that are unknown.
Since this research may have unknown effects on an unborn child and should not be done during pregnancy, it is necessary for a pregnancy test to be done first. By providing consent, you affirm that, to your knowledge, you are not pregnant at the present time. You also agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study.

5. Expected Benefits of the Study:

There may be no direct benefit to you from this study. But any information we get from this study will help others.

6. Other Treatments Available:

The procedures in this study are for research purposes only. There are no alternative procedures or courses of treatment. Participation in the study is voluntary.

7. Use of Research Results:

We will let you and your physician know of any significant new findings made during this study which may affect your willingness to participate in this study. Access to the research results generated from this study will be limited to Dr. Handrakis and his research team. These research materials will remain under their possession. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

Your medical records will be maintained according to this medical center's requirements and all electronic and hardcopy Research Records are currently not scheduled for destruction and will not be destroyed. Hard copies of your data are stored in locked cabinets in locked rooms in the James J. Peters VAMC Room 7A-13. Any code linking identities to data is stored separately from the data, electronically behind the VA firewall or hard copy in a locked cabinet in a locked room inside the James J. Peters VAMC. Thus, we will safely store your data in a data repository. Records will be retained according to National Archives and Records Administration, in accordance with Records Schedule RCS-10-1. Research Investigator Files and provide the planned practice for this study within the schedule requirements.

☐ _____By checking and initialing this box, you agree to be contacted by the Principal Investigator or his investigative team at a future date for additional studies being conducted in the National Center for the Medical Consequences of SCI.
In order to comply with federal regulations, research records identifying you may be reviewed by the following: Representatives of the sponsor of this study (VA RR&D), Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), and the Office for Human Research Protections (OHRP)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

8. Special Circumstances:

If you are a patient, a copy of this consent form will be placed in your medical record.

9. Compensation and/or Treatment in the Event of Injury:

The VA must provide necessary medical treatment in accordance with applicable federal regulations to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees.

10. Voluntary Participation:

You are not required to take part in this study; your participation is entirely voluntary and you can refuse to participate in this study or withdraw your participation in this study after you consent, without penalty or loss of VA or other benefits to which you are entitled. You will receive compensation for the time you spent before withdrawing.

11. Termination of Participation:

You can refuse to participate now, or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment if you are a patient. The investigator also has the right to withdraw you from the study at any time for reasons including, but not limited to, medical concerns (your health and safety are in jeopardy with continued participate in the study), non-compliance (you miss several scheduled appointments without notification), and protocol deviations (exclusion/inclusion criteria change and you are no longer eligible to participate).

12. Costs and Reimbursements:

As a veteran or non-veteran, you will not be charged for any treatments or procedures that are part of this study. For veterans who are required to pay co-payments for

medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study.
If you are an AB control, you will receive a stipend of $75 for your participation in this study to help cover any costs of transportation and time away from work.
If you are a person with Hi-SCI, you will receive a stipend of $100 per visit for your participation in this study to help cover any costs of transportation and time away from work. If you participate in both visits, you will receive $200 in total.
You will receive payment approximately six to eight weeks after completion of your visit.
You understand that if you choose to receive reimbursement through EFT, you will be required to provide the research staff information that includes name of your bank, routing number and account number.

13. Contact Person(s):

If you have any questions, at any time, about this research, or want to discuss any possible study-related injuries, please call telephone number 718-584-9000, ext. 5439 to reach Dr. Handrakis. You may contact Dr. Handrakis after hours at 917-312-5616.
To voice concerns or complaints about the research from someone outside of the research team, contact the following:
*I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact **Mary Sano, Ph.D.** ACOS/R&D Program by requesting an appointment at **(718) 741-4228** hospital extension 4228, first floor in the research building, **room 1F-01** If I have questions, concerns and/or complaints or to offer input.*
If you still have questions regarding the study or your rights as a participant in the study, then you may discuss them with an administrator of the Institutional Review Board at the Veterans Affairs Medical Center, Bronx, NY at telephone number 718-741-4228.

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Protocol #:1696610 **Principal Investigator: John P. Handrakis, PT, DPT, EdD, NCS**	**VAMC: James J Peters**
Title of Study: Development of a Novel Cooling Vest to Prevent Heat-Induced Thermoregulatory Dysfunction in Persons with Spinal Cord Injury	

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above.
Dr. Handrakis or his delegate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.
I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.
This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	Date
Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	Signature of Person Obtaining Informed Consent Date

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*Only include this section if the IRB approves surrogate consent for the research study for individuals with impaired decision-making capacity.
This also includes subjects with a disability who do not have the physical capacity to sign consent.

_____ _____
*Subject's Legally Authorized Representative (Print Name) Relationship to Subject

_____ _____ _____
Signature of *Subject's Legally Authorized Representative Date Time

_____ _____ _____
Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page) Signature of Person Obtaining Informed Consent Date

_____
Time

VERBAL CONSENT IF THE PARTICIPANT LACKS UPPER LIMB FUNCTION TO COMFORTABLY WRITE

_____ is unable to sign the consent form due to impaired arm function. I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.
Person Obtaining Consent:

Name: _____

Signature: _____

Date: _____

Witness Name: _____

Signature: _____

Date: _____