Development of Vision-Guided Shared Control for Assistive Robotic Manipulators

NCT04323449

October 9, 2023

Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 * **Study Name:**
Evaluation of Vision-Guided Shared Control for Assistive Robotics Manipulators

2.0 * **Brief Description (using layman's terms) - 500 words or less:**
The purpose of this study is to evaluate a new control (i.e., the vision-guided shared (VGS) control) for a wheelchair-mounted assistive robotic manipulator among powered wheelchair users. This study will consist of a questionnaire about general demographics, health information, and previous experience with assistive technology. Several tests will also be administered to test upper extremity function and ability as well as to test spatial orientation and visualization ability. Participants till then undergo a training phase with the assistive robotic manipulator mounted on a table to assess if they will be eligible for participation in the study. Eligible participants will move on to a second training phase where they will be asked to learn and practice slightly more complex tasks while using the vision-guided shared controller. After this training the assistive robotic manipulator will be mounted to the participants wheelchair, a table, or a stand and they will be asked to complete a number of everyday tasks from a task list. At the conclusion of the study, we will conduct a brief semi-structured interview with each participant and obtain more insight on how participants perceive the ease-of-use and usefulness of the VGS control.

3.0 * **Is this research study a Greater than Minimal Risk Clinical Trial?** ○ Yes ◉ **No**

4.0 * **Is this study a Greater than Minimal Risk Comparative Effectiveness research?** ○ Yes ◉ **No**

5.0 * **Principal Investigator:**
Dan Ding

5.1 * **VA hours per week the PI is devoted to project:**
15

5.2 * **Is the PI working with ionizing radiation?** ○ Yes ◉ **No**

5.3 * **Is the PI working with biological hazards?** ○ Yes ◉ **No**

5.4 * **Is the PI shipping biological hazards?** ○ Yes ◉ **No**

A completed and signed Research Financial Conflict of Interest Statement is required for all investigators (including Principal Investigators, Co-Principal Investigators, and Co-Investigators) listed on the study application. **Financial Conflict of Interest Form-Nov. 2013**

5.5 **Upload Financial Conflict of Interest Statement:**
Ding FCOI.pdf(0.02)

6.0 **Research Staff:**

7.0 **Type of Submission:**

	Description
◉	**This is a new study. This has not previously been submitted to the IRB.**

This is a new paper conversion. This study has been previously approved by the IRB.

If this is a 'New Paper Conversion' please include the MIRB Number:

Please upload a letter certifying that you have made no modifications or amendments in converting this research study from paper to electronic:

ID: Pro00003276 View: 1.0 Study Identification Information

Study Identification Information (Continued)

1.0

*** Do you certify that all research staff administering informed consent are knowledgeable about the study?**

yes

2.0

*** To the best of your knowledge do you, or any member of your research staff, have any potential, actual or perceived conflict of interest of a professional or personal nature that may affect any aspect of the research, including, but not limited to, the review and/or conduct of this study?**

Yes **No**

If yes, provide a description, including name of study team member with conflict:

3.0 *** Qualifications of the Investigators:**

Dan Ding, PhD received her Ph.D. in mechanical and automation engineering from the Chinese University of Hong Kong, Hong Kong, in 2001. She is an associate professor in the Department of Rehabilitation Science and Technology, University of Pittsburgh. Dr. Ding's research interests include rehabilitation and assistive devices, wearable devices for rehabilitation applications, and assistive robotics. Dr. Ding serves or has served expert reviewers of several peer-reviewed journals and conferences in the field of rehabilitation engineering. She has published over 100 papers in refereed professional journals and international conference proceedings. Dr. Ding will serve as the principal investigator of this project.

Dr. Cooper is a VA Senior Research Career Scientist and Distinguished Professor at Pitt. Dr. Cooper has extensive experience in developing and evaluating assist robotic interventions for people with severe physical limitations. He will assist with the overall direction of the project and provide guidance the training and testing procedures as well as data collection.

Dr. Chung is a research scientist at HERL, and has extensive experience and expertise in developing custom user interfaces and share control schemes for assistive robotics. He will be helping training and fitting the assistive manipulator to participants and the entire testing procedure. He will also assist with the exit interview with the participants.

Dr. Styler is a postdoctoral researcher at HERL. She has over 7+ years of industry software experience and advanced degrees from CMU in robotics. She will help with training and data collection on the software system as well as assisting participants during the testing procedure.

Lindsey Morris OTD OTR/L, completed her doctorate of Occupational Therapy at the Massachusetts General Hospital Institute of Health Professions(MGH IHP) in May of 2020. She has experience and expertise in developing and evaluating technology-based interventions for people with disabilities. She will service as a co-investigator in this project and assist with cognitive screening, baseline assessment, and subject testing.

ID: Pro00003276 View: 1.2 VA Involvement

VA Involvement

1.0 **Does the proposed research involve any of the following?:**

	Name
☑	**VA Funding**
☑	**VA Personnel Funded Effort**
☑	**VA Patients or their Private Health Information**
☐	Other VA Resources: Central IRB
☑	**Other VA Resources: VA Equipment**
☑	**Other VA Resources: VA Property (Including space leased to, or used by VA)**
☐	Other VA Resources: VA Databases
☐	None of the Above apply to this research

ID: Pro00003276 View: 1.3 Study Funding Information

Study Funding Information

1.0 * **Funding Sources:**

	Funding Source	(Other)	Code
View	Merit Review (CC 103)		9003

2.0 **Upload Grant Application, if applicable (If NIH, VA, voluntary agency, must upload):**

Name	Modified Date
VA Merit Review Proposal	10/21/2019 2:29 PM

ID: Pro00003276 View: 1.4 Resources

1.0

* **Do you currently have adequate resources (e.g., staff, physical space, information technology, etc.) to protect the safety of participants, staff, and the confidentiality of subjects' data during the conduct of this study?**

◉ **Yes** ○ No

If yes, include a listing of the VAPHS resources that will be used for this study and are necessary to protect participants.

The Human Engineering Research Laboratories (HERL) has over 20,000 square feet of laboratory space which includes separate areas focusing on: Biomechanics, Activities of Daily Living, Robotics, Standards Testing, and Design and Prototyping.

All necessary resources are readily available and experienced staff members (clinicians, engineers, research coordinators) assist the PI in implementing and overseeing the research. Protected servers and restricted access file rooms are available for the secure storage of study data.

If no, please describe the resources that will be needed and explain how the resources will be obtained before the study is initiated:

2.0 * **VAPHS requires that either the PI or co-PI have a *physical presence* at VAPHS. Please describe the role the PI and/or co-PI have at VAPHS with respect to clinical responsibilities or in relation to other research activities.**
Dr. Ding is a 4/8ths VA employee (VA Biomedical Engineer). Dr.Ding has an office at HERL in Bakery Square, where she is majority of her work time.

3.0 * **Will off-site ancillary service facilities (e.g., radiology services, central labs, non VA space, etc) be used for this study?**

○ Yes ◉ **No**

If yes, please provide the location and a brief description of the project activities to be conducted at the off-site ancillary facilities:

4.0 * **Will a firm be contracted to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects' research?**

○ Yes ◉ **No**

If yes, please provide a description of the contracted service(s):

* Please specify the IRB that has oversight of the firm's activity(ies):

Name of Site / Institution	IRB Approval Document	FWA Number

There are no items to display

5.0 **Collaborations**
Please list any non-VAPHS institutions or individuals (i.e. co-authors, mentors, etc.) that you will collaborate with and describe their specific role in the research:

5.1 If this is not Multi-Site Research, please upload the appropriate written agreement(s) here:

Name

There are no items to display

ID: Pro00003276 View: 1.5 Project Information

1.0 **Does the project involve any of the following (check all that apply):**

	Type
☐	Biological Hazards (including human biological specimens)
☐	Chemicals
☐	Ionizing radiation or use of radioactive materials
☐	Drug, Biological, or Nutritional (e.g. herbal or dietary) Supplement

2.0 **Project Focus (check if applicable):**

	Type
☐	Traumatic Brain Injury (TBI)
☐	Post Traumatic/Post Deployment Stress Disorder (PTSD/PDSD)
☐	Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF)

3.0

KEYWORDS

Please provide a minimum of 3, maximum of 6 keywords. Please use MeSH terms.

* Assistive robotics

* Upper limb impairments

* Power wheelchair users

Activities of daily living

4.0 * **Please describe the type of study:**
Randomized crossover design

5.0 * **Will any of the research being conducted as a part of this study be used to fulfill academic requirements (e.g., master's thesis, dissertation, or other academic program requirements necessary to obtain a degree/certification, etc.)?** ○ Yes ◉ **No**

ID: Pro00003276 View: 1.6 (CR) Study Locations

Study Locations

1.0 * **Please add the local sites where this study will be conducted:**

Location
View Other

If Other, Please Specify:
Human Engineering Research Laboratories (Bakery Square Location)
Participants' home

ID: Pro00003276 View: 1.6.1 (CR) Multi-Site Study

1.6.1 Multi-Site Study

1.0 * **Is this a multi-site study:**

○ Yes ◉ **No**

ID: Pro00003276 View: 1.7 Section Chief and Service Line VP approvals

Please upload the approval of the Section Chief, if applicable and the Service Line VP.

1.0 * **Institutional Approval Document:**
Request to Conduct Research.pdf(0.01)

ID: Pro00003276 View: 2 Study Objectives & Design

Study Summary

1.0 **Funding End Date:**
3/31/2023

2.0

* **Abstract. Please provide a brief description of the study**.

The purpose of this study is to evaluate a new control (i.e., the vision-guided shared (VGS) control) for a wheelchair-mounted assistive robotic manipulator among powered wheelchair users. This study will consist of a questionnaire about general demographics, health information, and previous experience with assistive

technology. Several tests will also be administered to test upper extremity function and ability as well as to test spatial orientation and visualization ability. Participants till then undergo a training phase with the assistive robotic manipulator mounted on a table to assess if they will be eligible for participation in the study. Eligible participants will move on to a second training phase where they will be asked to learn and practice slightly more complex tasks while using the vision-guided shared controller. After this training the assistive robotic manipulator will be mounted to the participants wheelchair, a table, or a stand and they will be asked to complete a number of everyday tasks from a task list. At the conclusion of the study, we will conduct a brief semi-structured interview with each participant and obtain more insight on how participants perceive the ease-of-use and usefulness of the VGS control.

3.0 * **Describe the study objectives. Please include primary aim and hypothesis, if applicable any secondary aims and hypotheses.**

Aim: To evaluate the Vision Guided Shared (VGS) control among 21 powered wheelchair users who will use a wheelchair-mounted ARM to complete a set of functional manipulation tasks.

Hypothesis 1: Subjects will be more efficient when using the VGS control as opposed to the default control, as measured by the number of mode switching, and time taken to complete individual tasks.

Hypothesis 2: Subjects will be more effective when using the VGS control as opposed to the default control, as measured by the number of tasks successfully completed.

Hypothesis 3: Subjects will report better usability for the VGS control than the default control as measured by the NASA Task Load Index (NASA-TLX) and the System Usability Scale (SUS).

4.0 * **Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous studies that provides a basis to show that the proposed research can be carried out without undue risk to human subjects.**

There has been a good amount of work on developing new ways to control assistive robotic manipulators (ARMs) and make them easier to use. However, most work focused on technology development and validation, and did not include subject testing with intended users on functional tasks. We have done a literature search on ARMs over the past five years, and found 28 articles (excluding our own work), where only six of them included users with disabilities in subject testing. For example, Pulikottil et al. (2018) developed a voice control approach and tested it with 2 individuals with disabilities in a laboratory setting on a single task of grasping a bottle, displacing it and simulating to pour its content into a glass. Lebrasseur et al. (2018) evaluated three simple control algorithms including preset position, filtering, and drinking mode among 14 individuals with disabilities in a laboratory setting on five tasks (i.e., reaching to a button that simulates pushing an elevator button, reaching above a plate on a table and a position near the mouth that simulates eating, grabbing a glass of water on a table, grabbing a pen from a pencil holder, and drinking with a straw). Park et al. (2019) developed a meal-assistance control system using a general-purpose mobile manipulator (i.e., a Willow Garage PR2) and tested it with 9 individuals with motor impairments in a laboratory setting. The system provided a user interface for users to select different tasks and feeding locations, and used computer vision and other sensors to enable the robot to autonomously deliver food to the user's mouth. Quintero et al. (2015) developed a vision-based interface and tested it with one individual with quadriplegia on two tasks, i.e., an orientation task where the user was asked to locate the robot hand in a right, top, and front orientation with respect to the object on a tabletop, and a drinking task. Although these four studies included testing with intended users, most had a very small sample size and a quite limited set of tasks. Finally, a majority of the work over the past five years developed new control interfaces for ARMs such as gaze control, tongue control, BCI (Brain Computer Interface) via EEG, body movement control via IMU (Inertial Measurement Unit), and

gesture control via computer vision, however, these new control methods are limited as a proof-of-concept and far from being deployable for real-world use by intended users. The goal of this project is to combine vision-guided shared (VGS) control with two types of environment modifications to address the effectiveness and efficiency of ARMs for real-world use. We will evaluate it with functional instead of discrete tasks.

5.0 * **Describe the overall significance of the research in terms of the problem to be studied and potential findings, as well as its relevance to the care of veterans, the VAPHS, and the VHA:**
Veterans who use powered mobility devices including those with high-level spinal cord injury (SCI), amyotrophic lateral sclerosis (ALS), and multiple sclerosis (MS) often experience severe upper extremity impairments. In addition, many older Veterans and Veterans with hemiplegia may also suffer from a functional loss in their upper extremities. About 1 in 10 adults aged 55 years and over had difficulty reaching or grasping, with rates for those aged 85 and over 2.5 times that of adults aged 55-64. Approximately half of the individuals with hemiplegia have a non-functional arm and hand even four years after a stroke. Upper extremity impairments can lead to functional limitations in many activities of daily living (ADLs) such as selfcare, eating/drinking, and meal preparation, resulting in decreased independence, participation, and quality of life. In a survey by Anderson et al. with 347 individuals with tetraplegia, 48.7% indicated that regaining arm and hand function would most improve their quality of life while only 7.8% considered regaining walking as the highest priority. In addition, the priority of regaining arm and hand function did not change whether someone was injured 0-3 years or more than 3 years post-injury. In a survey of 89 wheelchair users and 52 health care professionals, the ability to reach adequately for objects was rated as the most important concern.

Management and care of upper extremity impairments often involve a range of assistive solutions including implanted functional electrical stimulation (FES) devices, feeding robots, robotic orthoses, and assistive robotic manipulators. However, product availability and technological advancement for manipulation assistance fall far behind those for mobility. For example, powered wheelchair technologies have evolved to not only allow Veterans with severe physical limitations to move from point A to point B, but make it easier for them to stay in their wheelchairs for extended periods of time by providing advanced seating systems for comfort, stability, and medical benefits, remote monitoring, and autonomous navigation. However, many of these individuals, despite their independent mobility, cannot reach for a glass of water, make a simple meal, and pick up a toothbrush. They still require assistance from a personal caregiver for essential activities of daily living (ADLs) involving reaching and object handling/manipulation. Yet, the shortage of personal care attendants, unrelieved caregiver strain, financial concerns, and other care-related challenges make it difficult to fulfill the rapidly growing needs for caregivers. The inability to perform ADLs independently may also trigger the need for relocation to residential care settings, and significantly impact the quality of life and self-esteem of these individuals.

We expect to improve manipulation functions of Veterans with upper limb impairments through a more practical and usable implementation of vision-based robotic control and human-robot interaction technologies. The mission of the VA Prosthetic & Sensory Aids Service (PSAS) is to provide comprehensive support to optimize the health and independence of the Veteran. The proposed work clearly supports this mission by maximizing the potential of ARMs in assisting Veterans with everyday manipulation tasks and supporting the adoption of this advanced assistive technology. The use of enhanced ARMs in home and community could potentially lead to improved independence and the ability of Veterans with upper limb impairments to integrate into the community, as well as reduced attendant care need and cost.

6.0 **Please upload any additional documents:**

Name	Version
There are no items to display	

Required Reviews

1.0

Type of Submission:

New study

If this is a 'New Paper Conversion' please include the MIRB Number:

Please upload a letter certifying that you have made no modifications or amendments in converting this research study from paper to electronic:

2.0 * **Requested Review Type:**

	Name
○	Exempt
◉	**Expedited**
○	Full IRB Review
○	Not Human Subject Research

3.0

	Please check which of the following Service Lines/Departments/Entities will be impacted or used in the conduct of this study	**Upload Letter of Support**
☐	Clinical Support	
☐	Medical Specialty	
☐	Investigational Drug Service	
☐	Imaging	
☐	Community Based Care	
☐	Patient Care Services	
☐	Behavioral Health	
☐	Primary Care	
☐	Surgical Specialty	
☐	Critical Care	
☐	Clinical Trials Center	
	☐ Regulatory Coordinator Support Core	
	☐ Clinical Coordinator Support Core	
	☐ Ancillary Support Core	

	☐ Data Support Core	
☐	Research Registry Registry Number:	
☐	Other	

If Other, please specify:

ID: Pro00003276 View: 2.1.1 Expedited Qualification

REQUEST FOR EXPEDITED REVIEW

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

AND

Identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, or reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.

1.0 * **Please certify that ALL of the following are true:**

Case
Research presents no more than MINIMAL RISK to subjects (considering physical, psychological, social, legal and economic risk)
Identification of the subjects and/or their responses WOULD NOT reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, OR reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.
The research is not classified.
The research involves only procedures listed in one or more of the categories listed in Section 2.

2.0 **If you check any of the items below, the study is qualified for EXPEDITED review status under federal guidelines.**
* **Select all that apply:**

	Description
☑	**1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:** **(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.** **(b) Research on medical devices for which an investigational device application (21 CFR 812) is not required OR the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**
☐	2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: **(a)** From healthy, non-pregnant adults who weigh at least 110 pounds. [not to exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or **(b)** From other adults and children, considering the age, weight and health of the subjects, the

collection procedure, the amount of blood to be collected: The amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ 3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples:

(a) hair and nail clippings in a nondisfiguring manner;

(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction;

(d) excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.

☑ **4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are used, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications)**

☐ 5. This research involves materials (data, documents, records, or specimens) that have been collected for any purpose including previous research or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☑ **6. This research involves the collection of data from voice, video, digital, or image recordings made for research purposes.**

☑ **7. This research will be performed on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**

ID: Pro00003276 View: 3 Research Design

Methods & Procedures

1.0

* **Does this research study involve any of the following:**

	Name
☐	Deception
☐	Interview/Focus Groups
☐	Use of Drug, biological, or nutritional (e.g., herbal or dietary) supplement (investigational or FDA approved)?
☑	**Use of medical devices**
☐	Prospective Analysis of Specimens

- [ ] Banking of Specimens-Data
- [ ] Retrospective use of specimens
- [x] **Audio/Video Recordings or Photographs**
- [ ] Honest Broker or other similar service
- [ ] None of the Above

ID: Pro00003276 View: 3.4 Use of Medical Devices

Medical Devices

1.0 * **Specify all devices used on this study:**

Device Name	Manufacturer	Use of Device	IDE Number(if Applicable)	Device Brochure	Description of Use	Risk Level Determined by Sponsor
Kinova Gen3 Assistive Robotic Manipulator	Kinova	Investigational Device Not Yet Approved for use		Kinova Gen3 Brochure(0.01)	The Kinova Gen3 Assistive Robotic Manipulator is a device that was built for human-robot interaction with flexible functionalities to ensure better safety and performance in any research environment. It equips discrete 2D and 3D sensors for vision-based applications and 7 DOF robotic arm for the daily object manipulation. The Kinova Gen3 Assistive Robotic Manipulator is a commercially available robotic research system, which will be positioned on a commercial electric powered wheelchair to assist daily manipulation tasks. The Kinova Gen3 Assistive Robotic Manipulator will be used to object recognition and manipulation. The Kinova Gen3 Assistive Robotic Manipulator can be powered using the wheelchair batteries and wall outlet. The Kinova Gen3 Assistive Robotic Manipulator has three layers of safety. First is the mechanical layer, which includes soft cover of screws, smoothed edges and surfaces, and padding on connectors	Non-Significant Risk

and power cables. In the unlikely event of a power failure, the arm is freely movable to reposition. The second layer is electronic, which includes self collision prevention, joint limits, hard force limits, hard speed limits, user initiated stops, and force compliance, which allows the robot to elastically bend in under certain loading conditions. Most importantly, the Kinova Gen3 Assistive Robotic Manipulator does not move quickly, providing humans time to react to the devices movements. In addition, the manipulator stops when the user releases the joystick or control interface. The third layer is the software layer, which allows for programming of constraint spaces including slow moving and keep-out zones. The software layer is unique to robotic technologies and has potential to detect unsafe situations before they lead to accidents. A significant risk device is defined as an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(4) otherwise presents a potential for serious risk to a subject. The Kinova Gen3 Assistive Robotic Manipulator does not meet the definition of a significant risk device as it does not meet any of the 4 criteria listed above.

2.0 * **Describe your plan for storage and control of devices:**
The commercial robotic manipulator is attached to a commercially available electric powered wheelchair which will be stored in our testing laboratory. Prior to testing, the participants will be thoroughly informed about the device and instructed in its use through training sessions. At least one investigator will be present at all times when the device is in use.

ID: Pro00003276 View: 3.8 Audio/Video Recordings or Photographs

3.8 Audio/Video Recordings or Photographs

1.0 * **Please provide a description of the audio and/or visual recordings or photographs and who will have access to them:**
The performance test with functional tasks using the default control and VGS control will be video recorded so that they may be viewed by the study team during data analysis to confirm the user performance data collected. Investigators will make every attempt to video record from the neck down to maintain confidentiality; if, however, the subject's face be inadvertently included, investigators will blur out the subject's face during analysis and prior to any future use. Only VAPHS study members will have access to these videos.
The interviews with participants at the end of the study will be audio-recorded for later transcription and data analysis. Only VAPHS study members will have access to these audios.

2.0 * **Please describe why this study could not be done without collecting this information in this manner:**
Videos will be used to serve as a reference when analyzing the data. Without video, we would not be able to accurately assess user performance during data analysis.
Audios will be used for later transcription and data analysis. Without audio, we would not be able to capture all the comments and suggestions provided by the participants.

3.0 * **Please specify your plans for deidentifying or anonymizing the material and when it will be destroyed:**
Videos and audios will be captured electronically and files will be named, stored and maintained as described in Section 10: Data Security and Privacy.

ID: Pro00003276 View: 4 Research study methods

Research Study Methods

Describe all study related procedures following enrollment of a subject in this study.

Please see Section 6 for where the study team defines when a subject will be considered enrolled in the study.

1.0

* **Research Procedures/Interventions:**

All research activities will be performed in a controlled environment at the Human Engineering Research Laboratories (Bakery Square Location) or at participants' home by the study investigators comprised of research

engineers, clinicians, and a study coordinator. The testing session will consist of one visit of no more than six hours or can be conducted in multiple lab or home visits of 2-3 hours which add up to no more than 6 hours. If a participant cannot commit to a total of 6 hours, they will be given the option of one 3-hour visit.

Informed consent will be obtained verbally after eligibility screening or onsite. Participants will then complete a questionnaire that includes questions about general demographics, injury and health information, and assistive technology experience. They will also complete a SCI-FI self-care. These two assessments can be done via phone or in-person. In addition, we will administer MoCA, the Paper Folding Test and Cube Comparison Test. SCI-FI Sel-care is a validated patient-report outcome measure of physical functioning related to self-care for persons with SCI or other physical disabilities. The Paper Folding Test examines a person's spatial visualization ability by asking him/her to imagine the folding and unfolding of pieces of paper. MoCA is a cognitive screening test designed to assist health professionals in the detection of mild cognitive impairment. The Cube Comparison Test examines a person's spatial orientation ability. These user characteristics may influence their performance with the ARM control.

Participants will go through a training procedure following the training guide provided by Kinova Robotics. During the training phase, a Kinova Gen3 ARM will be mounted onto a table where the training exercises are set up. There will be two training sessions. The first training session will explain the basic operation principle of the ARM, where participants will learn to operate the ARM and practice the basic movements of the adaptive Wolf Motor Function Test (WMFT) for ARM (i.e., move the ARM to table, on top of the box, pick up a cup, simulate drinking, put the cup back to the top of box). They will be given opportunities to try different control interface options. They will start with the method they use to control their power wheelchair and be allowed to explore other options such as the touch interface. This session will last for about one hour. At the end of the training, a pretest will be performed to determine participants' eligibility for the subsequent experimental test procedures. Participants will be asked to perform three simple tasks on a task board including pushing a large round button, flipping a toggle switch, and pushing down a door handle. If participants can complete each task within 2 minutes, they will be considered eligible for participating in the study and move to the next training session. Otherwise, more practice and training will be provided. Investigators may also decide whether a participant has proficient skills to move onto the next session or if the trial should be concluded. The 2nd training session will explain more advanced features of the ARM such as the singularity avoidance system and obstacle avoidance, and we will also introduce the VGS control with fiducial markers and adaptive tools. This session will last approximately 1.5 hours. After training, we will install the ARM to the participants' wheelchairs, on a table, or on an upright stand and configure the control interface for them as needed.

Prior to testing, participants will be asked to rate tasks in a task list in terms of type of assistance needed, levels of difficulty, and levels of satisfaction. They will then be asked to select 5-10 tasks that they cannot complete on their own. They will then complete the selected tasks with two interventions, i.e., default control and VGS control (including fiducial markers and adaptive tools). The tasks will be randomly presented to each participant and the sequence of the two interventions will be counterbalanced using a cross-over design to minimize order and carryover effect. There will be a break after each intervention and participants can also request resting periods at task transitions. The testing session will last about 2 hours. The testing session will be video recorded so that they may be viewed by the study team during data analysis to confirm the user performance measures. We will collect the following measure for each intervention.

- Task completion time: The time it takes to complete each task successfully. A maximum duration will be assigned to each task based on the prior bench-top testing. Participants will be asked to stop the task when the maximum duration is reached.
- Mode Switching Frequency: The number of times a participant has to switch modes for task completion based on logged control commands.
- Robot Pause Time: The total time when the robot is not moving.
- Success rate: The number of tasks out of the selected tasks that can be completed successfully within the maximum assigned time.
- NASA Task Load Index (TLX): NASA TLX will be used to assess the subjective workload of participants after each intervention. It has been shown to be valid and has excellent test-retest reliability. It consists of six dimensions: mental demands, physical demands, temporal demands, performance, efforts, and frustration. Twenty-step bipolar scales are used to obtain ratings on these dimensions, resulting in a score between 0-100. The overall task load index will be a weighted average of all six dimensions, where the weight for each dimension is obtained through pairwise comparisons of these dimensions. The higher score indicates a higher workload.
- System Usability Scale (SUS): SUS will be used to collect perceived ease-of-use after each intervention. It provides a global measure of user satisfaction and has been shown to be reliable and

valid. It consists of 10 statements where users rate on a 5-Likert scale (from 0-strongly disagree to 4-strongly agree). Following a suggested formula, a final score between 0-100 will be obtained. The higher score indicates better usability and overall satisfaction.

At the conclusion of the study, we will conduct a brief semi-structured interview with each participant and obtain more insight on how participants perceive the ease-of-use and usefulness of the VGS control with environment adaptations, and obtain suggestions they may have for further development and deployment. The interviews will be audio-recorded for later transcription.

Please upload a table of procedures if applicable.
The study procedures table must be completed for:
- All Greater than Minimal Risk (GTM) studies; and
- All Minimal Risk studies that use Standard of Care or Usual Care/Interventions.

Name	Modified Date

There are no items to display

2.0

* **Will Usual Care Procedures/Interventions be used?"**

○ Yes ◉ **No**

If yes, please specify and include a description of what the usual care or expected level of care is at VAPHS (e.g., medications, testing, timing, etc.) for patients, similar to those individuals that meet the inclusion/exclusion criteria for this research study:

2.1 If Usual Care Procedures/Interventions will be used, who is the individual or entity responsible for relevant aspects of the usual care (i.e., which of the above usual care activities will the research study team be responsible for)?:

2.2 Does the usual care at VAPHS for the condition of interest in this research study differ from national guidelines/recommendations (i.e. standard of care)?

○ Yes ○ No

If yes, please describe the differences:

2.3 Are any procedures that are considered standard for this patient population performed more frequently than usual care?

○ Yes ○ No

If yes, please indicate which time points are considered usual care and which are considered research.

2.4 If there is more than one standard, does VAPHS limit which one is followed (e.g. warfarin use for atrial fibrillation vs. one of the newer anticoagulants).

○ Yes ○ No

If yes, please explain:

3.0

* **Does clinical expertise need to be enlisted?**

○ Yes ◉ **No**

If yes, please provide the provisions for enlisting the services of a clinician with appropriate expertise and privileges to perform duties, if the investigator is not a clinician [i.e. reviewing the data, adverse events,

and new study findings; also making required decisions to protect the health of the subject (e.g., stopping the participant's involvement in the study or determining when to notify the subject or the subject's health care provider of information that may affect the health of the subject)]:

4.0 Please upload any surveys, questionnaires, and data collection forms.

	Document	Description	Version Number
View	Cube Comparison(0.01)		0.01
View	Interview Quesions(0.01)		0.01
View	NASA-TLX(0.01)		0.01
View	Paper Folding(0.01)		0.01
View	Questionnaire(0.01)		0.01
View	Satisfaction(0.01)		0.01
View	SUS(0.01)		0.01

ID: Pro00003276 View: 4.1 Research study methods: analysis Plan

1.0 * Please describe the analysis plan for the study *(it is acceptable to refer to the sponsor/multi-site protocol for section if applicable):*
Statistical analyses will be preceded by a detailed descriptive analysis of the data, using standard descriptive summaries and graphical techniques. The task completion time will be aggregated over the self selected tasks. The key variables including the aggregated task completion time, [mode switching frequency], success rate, NASA TLX score, and SUS score will be examined to ensure that proposed statistical techniques are suitable. Significance level will be determined at 0.05 for all statistical tests. We will first use scatterplots to show each participant's key variables on the two interventions. Different symbols will be used to indicate the order of intervention for each participant and the line of equality will be superimposed for ease of interpretation. We assume neither carry-over nor period effects would be a problem, thus will use a paired t-test to compare the two interventions on all key variables. Qualitative data from the semi-structured interviews will be audio recorded and transcribed, and then analyzed using the affinity diagramming technique to extract themes.

ID: Pro00003276 View: 5 Sub-Studies

1.0 * Is there a sub-study or are there sub-studies associated with this study?
There is no sub-study associated with this study.

ID: Pro00003276 View: 6 Study Population Summary

Study Population Summary

1.0 * What is the maximum number of subjects you plan to enroll at VAPHS?
We aim to recruit a total of 21 participants.

2.0

*** Do you plan on enrolling patients into different categories:**

○ Yes ◉ **No**

If yes, please explain:

3.0 If this is a multi-site study, indicate the projected total subject accrual:

4.0

*** Please provide a justification for the sample size:**

[Based on our preliminary work, in the lab testing condition, the VGS control could reduce the task completion time by an average of 30% (ranging from 0.03% for the simple door handle task to 55% for the relatively difficult knob turning task). The functional tasks in our task list will contain more complex tasks,

thus we can reasonably assume at least 20% reduction in task completion time when using the VGS control as opposed to the default control for this power analysis.] Given an alpha of 0.05, a 20% reduction in task completion time, and a 25% standard deviation in the difference between the two interventions, we will need 12 participants to obtain 80% power for the study. We will, therefore, recruit 16 participants to account for attrition for the lab testing session. For the home testing session, since this is a pilot study, there is no prior data from our group and published paper. Thus, it is not applicable to calculate a power analysis. We aim to recruit 3-5 participants to assess the feasibility and collect preliminary date. Power analysis was performed using the G*power 3.1.9.2.

ID: Pro00003276 View: 6.1 Study Population

Study Population

1.0 * **Check all that apply to describe your study population:**

Study Population
☑ **Non-Veterans**
☐ Special Populations
☑ **Veterans**
☐ Vulnerable populations
☐ Other

2.0 * **Indicate the inclusion criteria for enrollment:**
The inclusion criteria are (1) 18 years of age and older; (2) using a power wheelchair as primary means of mobility; (3) having self reported difficulties in performing everyday manipulation tasks such as reaching for a glass of water, opening a refrigerator, and picking up a toothbrush.

3.0 * **Indicate exclusion criteria for enrollment:**
The exclusion criteria are (1) people with impaired vision; and (2) people with pressure ulcers that prevent them from sitting continuously for an extended period of time.

4.0 **If there are any age, ethnic, language, or gender-based exclusion criteria, including the exclusion of any pregnant or lactating women, or those of child-bearing potential, please provide justification:**
We would like to recruit participants who are 18 years of age and older, as the control method and tasks are designed for adult users instead of pediatric users.

5.0 **Please specify why vulnerable subjects and/or special populations will not be enrolled:**

6.0 **With some exceptions as listed in VHA Handbook 1200.05, incompetent subjects cannot be enrolled in VAPHS approved research. Specify that you will not enroll incompetent subjects and the general rules to be used in making that determination:**
Incompetent subjects will not be enrolled in this study. Competency will be determined based on whether or not the subject is able to provide informed consent by effectively communicating with study investigators.

ID: Pro00003276 View: 6.1.1 Non-Veterans

Non-Veterans

1.0 * **Target number of participants:**
21

2.0

*** Describe why you cannot complete enrollment in this study without the use of Non-Veterans:**

1. Specify why you require Non-Veterans in your study. Include information in your justification related to your study aims/goals; What role will the Non-Veteran population have in the study?

Given the nature of this research, which focuses on individuals who have limitations with activities of daily living, who use an electric powered wheelchair as primary source of mobility, our recruitment pool is small. There are insufficient Veterans available to complete this study in accordance with 38 CR 17.45 and 38 CFR 17.92. This necessitates recruiting both veterans and non-veterans for our research.

2. Provide information as to why there are insufficient Veterans suitable for this study. Include proof, whether through statistics, or another method, that you have used your resources in a good faith effort to enroll Veterans; Example- 'We are studying a rare disease that affects a very small population, in which Veterans would be an even smaller portion of that population.' *Provide the appropriate diagnostic statistics to support this*

We will need to recruit n=21 subjects to have sufficient power to obtain statistically significant data as to the superior performance of our custom vision-based control. We have only 19 Veteran participants in the HERL research registry that live within Pennsylvania and use a power wheelchair for the majority of their mobility. Of these registry participants, not all live close enough to Pittsburgh to participate, meet the inclusion/exclusion criteria or will want to participate in this study. Also, the information obtained from this study could be generalized to benefit the well-being of all power wheelchair users, including veterans. According to VHA Directive 1200.01 non-veterans may be recruited when there are insufficient veterans suitable for the study. According to the HERL research registry, we find this to be the case. We, therefore, would need to enroll non-Veterans to get statistical power for the study. However, we will also make every effort to actively recruit veterans into this study.

3. Provide information about how the inclusion of the Non-Veteran population will fulfill/remain consistent with the VA Mission. Explain how including Non-Veterans will enhance your study, yet still pertain to the Veteran population.

VA's Mission is to fulfill President Lincoln's promise: "To care for him who shall have borne the battle, and for his widow, and his orphan" by serving and honoring the men and women who are America's Veterans.

We believe the study results will provide knowledge base to help expand the manipulation capability of veterans with disabilities who use electric powered wheelchairs and improve their independence with activities of daily living.

4. How will the inclusion/recruitment of Non-Veterans benefit Veterans and their well-being?

It is necessary for us to include the veterans and non-veterans to increase the sample size and generalize the results to people who use electric powered wheelchairs as a primary source of mobility. We will meet the aims of the study, by enrolling veterans and non-veteran wheelchair users and having them test the our custom vision-based control for the assistive robotic manipulator.

Please upload the Inclusion of Non-Veterans Worksheet here:

3.0 * **If your study is a clinical trial, please indicate where the VHA Notice of Privacy Practices (VA Form 10-0483) will be stored once signed:**
Not applicable.

ID: Pro00003276 View: 7 Risk/Benefit Assessment-Risks

Risk/Benefit Assessment-Risks

1.0 * **Risk classification for this study (select one).**

	Name
◉	**Minimal Risk**
○	Greater than Minimal Risk

2.0 * **Basis for making the above recommendation:**
1. Participants will evaluate a new control approach for an off-the-shelf wheelchair-mounted robotic arm for a series of everyday functional tasks, and thus will not be exposed to greater risks than what they experience in everyday life.
2. There is a risk of breach of confidentiality.

3.0 * **Describe the safety precautions that will be taken to minimize risks/harms:**
There is the risk that the device/control could malfunction. To minimize this risk, the investigators will be working in close proximity to the subjects and provide supervision as needed. The device is designed to operate under slow speeds and allows investigators to specify safety zones where the arm cannot reach. In addition, safety switches are installed and investigators have the ability to completely shut down the operation of the device for any reason. Thus, no physical injury (e.g., swinging around and hitting the subject) can occur using this device.

Participants may experience frustration while learning to use a new device. Subjects will be provided with extensive training and also be informed that they may take a break and/or discontinue the study at any time. Subjects will also have the option to decline to complete a task if they are unable or choose not to.

In the home testing scenario, there are risks of damage to the testing objects and leaving tape trails on the object. To minimize the risk, no fragile items will be used as testing objects; also, the investigators will be working alongside the participants, giving instructions on robotic arm operation to avoid damage. In addition, no residue tape will be used for taping the fiducial tags to reduce the risk of leaving the tape marks on the object.

There is a potential risk for a breach of confidentiality from completing the questionnaires, the video recording during the testing session, and audio recording of the exit interviews. To minimize this risk, only associated research staff will have access to identifiable study information. Research activities that are video recorded will be recorded from the neck down. If someone's face is inadvertently included, investigators will blur out the subject's face prior to future use.

4.0 * **Provide details regarding the nature of each risk using the area provided below:**

	Risk Name
View	Interviews
View	Research activities
View	Questionnaires

5.0 * **Do you plan on using the research answering service:** ○ Yes ◉ **No**

If yes, please Upload the research answering service form:

6.0 **If your study involves a treatment or intervention, please upload the Patient ID Card:**

ID: Pro00003276 View: 7.1 Risk/Benefit Analysis-Potential Benefits and Alternatives

Risk/Benefit Analysis-Potential Benefits and Alternatives

Describe any potential for benefits to participants in this study:

1.0 * **Direct and Indirect Benefits to Subjects:**
There are no direct benefits to participants in this study.

The proposed work may benefit society by maximizing the potential of ARMs in assisting Veterans with everyday manipulation tasks and supporting the adoption of this advanced assistive technology. The use of enhanced ARMs in home and community could potentially lead to improved independence and the ability of Veterans with upper limb impairments to integrate into the community, as well as reduced attendant care need and cost.

2.0 * **Describe alternatives (research or non-research) that are available to subjects if they choose not to participate in this study:**
Alternative to participate is not to participate in this study. There also may be other projects the individual may qualify for.

ID: Pro00003276 View: 8 Methods of Recruitment and Retention

Recruitment Methods and Materials used for Retention

1.0 * **Select recruitment methods used on this study:**

	Name
☐	Mail Campaign
☐	Referral by independent source
☑	**Advertising such as fliers, letters, or ads (newspaper, TV, radio)**
☑	**Web Site**
☑	**Research registry**
☐	Selected from pre-existing records
☑	**Pre-existing relationship with participants**
☐	Other

If Other Methods Specify:

2.0 * **Specify how subjects will be identified and how study eligibility will be determined:**
As stated on pg. 11 of the grant, subjects will be recruited through IRB approved registries developed by the Human Engineering Research Laboratories and the Department of Physical Medicine and Rehabilitation.

They also can be recruited through Pitt+Me. All registry participants have provided informed consent to be contacted for future research studies.

All registry participants have provided informed consent to be contacted for future research studies. The IRB approved flyer for this study will be provided to the registry investigators to distribute to potential subjects according to the procedures established in the registry IRB approved protocols. In response to the flyer, potential subjects will directly contact the research team if interested in participating.

We also plan to recruit through distributing the recruitment flyer to rehabilitation facilities throughout the UPMC Center for Assistive Technology (CAT) and VAPHS. Potential subjects recruited through the CAT and VAPHS wheelchair clinic will be approached by their treating provider, asked if they would like to participate and will be given a flyer. The recruitment flyer mentioned is the same as above. We also intend to utilize the VAPHS Facebook page to post a flyer. Participants may also be recruited by placing flyers at informational tables sanctioned by the VAPHS Research Office. Study team members may elect to sit at the informational tables to provide information and enroll participants.

Flyers may be posted in local rehabilitation facilities, outpatient facilities, and disability organizations. Participants may also be recruited via flyers in print media (magazines, newspapers, newsletters). The flyer may also be posted on the HERL website. The flyer instructs potential subjects to contact HERL for additional information. No recruitment materials will be used without IRB approval. Subjects who wish to participate will call the laboratories and be scheduled for testing.

Individuals who are participating in other research studies at HERL may be given the study flyer and asked if they would like more information. If yes, the individual may be introduced to a member of the research staff.

3.0

*** Provide the location (or locations) of the sites where participants will be recruited:**

VAPHS, HERL, UPMC Center for Assistive Technology (CAT)

4.0 Please include information regarding any advertisements (print, TV, radio, etc) that will be used to recruit subjects including a general description of where this information will be posted:
The flyer may be used in print media (magazines, newspapers, newsletters) and web-based postings. Flyers may be posted in local rehabilitation facilities, outpatient facilities, and disability organizations. The advertisement will be posted on the HERL website (www.herl.pitt.edu). The flyers instruct potential subjects to contact HERL for additional information.

5.0

Please UPLOAD the documents that will be used for recruitment and an introductory statement or letter to accompany consent for those studies obtaining written informed consent using methods such as fax, email or mail (if applicable). Please also upload any screening/recruitment questions that will be verbally asked of potential research subjects. Also, if you will be providing any retention materials, please upload them here.

Name	Reviewer	Modified Date	Version Number
Public Affairs Office Approval	Post, Daniel Robert	11/21/2019 1:44 PM	0.01
VGS Flyer-converted.docx	Post, Daniel Robert	11/21/2019 1:43 PM	0.02

ID: Pro00003276 View: 9 Informed Consent

Informed Consent

1.0

*** Indicate the types of consent that will be involved in this study (check any or all that apply):**

Informed Consent Category
Written/signed consent by subject
Waivers are being requested.
Verbal consent or written information sheet(Requires a Waiver of Documentation of Informed Consent - see below)

2.0 * **Waivers: If you are applying for any waivers of consent (check any or all that apply):**

	Name
☐	Waiver of Informed Consent
☑	**Waiver of HIPAA Authorization**
☑	**Waiver of Documentation of Informed Consent (telephone consent, verbal script)**
☐	No Waiver at all

3.0 * **Will this study include non-English speaking participants?**

○ Yes ◉ **No**

ID: Pro00003276 View: 9.1 Waiver of HIPAA

You have indicated you are requesting a waiver of HIPAA.

1.0 * **Is the request only for Screening/Recruitment purposes?**

○ **Yes** ◉ No

If yes, please describe your screening/recruitment method:

If no, the request is for the full study (e.g. retrospective chart reviews and certain observational studies)

We are requesting a waiver to allow us to conduct a brief phone screening of potential subjects who contact HERL and express an interest in the study. The screening will assist in determining potential subject eligibility prior to scheduling an appointment. Verbal consent for screening will be obtained and documented on the screening script. We are also performing some initial surveys via phone before the participant comes onsite that will ask some basic demographic and health information.

Please describe the types of records and/or databases to be accessed:

THE IDENTIFIABLE INFORMATION BEING REQUESTED:
Note: If participants will be receiving payment and HIPAA Authorization is not being obtained, you must select Names, Addresses and Social Security Numbers as that information will be disclosed for payment purposes.

2.0 * **Identifiable Information per HIPAA Definition**

	Name
☐	None
☐	Account numbers
☐	Biometric identifiers, including finger and voice prints
☐	Certificate/license numbers
☐	Device identifiers and serial numbers

- [ ] Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89)
- [ ] Email Address
- [ ] Fax Numbers
- [ ] Full-face photographic images or any comparable images
- [ ] Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)
- [ ] Health plan beneficiary numbers
- [ ] Internet Protocol (IP) address numbers
- [ ] Medical Record Numbers
- [x] **Name or any derivative of name such as initials**
- [ ] Social Security Numbers
- [x] **Telephone Numbers**
- [ ] URLs (Web Universal Resource Locators)
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Any other unique identifying number, characteristic, or code (Note: The study ID number, code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification)

3.0 * **Patient Protected Health Information:**

Name
☑ **Demographic Information (e.g., Name, Address, Phone Number, Social Security Number**
☐ Billing and Payment Information
☐ Hospital or Medical Records
☐ History and Physical Exam Notes
☐ Mental Health Records
☐ Data Previously Collected for Research Purposes
☐ Progress Notes
☐ Consultation Reports
☐ Laboratory Test Results
☐ Operative Reports
☑ **Other**

Please indicate the 'Other' Patient Protected Health Information:
difficulties in every day life; impaired vision; history of pressure sores; age

4.0 **Other Health Information:**

Name

There are no items to display

Waiver of HIPAA- More Information

1.0 * **Describe how the identifiable information is to be used and/or disclosed only by members of the research team and the following persons *(identify with specificity and justify the need to disclose the information to anyone outside the VHA.)* Note: If participants will be receiving payment and HIPAA Authorization is not being obtained, you must also describe this disclosure to representatives of the VA for administrative purposes here.**

Also describe how this activity meets the "minimum necessary standard" described in the HIPAA Privacy Rule:
For those subjects who contact an investigator via phone to inquire about participation, a telephone screening script will be administered. For the purposes of scheduling, the participant's name and contact information will be recorded.

The proposed study poses minimal risk to the privacy of the subjects because...

2.0 * **Describe how the identifiable information will be protected from improper use or disclosure by (detail how this will be accomplished including the limitations of physical or electronic access to the information and other protections):**
This information will be stored in a secure file room in the Human Engineering Research Laboratories with restricted access. Access to the file room is limited to the PI and associated research staff. Electronic information will be on a secure survey with only access to associated research staff and the PI.

3.0 * **Describe how the identifiers will be destroyed at the earliest opportunity consistent with the research (discuss the timeframe or the reasons the identifiers must be retained, including health or research justifications or any legal requirement to retain them) (Note: At this time, identifiers used for research screening and all other screening records must be retained indefinitely and this must be documented by checking "Other" below):**
If the participant is eligible to participate, their information will be stored in their research file or electronically. If the participant is not eligible to participate, contact information will not be collected.

* **When will screening data be de-identified or destroyed:**

Name
Other

If Other, please describe:
All research records will be maintained in accordance with the Veterans Health Administration (VHA) Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.

4.0 * **Describe how the identifiable information will not be reused or disclosed to any other person or entity outside the VHA other than the manner described in the protocol, except as a required by law, for authorized oversight of this research study, or as specifically approved for used in another study by an IRB:**
This information will be stored in a secure file room in the Human Engineering Research Laboratories with restricted access.

5.0 * **Describe why the proposed study cannot be practicably conducted without a waiver of authorization: (discuss reasons why it would not be possible to obtain authorization from individual subjects. Time constraints themselves are generally not considered adequate for this justification:**
Screening is done via the telephone. It would not be practical to mail out the HIPAA authorization to potential participants who contact us prior to asking a few questions to determine potential eligibility. The option of conducting initial surveys via phone will also be available to help with recruitment and decrease onsite participation time. Individuals who potentially qualify will subsequently be scheduled to sign an informed consent form and HIPAA authorization. If they do informed consent via phone, they will sign the standalone HIPAA authorization onsite.

6.0 * **Describe why the proposed study cannot be done without the specified identifiable information: Discuss reasons why it would not be possible to conduct the research without the**

identifiable information being collected.
Contact information is collected for eligible subjects for scheduling purposes only. We are also asking screening questions to determine eligibility. We want to confirm that the participant meets the eligibility criteria before being scheduled for testing to reduce the risk of participants traveling to the research lab, only to learn they are not eligible to participate.

ID: Pro00003276 View: 9.3 Waiver of Documentation of Informed Consent

Waiver of Documentation of Informed Consent

You have selected a waiver of Documentation of Informed Consent

1.0

This is a request for Waiver of Documentation of Informed Consent because this research study conforms to either A and/or B (Check if 'yes' and provide the verifying information requested):

* A: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. ○ Yes ◉ **No**

AND/OR

* B: The proposed study poses minimal risk to the subjects. ◉ **Yes** ○ No

If yes, please explain why the proposed study poses minimal risks to the subjects. (Outline the subject's involvement in the project and why the study poses minimal risk) :
The waiver of documentation of informed consent will cover screening procedures, and questionnaires that can be performed over the phone that include questions about general demographics, injury and health information, and assistive technology experience. They will also complete a SCI-FI self-care. These two assessments can be done via phone or in-person, but if selected to do via phone, it will be after verbal consent. The information collected during screening is minimal and limited to what's necessary to verify eligibility. The study is minimal risk because participants will not be doing any activities they would not normally do on a day to day basis.

2.0 * **The research involves no procedures for which written consent is normally required outside of the research context. Research procedures include:**
Information regarding the research study will be provided and if interested, the participant will be asked to answer several eligibility questions. If time allows, they will also be asked to complete initial surveys via phone. The information collected is used to verify eligibility. Questionnaires include basic demographics, injury information, SCI-FI and assistive technology experience. Any contact information needed will only be used to schedule an appointment for research participation. Basic demographic and contact information collected during the screening procedure presents no more than minimal risk and would not require informed consent outside of the research context. If the individual is deemed ineligible, the screening script used for this person will be stored securely within a locked file room at the Human Engineering Research Laboratories.

We are requesting a waiver to allow us to conduct a brief phone screening of potential subjects who express interest in participating in this research study. The waiver also allows completion of the demographic questionnaire and SCI-FI self-care survey via phone. This information will be stored in a locked secure file

room in the Human Engineering Research Laboratories with restricted access, and electronic forms will be saved on the secure network drive. Access to the file room is controlled by the Clinical Coordinators and will be limited to the PI and associated research staff.

3.0 * **Explain how whenever appropriate, the subjects will be provided with additional pertinent information (e.g. an information sheet):**
The participant will have the opportunity and will be encouraged to ask questions during the screening procedures. When the participant comes onsite, they will be provided with a hardcopy of the consent form for their records. Participants that consent verbally will also be required to sign a HIPAA authorization onsite.

4.0 **Please upload SCRIPT here:**

	Document	Description	Version Number
View	VGS Screening Script_VA IRB clean version(0.05)		0.05

ID: Pro00003276 View: 9.4 Consent Forms & Process of Consent

Consent Forms & Process of Consent

1.0 Upload the completed forms into the correct lists below.

1.1 **Informed Consent Form (clean copy):**

	Document	Modified Date	Version Number
View	VGS ARM Consent(0.07)	1/3/2020 12:00 AM	0.07

1.2 **Provider Behavior Informed Consent Form (clean copy):**

Document	Modified Date	Version Number
There are no items to display		

1.3 **Screening Informed Consent Form (clean copy):**

Document	Modified Date	Version Number
There are no items to display		

2.0 **Consent Forms (modified copy):**

	Document	Modified Date	Version Number
View	track change version(0.02)	1/3/2020 5:11 PM	0.02

3.0 * **Describe how, where, when, and by whom the consent process will be initiated:**
Written informed consent will take place at HERL using the VA IRB approved consent form. If possible, the participant will be given the option of doing a verbal consent for performing initial surveys by phone. The following procedures will be followed:

Potential subjects will be provided an explanation of the purpose of the research, why they are being asked to participate, and the duration of the study. In addition, the potential participant will be made aware of any foreseeable risks associated with the study as well as any potential benefits. Potential participants will be made aware of the alternative to participation in the study and the methods used to protect the confidentiality of the records during the study. Also, subjects will be told that their participation in this study is completely voluntary and that they can withdraw at any time. Information on who to contact if they were to have any questions, concerns, or complaints about this research will also be provided. Subjects will also be asked if they understand the purpose, risks and benefits, procedures, and their rights as a research subject. Any questions the subjects have at any time will be answered by one of the listed research staff. The entire process will occur prior to obtaining written informed consent. The principal investigator or a study team member of this study will be involved in the consent process described above. The consent process will take place in a private location at HERL or via phone

4.0 * **Will you be maintaining a Master List of Subjects?**
Yes

5.0 * **Describe when the subject's name will be added to the master list and how the list will be maintained in a secure fashion.**
Only once verbal consent has been obtained from the subject and it has been documented, will the study subject's name be added to the master list of subjects. The master list will be secured in compliance with all VA confidentiality and information security requirements.

ID: Pro00003276 View: 10.0.0 Data Security and Privacy: Data Types Storing

10.0 Data Types Collecting and Storing

1.0

Click the add button (below) to open an entry form to indicate the types and/or sources of the data that will be collected/stored as part of the project.

Instructions: **For each type/source of data that will be collected as part of the project, this includes screening data, click the add button to open an entry form that lists the types and/or sources of data. Select a source/type of the data that will be collected/stored. Then indicate what, if any, identifiers or sensitive information will be collected/stored from the source/type (None is an option). To add another source/type click "OK Add Another" button to open up a new entry form to repeat the process.**

Example 1: You are collecting data from VA Medical records including names, last 4 of SSN, and addresses. Therefore, you would select "VA medical record data" as the source, and then select in the identifiers: "Name or any derivative of name, such as initials," "Social Security Numbers," and "Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)" as the identifiers being collected.

Example 2: You are screening VA Medical Records and recording the information you use to screen (i.e.: names, last 4 of SSN, and addresses, etc.) Note: This information must be treated as a Source document, please select "Screening" as the source and then select the identifiers "Name or any derivative of name, such as initials," "Social Security Numbers,", as applicable.

*

	Data Type/Source	Collection Details	Identifiers
View	Audio or video recordings	Data will be collected at VAPHS	• Any other unique identifying number, characteristic, or code (Note: The study ID number, code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification)
View	Other *Data from study device*	Usage data from assistive robotic arm during the laboratory	• None

		testing will be collected at VAPHS.	
View	Questionnaires/Surveys, paper	Data will be collected at VAPHS, or via phone.	• Any other unique identifying number, characteristic, or code (Note: The study ID number, code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification)
View	Other *Consent form/HIPAA Authorization*	Data will be collected during the process of obtaining informed consent. Only the last 4 digits of the Social Security number will be collected. Data will be collected by approved research staff. HIPAA authorization will be signed onsite if the participant does verbal consent via phone.	• Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89) • Telephone Numbers • Social Security Numbers • Name or any derivative of name such as initials

ID: Pro00003276 View: 10.0.1 Data Security and Privacy: Social Security Numbers

10.0.1 Data Security and Privacy: Social Security Numbers

1.0 You indicated that you will be using all or some part of the research subjects' SSNs as part of this study. Which of the following will you be using:

Real Social Security numbers	*	(•) **Yes**	( ) No	
Scrambled Social Security numbers	*	( ) Yes	(•) **No**	
Last 4 digits of Social Security Number	*	(•) **Yes**	( ) No	
Other (some derivation of the SSN)	*	( ) Yes	(•) **No**	

If other, please explain:

2.0 * Please describe how subjects' Social Security numbers will be used in this study:
The last 4 digits of the subjects' social security number will be collected on the informed consent document and the HIPAA Authorization form. The full SSN and bank account number will be used by the VA to issue EFT payment.

3.0 * Please describe the security measures that will be taken to protect SSNs.
This information is collected as required. The security measures that will be taken to protect SSNs are the same as those applied to all study data. The HIPAA authorization will be stored securely within a locked file room at the Human Engineering Research Laboratories. Paper documents will be stored in room 4103 of the Human Engineering Research Laboratories.

ID: Pro00003276 View: 10.1.0 Data Security and Privacy: Incoming Data

10.1.0 Incoming Data

1.0 * Will data be transferred into VAPHS?
No. Data is not being transferred into this facility

ID: Pro00003276 View: 10.2.0 Data Security and Privacy: Outgoing Data

10.2.0 Outgoing Data

1.0 * **Will any of the data being collected/stored be transferred outside of VAPHS?**
No. The data is not being transferred outside of this facility.

ID: Pro00003276 View: 10.3.0 Data Security and Privacy: Local Data Storage Types

10.3.0 Local Data Storage Types

1.0 * **How will data be stored on this project? (Select all that apply)**
On Paper
Electronically

ID: Pro00003276 View: 10.3.1 Data Security and Privacy: Local Data Storage Types - Paper

10.3.1 Local Data Storage Types - Paper

1.0

* **All VA research data collected in paper must be stored in a locked room at VAPHS.**

List the room number(s) and the campus(es) where data will be stored in the text box below.

Paper documents will be stored in room 4103 of the Human Engineering Research Laboratories. Room 4103 is a double locked file room where HERL stores all VA data. Access to this room is limited to only clinical coordinators.

ID: Pro00003276 View: 10.3.2 Data Security and Privacy: Local Data Storage Types - Electronic

10.3.2 Local Data Storage Types - Electronic

1.0 * **Where is the electronic data being stored? Select all that apply.**
VAPHS Network (shared drive)
VA redcap

If "Other" please describe OR if you would like to provide additional information for clarification, please elaborate in the text box below.

If you selected VAPHS or VA Network (Shared Drive), please provide the name of the drive (i.e. "MySharedDriveName (\\vapthshsare) (X:)"):

\\oitpthhsmsvm200.v04.med.va.gov\Research\Ding_Pro3276_VGS_ARMS_542

ID: Pro00003276 View: 10.4.0 Data Security and Privacy: Reusing Data

10.4.0 Data Security and Privacy: Reusing Data

1.0

* **Will the data collected in this study be reused in other studies?** (●) **Yes** ( ) No

If yes, please describe where the data to be reused will be stored and how access to that data will be provided and monitored:

The final data set will be maintained at VAPHS share drive (\\vhapthmulherl07\HERL07\HERL07\HERL Projects Ding\VGS ARM), until enterprise-level resources become available for long-term storage and

access. Guidance on request and distribution processes will be provided by ORD. Prior to distribution, a local privacy officer will certify that the dataset contains no PHI.

2.0 If this research is part of a grant, please upload the Data Management Access Plan (DMAP) or Resource Sharing Plan for this study.

Name	Modified Date
DMAP	11/18/2019 2:04 PM

ID: Pro00003276 View: 10.6.0 Data Security and Privacy: HIPAA

10.6.0 Data Security and Privacy: HIPAA

The Healthcare Insurance Portability and Accountability Act (HIPAA) prohibits the use of a person's Protected Health Information without a valid authorization.

1.0 * Select the option which fits this study:

	Name
○	Not applicable: No PHI is being used or disclosed by VAPHS
○	Not applicable: Waiver has been requested
○	HIPAA Authorization (Combined Consent and HIPAA Authorization)
◉	**HIPAA Authorization (Standalone)**

Upload HIPAA authorization (Standalone) here:

	Document	Modified Date	Version Number
View	HIPAA Placeholder(0.01)	11/18/2019 11:38 AM	0.01

2.0 At screening will clinical personnel be asked to share potential participants PHI:

○ Yes ◉ **No**

If yes, please upload the 10-5345:

ID: Pro00003276 View: 10.7.0 Data Security and Privacy: Additional Information

10.7.0 Data Security and Privacy: Additional Information

1.0

Does this research involve...

*** ...specially obtained software?** ○ Yes ◉ **No**

If yes, please describe the software and what it is being used for:

*** ...one or more Web-based applications?** ○ Yes ◉ **No**

If yes, please describe the application and what it is being used for:

*** ...mobile devices?** ◉ **Yes** ○ No

If yes, please describe:

A VAPHS video recorder (not mobile device/audio recorder) will be used for video recordings. The video files will be stored on a secured server affiliated with Human Engineering Research Laboratories and only be made available to personnel involved in the study through the use of access privileges and passwords.

2.0

*** Will a Certificate of Confidentiality be obtained for this study?** ○ Yes ◉ **No**

If yes, please attach the Certificate of Confidentiality:

3.0

*** Will VA sensitive information be transported and utilized outside protected environments?** ○ Yes ◉ **No**

If you answered yes above, please upload a fully executed VAPHS Memo to Take VA Sensitive Information Outside a Protected Environment by following **these instructions** .

ID: Pro00003276 View: 10.8.0 Data Security and Privacy: Certifications

10.8.0 Certifications

1.0 *** I certify that all study staff are up-to-date and will remain up-to-date with Information Security Awareness Training, Rules of Behavior, and VHA Privacy Training.** ◉ **Yes** ○ No

2.0 *** I also certify that when an individual is no longer part of the study team, access will be removed to research study data.** ◉ **Yes** ○ No

3.0 *** I certify that all research records will be maintained in accordance with the Veterans Health Administration (VHA)Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.** ◉ **Yes** ○ No

4.0 *** I certify that any loss or compromise of any VA sensitive information (including research data), VA equipment or device, or any non-VA equipment or device that is used to transport, access, or store VA information will be reported in accordance with the reporting requirements outlined in VA Handbook 6500.** ◉ **Yes** ○ No

5.0 *** I certify that, in accordance with VA Handbook 6500, no personal laptops will be used for official VA business in conjunction with this study.** ◉ **Yes** ○ No

ID: Pro00003276 View: 11 Local Data Safety Monitoring Plan

Local Data Safety Monitoring Plan

For local studies, a data and safety monitoring plan (DSMP) must be established.

1.0 *** Please describe how the study procedures and data being collected will be continuously monitored so that changes in the risk/benefit ratio can be determined in a timely fashion during the course of the study:**

A data and safety monitoring plan will be implemented to ensure that there are no changes in the benefit/risk ratio during the study and that confidentiality of research data is maintained. Any instances of protocol deviations or other problems identified will be reported as soon as possible within the required reporting time frames using the standard forms and/or procedures set forth by the IRB. A data safety and monitoring report will be sent to the IRB at the time of renewal.

2.0 * **Describe how frequently Investigators, study personnel, and the clinical coordinators involved in the study will meet and/or review study data.**

Investigators, study personnel, and the clinical coordinators involved in the study will meet weekly to discuss the study and address any issues or concerns at this time. These meetings are overseen by the Directors of Human Engineering Research Laboratories or their designees.

3.0 * **Will this study use a Data Safety Monitoring Board or Data Monitoring committee?**

( ) Yes (•) **No**

4.0 * **Will this study use a Medical Monitor?**

( ) Yes (•) **No**

ID: Pro00003276 View: 12 Costs and Payments

Costs and Payments

1.0 * **Does this study have a budget?:**

(•) **Yes** ( ) No

If yes, please upload the current budget:
VGS ARMS Budget.xls(0.01)

2.0

* **Will patients receive payments for this study?**

(•) **Yes** ( ) No

If yes, please upload the financial letter of support (either from the Business Service line or the Veterans Health Foundation) or documentation waiving the requirement of a letter of support:
Financial Letter of Support.pdf 0.01

3.0 * **Are you paying patients using the WePay system?**

no

ID: Pro00003276 View: 12.1 Costs

Costs

1.0 * **Will subjects be required to pay for any services outside of the VHA that may be required as part of participating in this research study?**

Not applicable.

ID: Pro00003276 View: 12.2 Participant Payments

Participant Payments

1.0 * **Please explain how the proposed payments are reasonable and commensurate with the expected contributions of the subject:**
Because the subjects will be spending about 6 hours in the lab, the study team feels that $150.00 (which is $25/hour) is both reasonable and commensurate for the activities involved with the research study.

2.0 * **Please provide information on how the subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the prospective research subjects to volunteer for, or to continue to participate in, the research study. In additional the payments do not constitute (or appear to constitute) coercion to participate in, or continue to participate in, the research study:**
Participants will be reimbursed for the time and effort they invest in participating in this study. The study time will be limited to 6 hours at most. $150 is similar on a per hour basis to how much a majority of other studies pay. The study activities are also simple in nature and of minimal risk, furthering the fact that $150 for 6 hours or $25/hour is a fair payment. The participate is free to withdrawal from the study at any time and receive $25 for their participation.

3.0 * **Specify the amount, form of payment and the specific disbursement schedule of payments:**
Subjects will be compensated $25/hour for their time and effort in completing the study. If they are determined not eligible for participating in the study during the pretest session, they will receive $25. Subjects will be compensated by the VA using Electronic Funds Transfer.

4.0 * **Are the subjects being paid employees?**
no
If yes, please describe how it will be in accordance with the SOP:

ID: Pro00003276 View: 14 References

References:

1.0

* **Please provide a list of references** *(Multi-site protocols: You may reference the page numbers in the original protocol):*

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ID: Pro00003276 View: 15 Miscellaneous Documents

Miscellaneous Documents

If you have any documents that need to be included in this submission, but do not fit in any of the previous sections please upload them here.

Document	Description	Version Number
There are no items to display		

ID: Pro00003276 View: SF - Final Page

Final Page

You have completed your application!

Please hit "Finish" to save and exit the application. Doing so will NOT submit the application for review.

Please note that a submission may only be forwarded to the IRB by the Principal Investigator. To do this, the Principal Investigator must press the "SUBMIT STUDY" button in My Activities for this Study ID:Pro00003276.

You can track the ongoing status of your submission by logging into the study workspace.

Please feel free to contact the IRB with any questions or concerns.

ID: Pro00003276 View: Create/Edit

Study Funding Source

1.0 * **Funding Source Name:**
Merit Review (CC 103)
If you can't find the Funding Source above, choose "Other" and enter it here:

ID: Pro00003276 View: VA Create-Edit

* **Device Name:**	Kinova Gen3 Assistive Robotic Manipulator
* **Use of Device:**	Investigational Device Not Yet Approved for use
Manufacturer:	Kinova

IDE Class:

IDE Number(if Applicable):

Risk Level Determined by Sponsor: Non-Significant Risk

Kinova Gen3 Brochure(0.01)

Upload Device Brochure

Provide any other notes about how this device will be used or justification for lack of IDE number

The Kinova Gen3 Assistive Robotic Manipulator is a device that was built for human-robot interaction with flexible functionalities to ensure better safety and
performance in any research environment. It equips discrete 2D and
3D sensors for vision-based applications and 7 DOF robotic arm for the daily object manipulation. The Kinova Gen3 Assistive Robotic Manipulator is a commercially available robotic research system, which will be positioned on a commercial electric powered wheelchair to assist daily manipulation tasks. The Kinova Gen3 Assistive Robotic Manipulator will be used to object recognition and manipulation. The Kinova Gen3 Assistive Robotic Manipulator can be powered using the wheelchair batteries and wall outlet. The Kinova Gen3 Assistive Robotic Manipulator has three layers of safety. First is the mechanical layer, which includes soft cover of screws, smoothed edges and surfaces, and padding on connectors and power cables. In the unlikely event of a power failure, the arm is freely movable to reposition. The second layer is electronic, which includes self collision prevention, joint limits, hard force limits, hard speed limits, user initiated stops, and force compliance, which allows the robot to elastically bend in under certain loading conditions. Most importantly, the Kinova Gen3 Assistive Robotic Manipulator does not move quickly, providing humans time to react to the devices movements. In addition, the manipulator stops when the user releases the joystick or control interface. The third layer is the software layer, which allows for programming of constraint spaces including slow moving and keep-out zones. The software layer is unique to robotic technologies and has potential to detect unsafe situations before they lead to accidents. A significant risk device is defined as an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject. The Kinova Gen3 Assistive Robotic Manipulator does not meet the definition of a significant risk device as it does not meet any of the 4 criteria listed above.

Is the investigator hold the IDE for this device?

Yes **No**

If yes please provide a basis for risk level.

ID: Pro00003276 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Interviews

Common Risks:

Infrequent Risks:
Audio recording may incur risk of breach of confidentiality.

Other Risks:

ID: Pro00003276 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Research activities

Common Risks:

Infrequent Risks:
Video recording may incur risk of breach of confidentiality.

Participants may experience frustration due to learning to use a new device or device malfunction.

Other Risks:

ID: Pro00003276 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Questionnaires

Common Risks:

Infrequent Risks:
Risk of breach of confidentiality.

Other Risks: