Impact of Mobile Manual Standing Wheelchair on Standing Dosage and Utility

NCT04668326

July 24, 2024

Participant Name: _____ Date:_____

Title of Study: **Impact of Mobile Manual Standing Wheelchair on Standing Dosage and Utility - Full Study Consent**

Principal Investigator: _____ VA Facility: _____

Principal Investigators for Multisite Study: Jenny Kiratli, PhD and Andrew Hansen, PhD

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

People with spinal cord injury (SCI) who use wheelchairs for their primary mobility are exposed to excessive sitting which may contribute to pressure injury, pain, osteoporosis, joint stiffness, spasticity, and worsening bowel and bladder function. Upright posture may be possible using a standing frame or a standing wheelchair, but these only provide static standing. Mobility while upright may be possible with an exoskeleton, but functional tasks are limited because of the need to use crutches or a walker for stability; the exoskeleton is also limited because of the amount of energy used as well as the need to transfer to and put on the device to walk.

We have adapted an existing manual wheelchair that provides a standing option to allow mobility in the upright position – that is, a mobile manual standing wheelchair (MMSW). We have tested this in our laboratory and made adjustments suggested by users, and now we would like to deploy this device for use in the home and community.

The purpose of this research study is to explore the utility and frequency of using a mobile and non-mobile standing wheelchair in the home and community and the impact of short-term use on health outcomes. That is, we will investigate whether and how much people will use a built-in standing feature that allows mobility while standing. We are particularly interested in what activities people will choose to perform while standing and while mobile in standing. We will also measure any changes in pain, spasticity, bowel and bladder function and overall health status that may be associated with increased time standing. By doing this study, we hope to gain useful information to improve the wheelchair design based on users' input and plan ahead for a larger study. Our eventual goal is to make this technology available through VA Prosthetics Service.

Your participation in this study will last approximately 5 months or less; the total duration will depend on several things including whether you regularly use a standing device and how much time you may need to get accustomed to standing upright. The exact number of visits may vary based on your individual situation (up to a total of 10 visits, 1-2 hours per visit). You will be

required to visit the [local site] VA medical center for training and testing at the beginning and at the end of the study, but most of your time will be at home, using the wheelchair on your own. We are particularly interested in your assessment of whether this device is useful to you and suits your needs.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this study, you will learn about and have the opportunity to use a standing wheelchair, either non-mobile in standing or mobile in standing, and you may gain health benefits while using either of the two devices. You will be able to inform how these devices may be further engineered to help others with SCI who may benefit in the future if we are able to advance this technology for broad use beyond this research study.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

As with any research study, there may be risks and inconveniences. Here are the main reasons you might not want to volunteer. For a complete description of risks, refer to the Risks Section later in this document.

You may experience inconvenience by coming to the [study site] for multiple visits. You may also find that using the study wheelchair at your home rather than your own wheelchair is inconvenient. If this feels too burdensome, you may withdraw from the study at any time.

You may find some of the items on the questionnaires uncomfortable to answer. However, if you experience distress or discomfort, you may choose to not answer such questions. In addition, you may feel uncomfortable or embarrassed to be videotaped using the study wheelchair; if this is the case, you may choose not to be videotaped.

There is a small risk of physical harm while using the study wheelchair such as falling while upright or experiencing skin injury if the wheelchair supports are in contact with your skin or a very unlikely risk of bone fracture. While we will take precautions for your safety throughout the study and monitor for any potential harm, we cannot guarantee that no adverse events may occur. If you are harmed by participating in this study, we will provide treatment and follow-up as needed. Furthermore, if you become concerned about the potential for injury, you may always withdraw from the study at any time.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits or rights you would normally have if you chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [LSI name] at the [study site]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his/her contact information is: [LSI contact information].

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research study, we hope to improve our understanding of how people use manual standing wheelchairs and the potential impact of mobility in the standing posture. We will be comparing two wheelchair options, a commercially available manual standing wheelchair and an adapted version that provides mobility while standing. We seek to discover how much people will use the standing feature to change their postures for both pressure relief and to participate in self-selected functional activities. The primary purpose is to know how often people will choose to use this upright mode and what they do while standing and while mobile in standing. We further seek to understand how upright mobility may impact daily activities as well as learn about health benefits that may result from increased standing.

HOW LONG WILL I BE IN THE STUDY?

This is a multi-site study being conducted at the VA Palo Alto Health Care System and the Minneapolis VA Health Care System. Up to 60 participants are expected to be enrolled in this study over the course of approximately 4 years. There may be up to 30 participants enrolled at each study site.

Your individual participation in the project will take up to 5 months total, with up to 9 study visits to [local study site]. This is a maximum and you may not require all of these visits, depending on your ability to stand and how long much training you may need. Each visit may take up to 2

hours. In rare instance, if we find that data are missing or corrupted, we may ask you to come back for another visit so we can collect the data again.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Your primary contact will be with the research coordinator who guide you through the study visits, including explaining instructions for using the study wheelchair, timing of study visits, physical tests and surveys, and how to contact the study team with any questions or concerns, including if you experience an injury or have a problem with the equipment.

Screening/Evaluation (1-2 Lab Visits)

Your initial visit will be to review and confirm your eligibility for the study including assessing your tolerance for standing.

During the first visit, study personnel will explain the study purpose, procedures, timeline, and risks and answer any questions; and you will be required to sign this consent form.

Each participant will meet with a physical therapist (PT) or occupational therapist (OT) for wheelchair fitting. For this study, you will be using a standing wheelchair made by LEVO. The PT or OT will measure you using a standard LEVO wheelchair order form, allowing the loaner study wheelchair to be adapted/customized for each individual. This is not a modification of your personal wheelchair but a customization of the LEVO wheelchair you will use during the study.

As part of your wheelchair fitting, the PT or OT will determine whether your existing seating cushion will work in the study wheelchair. If your personal seating cushion will not work, then a ROHO cushion will be tried instead and we may need to perform pressure mapping as would be done clinically to ensure safety. If a clinically acceptable seating system cannot be found, you may be excluded from the study.

Training for Standing Tolerance (up to 4 Lab Visits) – *As needed, depending on participant need*

For those who do not stand often or who may have challenges with standing, multiple standing training visits may be needed to ensure that you are safely able to achieve an upright position. These training sessions will be conducted with a stationary LEVO standing wheelchair frame. Participants will be guided thru simple progressive increases of inclination so they can assess

their ability to acclimate to and tolerate full upright positions. Up to four sessions will be provided to determine if a person can safely become used to the full upright positions. You may be asked to try abdominal binders to help support blood pressure. If your body is unable to accommodate to full standing positions after these training sessions, you may be excluded from the study.

Home Visit – *Only for participants with an existing standing device*

For participants who have a current standing device, research personnel will do a home visit to mount a measurement device on your current standing device. This device simply tracks time and frequency of how the standing frame is used. Data collection on the current standing device will take place for two months prior to randomization. We will ask you not to change your regular use patterns just because you are entering the study. This is not a test but rather data collection on how much or how little you normally standing during the day. At the conclusion of the study, we will return to remove the measurement device.

Randomization

If you meet all eligibility criteria, you will be randomized (like flipping a coin) into one of the two groups - non-mobile manual standing wheelchair (NMMSW) or the mobile manual standing wheelchair (MMSW). You will have an even chance to be in either group. However, if you already use a standing device, we will need to conduct a two-month evaluation of your regular use before you are randomized into a study group, as described below.

Baseline Assessments (Lab Visit)

After being randomized, you will visit the lab at [local study site] for baseline assessments. We will ask you to perform a wheelchair skills test that has 32 skills to demonstrate and also to complete survey questionnaires about your health including for pain, bladder and bowel function, spasticity, sleep, and global quality of life. Completion of all these tests may take up to 2 hours. You will be able to take breaks if you need to. You will be able to skip any questions that make you uncomfortable and also ask for help understanding any questions that may be confusing.

You will be asked to describe your current standing activity. If you have a standing device at home (whether you currently use it or not), we will ask you to describe your perceptions of your standing device in terms of utility. All participants will be asked to describe activity goals for standing (if you were randomized to the NMMSW group) and what you would like to do with

mobile standing (if you were randomized to the MMSW group) and the importance of these activities to you.

Training and Evaluation (2 Lab Visits)

Once you have demonstrated that you are able to stand safely, you will receive training in the operation and safety of either the NMMSW or MMSW wheelchair depending on which group they were randomized into. You will be guided through the use of the standing features and provided opportunities to practice using the device to accomplish standing tasks. Participants in the MMSW group will participate in a 100-meter push test to measure your speed and push cadence during mobile standing. Opportunities to simulate activities you may want to perform at home or in your community will be discussed and practiced, if possible.

You will be expected to demonstrate safe and competent use of the study wheelchair prior to release of the chair for home/community use. Study personnel reserve the right to not release the device if, in their clinical judgement, you do not demonstrate competency in its use.

Home and Community Use

After you have completed all assessments and training in the lab and have been cleared for safe use, you will be provided a study wheelchair for a two-month home/community use trial. The evaluation period may be extended by one month in situations of illness, travel, or other extenuating circumstance that interfere with your ability to fully trial the device. However, the evaluation period will not be extended simply due to non-use as this will be relevant information. Situations where extension may be granted will be decided on an individual basis.

You will be expected to use the study wheelchair as much as you would like to and for any activities you can as long as you maintain safe usage. You may use the study wheelchair completely in place of your regular wheelchair, but we do not require this. It will be up to you to decide how much and in what ways you use your study wheelchair during the two-month period. Each wheelchair has a monitor attached so that we can track use and standing time, and we will ask you to log the activities you perform on a daily log sheet.

Weekly Calls

During the two-month home/community study period, the research coordinator will schedule weekly phone calls with you to ask you about your use of the study wheelchair, any questions you have or any problems you have encountered, and whether you have experienced any falls or other injuries. You are expected to answer honestly during these weekly calls. You are also expected to call the study team immediately if you experience a serious injury related to the study, including calling emergency services if needed.

Final Assessment (Lab Visit)

You will return to the lab at [local study site] at the end of the home/community trial and repeat the same assessments that were performed at Baseline. This includes the wheelchair skills test and survey questionnaires. You will be asked about changes in your medication use and health. At the end of the study, you will be responsible for returning the wheelchair to the study center.

Final Assessment (Phone interview)

We will ask you to provide your feedback on the study wheelchair and your satisfaction with your ability to perform standing or mobile standing activities. This will be conducted as a phone interview and will be audio-recorded so we can be sure to correctly capture your responses.

Initial one item:

_____ I agree to have my final assessment phone interview audio-recorded.

_____ I do NOT agree to have my final assessment phone interview audio-recorded.

Photos and video recording (optional)

We may take video and photos of you during portions of this study for documentation and use in research publications and/or educational materials. Any identifying marks (e.g., tattoos) will be covered. We will blur out your face and if any identifiable features or marks are mistakenly captured they will be blurred out prior to any use outside of the research team that captured the images. Photos and videos that do not contain identifiable information may also be stored on non-networked password-protected computers for future use in dissemination efforts and educational materials. Videos will be recorded without sound so that we do not record your voice print. If your voice is accidently recorded that section of video would be altered prior to any

use outside of the VA study team. Any photographs and/or video recordings we take of you may be used either internally (shared within VA) or externally (shared outside the VA), for procedure documentation, data analysis, training purposes, and research publications, presentations, or conferences. Only videos and photos in which you cannot be identified would be used in research publications and presentations.

Initial one item:

_____ I agree to have videos and photos taken of me.
_____ I do NOT agree to have videos and photos taken of me.

Future Contacting (optional)

We may contact you about future research opportunities.

Initial one item:

_____ I agree to be contacted by study staff about future research opportunities.
_____ I do NOT agree to be contacted by study staff about future research opportunities.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Ask questions as you think of them.
- Complete study questionnaires and provide feedback to study personnel as requested. (However, you may skip any questions that make you uncomfortable; just let us know.)
- Take care of the study wheelchair that is loaned to you and report any maintenance or malfunctions of the wheelchair as soon as you are aware of them.
- Adhere to the safety and usage guidelines that were provided to you.
- Report any adverse events including things such as falls or skin injury, even if it seems minor.
- Return all equipment that is loaned to you for the study at the conclusion of your participation.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described below, you may experience a previously unknown risk or side effect. We may need to contact you if we learn of a new study risk. You may be asked to sign an updated Consent Form to document that this new information has been explained to you.

We believe that the risk of injury is minimal during wheelchair testing in the laboratory as well as during home and community use, but it is important to be aware of any potential problems that may occur. Below are the potential study-related risks that are known/expected at this time:

Risk of Skin Injury: Supported standing requires transitions in positions that can increase pressure to the feet, knees and across the chest. It is therefore possible as people spend more time standing that we might see occurrence of pressure injuries in these new areas. The wheelchair design has padding in appropriate places to protect participants from skin injuries, but as each person is shaped differently and may move differently, we anticipate that individual adjustments may be needed for maximum prevention of skin injuries. We will monitor carefully during training and lab sessions for any indications of pressure injuries such as redness, bruising or skin abrasions and will provide individual instructions on what to look for during home use. We will specifically enquire about skin integrity during weekly phone calls.

Risk of Falling: The potential risk of falling during use of the standing wheelchair is primarily associated with improper use. That is, exceeding the prescribed usage of the device on terrain or risky activities outside of instructed safety guidelines could potentially result in a fall and subsequent injuries such as skin injury or a bone fracture. Operating the chair in safe environments, using chest restrains and other safety features correctly, and choosing safe activities when upright will greatly reduce this risk. Fall risk will be mitigated by (i) oversight and standby supervision by trained study personnel at all times during testing in the laboratory and (ii) providing you with detailed instructions for use in the home and community. During laboratory sessions, especially during initial training and familiarization, study personnel will be present close by to prevent falls or instability. Please tell us immediately if you feel unbalanced

during any of the procedures. Both standing wheelchairs have secure supports and we anticipate that the risk of falling to be extremely low.

Risk of Shoulder Pain: As the study wheelchair is heavier than your normal wheelchair, you may experience some shoulder discomfort. The potential for increased shoulder discomfort will primarily be related to the frequency and duration of use. It will be important to contact study staff if you experience any new shoulder pain that you believe may be related to the wheelchair.

Fracture Risk: A lower limb fracture is a potentially serious injury that a participant might sustain due to standing and/or if a fall from standing were to occur. However, given the bone mineral density eligibility criterion as well as the design of the support stabilization for upright posture, we believe that this would be an unlikely occurrence. Nonetheless, we will monitor carefully during laboratory sessions and through weekly phone calls and advise a clinical evaluation by the study physician if there are any indications of a potential bone fracture.

Risks to Privacy/Confidentiality: Although we will make every effort to keep your information secret as with any interaction within a medical center, no system for protecting information can be completely safe. It is still possible that someone could find out that you were in this study and could find out information about you. This risk is highly unlikely given the extreme caution used to protect Veterans' health information and personal identifying information. The Confidentiality section below describes how we will protect your privacy to the best of our ability.

Other Risks:
You may experience some stress or inconvenience by coming to the [local study site] for multiple visits. If this feels too inconvenient, you may withdraw from the study at any time. We will also do our best to arrange study visits at a time that is convenient for you as well as keep appointments to a length of time that suits your schedule. That is, for the initial informational and training visits, we may arrange more visits if you cannot spend too much time at once, or we may be able to combine several activities in a single visit if that would be more convenient.

You may find some of the items on the questionnaires uncomfortable to answer. However, if you experience distress or discomfort, you may choose to not answer such questions. In addition, you may feel uncomfortable or embarrassed to be videotaped while using the study wheelchair; if this is the case, you may choose not to be videotaped.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, the information we get from this study might help others with SCI who use wheelchairs for primary mobility in the future. Possible benefits to you of your participation may include short-term improvement in health-related outcomes such as pain, spasticity, bowel and bladder function as well as reduced skin pressure with decreased sitting.

We will provide the results of your study participation to you at the conclusion of the study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. Your research information will be kept confidential. Access to your records, including your medical records, might be required for study-related purposes or to make sure your research study record meets all legal, compliance, and administrative requirements.

Electronic data with information that could be used to identify you will be stored on VA secured servers at each study site. These data will only be accessed by authorized study personnel at each site. Paper files with information that could identify you will be stored in locked file cabinets in locked offices at each site. Each study site will maintain its own documentation that contains information that could identify you, and identifiable information from the different sites will not be combined.

A unique study code instead of your personal information (such as name or SSN) will be used to identify your study data. The key to the code will be stored separately from the data, in a protected electronic file on a secure server at each study site. We will securely store the key to the code and any other identifiable study data until the end of the study. The key to the study code, data and any other study documents with information that could identify you will be stored after the end of the study per the VHA records control schedule for research.

Data from all participants will be combined without any identifiers for analysis. A copy of the de-identified dataset will be sent to our biostatistician so that she may assist with data analysis, interpretation and writing publications. A copy of the de-identified electronic data will be kept indefinitely at the Minneapolis VA. Some technical logs may be shared with the wheelchair manufacturer, if needed, related to performance of the adapted mobile standing wheelchair and

any problems encountered. This log information cannot be used to identify you and will not be associated with the study assigned code.

In the future, researchers may publish the results of this study for others to read about. These publications will not include any identifying information about you such as your name, social security number, address, telephone number, or any other direct personal identifier. Videos and photos that do not identify you may be used in academic publications and presentations should you opt in.

In addition, your study information, after removal of all identifiable private information, could be used for future research studies or distributed to another investigator for future research studies without requiring additional informed consent.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board (IRB), our local Research and Development Committee, the Food and Drug Administration (FDA), and other study monitors may look at or copy portions of records that identify you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time; the study ID number is #NCT04668326.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

Costs to Participants*:* You, or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date:

LSI Approval Date:

LSI Verification Date:

WILL I RECEIVE ANY PAYMENT IF I TAKE PART IN THIS STUDY?

Payment Offered for Participation: You may receive up to $550 (plus travel reimbursement as detailed below) by the end of the study. You may have up to nine study visits, depending on the amount of training that is needed to be able to safely use the study wheelchair before you can take it home. We will submit a payment request of $50 for you after each completed visit and a final payment of $100 for completion of all procedures and return of the study wheelchair to us. Payments will be made by direct deposit to your bank account.

Reimbursement for Transportation: Reasonable transportation costs may be reimbursed. If you need to travel more than 50 miles in each direction for the study visits, you may be eligible for reimbursement for miles traveled. This reimbursement will be calculated based on the IRS mileage rate for the distance traveled to the [local study site], with appropriate documentation, or to cover use of an eligible paratransit service. Transportation arrangements should be approved in advance by the local study team.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you, or your insurance unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

Every reasonable safety measure will be used to protect your well-being. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act. Emergency and ongoing medical treatment will be provided as needed. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

If you should have a medical concern or get hurt as a result of taking part in this study, call the study coordinator at [local contact phone #].

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PI/SC Approval Date:

LSI Approval Date:

LSI Verification Date:

DO I HAVE TO TAKE PART IN THE STUDY?

It is your decision to decide whether to take part in this study; your participation is entirely voluntary. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you do not take part, you may still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you choose to withdraw, data already collected, including pictures and videos of you will be kept, but we would not be able to collect any additional information about you except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The Principal Investigator (PI) may terminate your participation in this study if you cannot safely perform the tasks described as part of the study or if she or he feels it is not in your best interest to continue in the study. The site PI may terminate your participation if you develop a moderate to severe medical condition (i.e. fall injury, fracture, significant pressure ulcer, etc.) where the use of an upright wheelchair feature is contraindicated, as determined by the study physician. If you are unable to tolerate upright postures in the wheelchair and or unable to demonstrate safety awareness and skills during the training sessions, you will not continue to be in this research. You will be provided with an explanation of why you were withdrawn but this will not require your consent. If you decide to withdraw, or if you are terminated from the study, a person from the study team may need to meet with you to discuss the steps that are necessary to end your participation in the study.

If you are terminated as a study participant, the usual care you receive as a patient will not be affected. You will be required to return all equipment related to the study. In order to return the equipment, you will be required to bring the equipment back to the VA Medical Center. In some instances, the study research staff may assist you with returning the equipment on an as needed basis.

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LSI Approval Date:

LSI Verification Date:

Participant Name: _____ Date:_____

Title of Study: **Impact of Mobile Manual Standing Wheelchair on Standing Dosage and Utility - Full Study Consent**

Principal Investigator: _____ VA Facility: _____

Principal Investigators for Multisite Study: Jenny Kiratli, PhD and Andrew Hansen, PhD

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, or concerns about the research or related matters, you can contact the study coordinator at [local contact phone #].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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Principal Investigator: _____ VA Facility: _____

Principal Investigators for Multisite Study: Jenny Kiratli, PhD and Andrew Hansen, PhD

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The PI or research study coordinator has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date:

LSI Approval Date:

LSI Verification Date: