Cover page

Official Title on ClinicalTrials.gov:	Remote Wheelchair Skills Training Efficacy
ClinicalTrials.gov ID NCT number:	NCT03499951
IRB approved Date:	April 10, 2019

lJniversity of Pittsburgh **OSIRIS**

!Section: Triage!

[reviewer notes-.)

Provide a short title for this study (200 characters or less):

Remote Wheelchair Skills Training Efficacy

Tl,0

Select the type of application:
New Coordinating Center (CC) Application (do not convert approved CC applications)

T2.0

Is the proposed research study limited to the inclusion of deceased individuals?
" No

T2.1

Are any research activities being conducted at the VA Pittsburgh Healthcare System or with VA funds?

* No

[reviewer notes-.]

T3.0 **What is the anticipated risk to the research participants?**

Minimal Risk

T3.1 **Whydo you feel that all aspects of this research study, including screening and follow-up, involve no more than minimal risk to the research subjects?**

This research protocol involves no more than minimal risk because no research subjects will be enrolled in this coordinating center protocol. Breach of confidentiality is the primary risk associated with this study. We feel that we have appropriate mechanisms in place to minimize this risk.

T4.0

Does the proposed study qualify for 'exempt' IRB review or for a determination of either 'not research' or 'no human subject' involvement?

'" No

TS.O

Does the proposed research study qualify for 'expedited' IRB review status?

* Yes

!section: Triage!

ection: Coordinating Cented

[reviewer notes-.J

CC1.0 **Indicate the oversight responsibility of the principal investigator named on this IRB application:**

Coordinating Center

Briefly describe the role of the Center:
The University of Pittsburgh will be the coordinating center for the multi-center project "Remote Wheelchair Skills Training Efficacy." The University of Pittsburgh will coordinate most aspects of this multi-center project. We will be responsible for the design and development of the protocol and consent templates and data collection forms. We will also assist with the tracking of enrollment. We will be responsible for tracking, reporting, and maintaining serious adverse events and unanticipated problems involving risk to subjects or others, and dissemination of information to all sites. In addition, we will provide periodic updates to sites on the study on enrollment, progress, and any other relevant information. We may also monitor each site to assess study progress, protocol adherence, consenting processes, and accuracy of research records. The University of Pittsburgh will also be responsible for overseeing the analysis of data collected from this study.

We will also review and moderate the web environment where the training materials are hosted. Through this, we will have access to video and/or photographs of training tasks being completed by participants. The coordinating center will provide feedback to participants on the training tasks.

Note that copies of training records, licenses, certificates should be maintained in the study regulatory binder and are subject to audit by the Research Conduct and Compliance Office (RCCO).

CC1.1 Projected number of subjects to be enrolled at all study sites:
96

[reviewer notes-.]

This application is specific to the coordinating center research activities. It does not include the local site research activities. Each site must obtain approval from their respective local IRB.

The investigator must upload the applicable protocol and consent templates, drug, device, or biologic information for review purposes only. The IRB will determine if the center has mechanisms in place to ensure that the management, data analysis, and data/safety monitoring systems are adequate.

- **DO NOT** list any of the sites in questions CC3.0 or CC4.0 until site authorization or local !RB approval has been obtained. List potential sites in the Abstract, question CS2.1.
- Once local site approval is obtained, submit a **Modification** to upload the approval notification.
- A **Modification** must be submitted if revisions to the protocol and/or consent form result in changes to the responsibilities of the coordinating center as described below.
  - Changes to Exempt projects require use of 'Send comments to IRB staff' so the IRB can determine if the project still meets the exemption criteria or if a new application needs to be submitted.

@ection: Coordinating Cented

Important: If subjects will be enrolled at this site, a separate local site application must be submitted.

Has the Coordinating Center PI assumed the responsibility for the following?

cc2.1 Design and development of the protocol and/or consent template: Yes

CC2.2 * Design and development of case report forms/ data collection tools: Yes

CC2.3 Randomization, registration, and/or tracking subject enrollment: Yes

If Yes, describe the process:
The Coordinating Center will be responsible for developing the study protocol and/or consent templates. The templates will then be provided to the participating centers, so that they can submit the project to their local IRB. Sites will be instructed to modify the templates to include their site specific information and to meet the requirements of their local IRB. The executive committee, which will consist of the project directors at each participating center will be responsible for tracking subject enrollment. The executive committee will have regularly scheduled conference calls to discuss study progress including enrollment. Enrollment will be tracked using a tracking sheet.

CC2.4 * Tracking, reporting, and maintaining serious adverse events and unanticipated problems involving risk to subjects or others, and dissemination of information to all sites: Yes

* 1) If Yes, the mechanism to be employed and 2) if No, indicate who (by role) is responsible:
All serious adverse events and unanticipated problems involving risks will be recorded on paper forms. Participating sites will be asked to fill out the adverse event form and send it via email to the Coordinating Center PI within 10 working days of learning of the event. This e-mail will be forwarded to the University of Pittsburgh IRB and other participating sites to notify them of the event within 10 working days of receipt by the coordinating center.

CC2.5 * Providing periodic updates to all sites on subject enrollment, study progress, amendments and relevant scientific advances: Yes

1) If Yes, the mechanism to be employed and 2) if No, indicate who (by role) is responsible:
The coordinating center will have regularly scheduled conference calls with the executive committee to discuss overall project direction, problems that arise, and new research findings. During each conference call, the progress at each site will be reviewed and discussed and potential barriers to project progress and their solutions will be identified. The executive committee will also be responsible for any changes to the protocol and documentation for human subjects protection. All site Principal Investigators will be held accountable for the progress of their portion of the project. Minutes will be taken during each conference call to formally document progress and identify specific action items. A list serve will also be created to provide a method of communication with all participating sites.

Sites will be sent periodic emails regarding participant progress through the training materials. Emails may occur weekly while the participant is active in the study.

CC2.6 Monitoring/auditing each site to assess study progress, protocol adherence, consenting processes, accuracy of research records: Yes

1) If Yes, the mechanism to be employed and 2) if No, indicate who (by role) is responsible:
The coordinating center will have regularly scheduled conference calls with the executive committee to assess the study progress and ensure that the participating centers are adhering to study procedures outlined in the study manual of operation. It is the responsibility of the site Principal Investigators to ensure that their staff are obtaining informed consent prior to conducting any study procedures. The original research files will

fuection: Coordinating Cented

be stored at each of the participating sites. Each site will be responsible for ensuring that their research data/documents are restricted to associated investigators and research staff. Each site will be asked to keep research files under double lock and key and be only accessible to authorized study personnel. The coordinating center may conduct site visits to monitor protocol implementation, data collection procedures at each site, documentation, and to provide consultation on study implementation issues. The coordinating center may also complete periodic cross-checks of the data to ensure its quality.

CC2.7 Ensuring that the affiliated sites are using the correct version of the IRB protocol and consent documents and maintaining IRB approval throughout the conduct of the study: Yes

1) If Yes, the mechanism to be employed and 2) if No, indicate who (by role) is responsible:
The Principal Investigator at each site will be responsible for ensuring that the correct versions of the IRB protocol and consent document are being used throughout the study. The site Principal Investigator will also be responsible for maintaining IRB approval by ensuring renewals are submitted in a timely manner. Each site will be required to send the coordinating center a copy of their initially approved protocol and consent document as well as continuing review and modification approvals.

CC2.8 * Data management, including transmission, storage, and analysis: Yes

If Yes, indicate if only de-identified data will be received, describe the process and tools to be used to ensure confidential transmission/storage, and analysis of the data:
The original research files (including the consent forms) will be stored at each of the participating sites. Each site will be responsible for ensuring that their research data/documents are restricted to associated investigators and research staff. Each site will be asked to keep research files under double lock and key and be only accessible to authorized study personnel.

Data will be collected using paper and pencil or using the web-based system Qualtrics. Security measures including log-in procedures for data entry that will be restricted to associated research staff will be implemented. Participant confidentiality will be preserved by linking participant names to numeric IDs at the study sites. This linkage code file will be stored securely at the study sites.

The coordinating center will receive coded data from the participating centers through Qualtrics. We may also receive images and videos of the training tasks from participants through Qualtrics.

CC2.9 * Distributing or storing drugs and/or devices: N/A

1) If Yes, the process for distribution and 2) if No, indicate who (by role) is responsible:

CC2.10 * Indicate other responsibilities not listed above:
The coordinating center will also be responsible for developing the manual of operations for this study.

CC2.11

Describe the steps that will be taken to ensure that each external site is fully informed of study procedures and requirements prior to its initiation of research procedures. Also describe what steps will be taken to ensure regulatory compliance.

To ensure that all sites are fully informed of study procedures and requirements prior to clinical testing we will conduct in person training sessions and/or teleconferences to educate all sites on the manual of operations developed, ensuring participant confidentiality and data security. The training session(s) will educate all investigators to ensure data integrity and standardized data collection. Topics for discussion during the training include recruitment methods, informed consent, eligibility criteria, and data collection. We will also develop and distribute a sample IRB protocol, consent form, recruitment flyer, and data collection forms to all sites.

ection: Coordinating Center

CC2.12 **Is the center responsible for the long-term storage (banking} of biological specimens?**

No

If Yes, broadly describe the intended future use, storage and distribution process:

[reviewer notes.)

CC3.0

Will this research be conducted in (a} a foreign country and/or (b} at a site (e.g., Navajo Nation} where the cultural background of the subject population differs substantially from that of Pittsburgh and its surrounding communities?

No

[reviewer notes.)

CC4.0

Address the following for each U.S. site where this research will be conducted:

- Name of site or institution
- Approval letter from a local IRS for this site and date of initial approval
- Append a copy of either a letter of authorization to conduct the research at the facility or a signed statement of work
- Name and qualifications of the local collaborator
- If Federally funded, provide the Federalwide Assurance number (FWA) assigned to the site

	Site	Date Modified
View --	Midwest Regional Spinal Cord Injury Care System	612512018
View --	Northern New Jersey Spinal Cord Injury System	311212018
View	South Florida Spinal Cord Injury System	6/25/2018
View	University of Pittsburgh Model Center on Spinal Cord Injury	513012018

Midwest Regional Spinal Cord Injury Care System (FWA: FWA: 00001549)

Has local IRB or ethical review been obtained for this site?	yes
Has authorization to conduct research at this facility been obtained?	yes
Approval Letter(s}:	Approval
Date of Local Approval:	6/22/2018

fuection: Coordinating Centerl

Name and qualifications of the local collaborator:
Allen Heinemann, PhD is the Associate Director of Research and the Director of the Center for Rehabilitation Outcomes Research at the Rehabilitation Institute of Chicago. He is also a Professor in the Department of Physical Medicine and Rehabilitation at the Feinberg School of Medicine, Northwestern University.

Northern New Jersey Spinal Cord Injury System (FWA: FWA: 0001357)

Has local IRB or ethical review been obtained for this site?	yes
Has authorization to conduct research at this facility been obtained?	yes
Approval Letter(s):	IRB Approval letter
Date of Local Approval:	3/6/2018

Name and qualifications of the local collaborator:
Trevor A. Dyson-Hudson, MD is the Director of the Northern New Jersey Spinal Cord Injury System, the Interim-Director of the SCI Research at Kessler Foundation, and an Assistant Professor in the Department of Physical Medicine and Rehabilitation (PM&R) at the University of Medicine and Dentistry of New Jersey - New Jersey Medical School (UMDNJ-NJMS). Dr. Dyson-Hudson received his medical degree from the Albert Einstein College of Medicine (AECOM) in 1995.

South Florida Spinal Cord Injury System (FWA: FWA: 00002247)

Has local IRB or ethical review been obtained for this site?	yes
Has authorization to conduct research at this facility been obtained?	yes
Approval Letter(s):	Approval
Date of Local Approval:	5/7/2018

Name and qualifications of the local collaborator:
Rachel Cowan, PhD is a Research Assistant Professor at the Miami Project to Cure Paralysis, Miller School of Medicine, University of Miami.

University of Pittsburgh Model Center on Spinal Cord Injury (FWA: FWA: 00006790)

Has local IRB or ethical review been obtained for this site?	yes
Has authorization to conduct research at this facility been obtained?	yes
Approval Letter(s):	Approval Letter
Date of Local Approval:	4/17/2018

fuection: Coordinating Cented

Name and qualifications of the local collaborator:
Michael Boninger, MD is Professor and Chair for the Department of Physical Medicine and Rehabilitation and Director of the UPMC Rehabilitation Institute. He is also a Professor in the Departments of Bioengineering and Rehabilitation Science and Technology and a physician researcher in the Department of Veterans Affairs. Dr. Boninger is the Medical Director of the Human Engineering Research Laboratories. Dr. Boninger received a mechanical engineering degree and Doctorate of Medicine from The Ohio State University

!section: Cover Sheeij

[reviewer notes.]

CS1,0 What is the reason for this submission?

New Research Protocol Submission

Has this research study been approved previously by the University of Pittsburgh IRB?

No

CS1.1.1

Has this research study (or a substantially similar research study} been previously disapproved by the University of Pittsburgh IRB or, to your knowledge, by any other IRB?

No

[reviewer notes-.]

CS2.0

Title of Research Study:

Remote Wheelchair Skills Training Efficacy Coordinating Center

cs2.o.1

Requested approval letter wording:

CS2.1 Research Protocol Abstract:

The University of Pittsburgh Model Center on Spinal Cord Injury is the coordinating center for this multi-site study. This coordinating center protocol outlines how the principal investigator, investigators, and associated research staff will coordinate this study and ensure its successful implementation. The collaborating sites for this project include the Northern New Jersey SCI System, Midwest Regional SCI Care System, and Southern Florida Spinal Cord Injury System.

CS2.2

Select the category that best describes your research:
Social, behavioral, educational, and/or public policy research

[reviewer notes-.]

CS3.0 Name of the Principal Investigator:

Michael Boninger

Note: Adjunct faculty of the University, including lecturers and instructors, are not permitted to serve as a PI or Faculty Mentor but may serve as co-investigators. Refer to Chapter 4 on the HRPO website for more information.

fuection: Cover Sheetj

CS3.1 Affiliation of Principal Investigator:

UPitt faculty member

If you chose any of the Pitt options, please indicate the specific campus:
Main Campus - Pittsburgh

If you chose the UPitt faculty member option, provide the PI's University Faculty Title:
Professor and Chair in the Department of Physical Medicine & Rehabilitation

CS3.2 Address of Principal Investigator:

Kaufmann Building
3471 Fifth Avenue
Pittsburgh, PA 15213

CS3.3 Recorded Primary Affiliation of the Principal Investigator:

U of Pgh | School of Engineering

CS3.4 Identify the School, Department, Division or Center which is responsible for oversight of this research study:

U of Pgh | School of Medicine | Physical Medicine and Rehabilitation

CS3.5 Telephone Number of Principal Investigator:

412-822-3700

CS3.6 Recorded Current E-mail Address of Principal Investigator to which all notifications will be sent:

BONINGER@pitt.edu

CS3.7 Fax Number:

412-822-3699

CS3.8 Does this study include any personnel from Carnegie Mellon University, and/or use any CMUresources or facilities (e.g., Scientific Imaging and Brain Research Center (SIBR)?

* No

CS3.9 Is this your first submission, as PI, to the Pitt IRB?

No

[reviewer notes-.)

ection: Cover Sheeij

CS4.0 List of Co-Investigators:

Last	First	Organization
Greenwald	Karen	U of Pgh | School of Medicine | Physical Medicine and Rehabilitation
[illegible]	[illegible]	U of Pgh | School of Health and Rehabilitation Sciences | Rehabilitation Science and Technology
Tempest	Marshall	U of Pgh | School of Medicine | Physical Medicine and Rehabilitation
Worobey	Lynn	U of Pgh | School of Engineering

[reviewer notes-.]

CSS.O Name of Primary Research Coordinator:

Marshall Tempest

CSS.1

Address of Primary Research Coordinator:

1400 Locust St,
Pittsburgh, PA 15219

CSS.2

Telephone Number of Primary Research Coordinator:

412-232-7949

CS6.0

Name of Secondary Research Coordinator:

Karen Greenwald

CS6.1 Address of Secondary Research Coordinator:

1400 Locust St,
Pittsburgh, PA 15219

CS6.2 Telephone Number of Secondary Research Coordinator:

412-232-7949

CS6.3 Key Personnel/Support Staff (Only list those individuals who require access to OSIRIS):

Last First Organization
There are no items to display

[reviewer notes-.]

CS10.0 Is this research study being conducted under a University of Pittsburgh-based, sponsor-investigator IND or IDE application?

No

If YES, you are required to submit the IND or IDE application and all subsequent FDA

@ection: Cover Sheeij

correspondence through the Office for Investigator-Sponsored IND and IDE Support (03IS). Refer to applicable University policies posted on the 03IS website (www.03IS.pitt.edu).

[reviewer notes-.)

csu.o

Use the 'Add' button to upload one or more of the following:

- **the sponsor protocol (including investigator initiated studies) and/or other brochures**
- **the multi-center protocol and consent form template, *if applicable***

Name	Modified Date
Consent template (Trainer) clean	4/17/2018 11:39 AM
Consent Template (trainee)	4/17/2018 11:38 AM
Protocol template (clean)	4/17/2018 11:39 AM
Consent Template (trainer)	4/17/2018 11:38 AM
Consent template (trainee) clean	4/17/2018 11:38 AM
Protocol Template	4/17/2018 11:38 AM

Is this research study supported in whole or in part by industry? This includes the provision of products (drugs or devices).

* No

Is this a multi-centered study?

Yes

[reviewer notes-.]

CSIS.O

Indicate the sites where research activities will be performed and/or private information will be obtained.

Choose all sites that apply and/or use Other to include sites not listed:

Sites:
University of Pittsburgh

University of Pittsburgh
Campus:
Main Campus - Pittsburgh

List university owned off-campus research sites if applicable:

ection: Cover Shee

If you selected School, International or Other, list the sites:

*For research being conducted at non Pitt or UPMC sites, upload a site permission letter granting the researcher permission to conduct their research at each external site:
Name Modified Date

CS15.1 Have you, Michael Boninger, verified that all members of the research team have the appropriate expertise, credentials, and if applicable, hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB protocol?

* Yes

CS15.2

Describe the availability of resources and the adequacy of the facilities to conduct this study:

Adequate staff, time and funds have been allocated to coordinate this multi-site project. The PI, co-investigators and staff working on this project have previous experience coordinating multi-site projects.

!Section: Section 1 - Objective, Aims, Background and Significance!

[reviewer notes-.]

1.1 Objective: What is the overall purpose of this research study? (Limit response to 1-2 sentences.)
The objective of the study is to evaluate the effectiveness of remote training to teach clinicians how to train others in wheelchair skills.

1.2 Specific Aims: List the goals of the proposed study (e.g., describe the relevant hypotheses or the specific problems or issues that will be addressed by the study).
Evaluate the ability of remotely trained clinicians (trainers) to teach other individuals (trainees) using the skills and techniques presented in the Wheelchair Skills Training Program (WSTP) by evaluating:

1) Wheelchair skills capacity of trainees.

2) Wheelchair skills confidence of trainees.

!section: Section 2 - Research Design and Methodaj

[reviewer notes,)

2.17 What are the main outcome variables that will be evaluated in this study?

The main outcome variables are to determine the effectiveness of remote wheelchair skills training include the Wheelchair Skills Test Questionnaire questions on capacity (WST-Q capacity) and confidence (WST-Q confidence), knowledge questions about wheelchair skills (WST knowledge), and remote evaluation through video analysis by the study team on capacity to perform skills. Additionally, we will gather feedback on how the training process could be improved.

2.18 Describe the statistical approaches that will be used to analyze the study data.

* Addressed below:

We will use a paired t-test to evaluate if there is an improvement in knowledge of skills following the respective training programs through knowledge based questionnaires for the trainees. We will determine if capacity and confidence increases through paired comparisons between baseline and follow-up for the WST-Q total scores. Capacity will also be evaluated based on whether participants are successful in each task as determined by a remote rater; in this success will be determined with at least 75% of participants achieving capacity in each task.

A power analysis was completed based on the published study completed with Occupational Therapy students with a pre-WSTP score of 64.8+/-9.0 and post-WSTP score of 81.0+/-5.2. Taking this into consideration, we will need a sample size of 23 individuals for a 95% power to detect a difference in the pre-WSTP and post-WSTP scores. We have estimated a sample size of 24 trainers and 72 trainees to account for participants who do not complete the study.

!Section: Section 5 - Potential Risks and Benefit

[reviewer notes,]

5.2

What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study?

Not Applicable

[reviewer notes,]

5.8

Will any individuals other than the investigators/research staff involved in the conduct of this research study and authorized representatives of the University Research Conduct and Compliance Office (RCCO) be permitted access to research data/documents (including medical record information) associated with the conduct of this research study?

Yes

5.8.1

Identify the 'external' persons or entity who may have access to research data/documents andthe purpose of this access:

Collaborators of this multi-site study may have access to coded research data collected by other participating sites for data analysis purposes. Images or videos of participants completing wheelchair tasks may be shared for the purposes of data analysis with collaborators as well.

5.8.2

Will these 'external' persons or entity have access to identifiable research data/ documents?

Yes - Describe below:

If Yes, describe how they will protect the confidentiality of the research data:
Images or videos of participants completing wheelchair tasks may be shared for the purposes of data analysis with collaborators as well to assist with the development of the training program and for the training of clinicians. These images will be taken by participants, and every effort will be made to avoid recording identifiable features. Participants will have the option to not participant in the video recording, or to re-record tasks to eliminate identifiable features. As the videos will focus on wheelchair skills or maintenance tasks, the presence of identifiable images should be limited to parts of the wheelchair and/or body positioning.

5.9

Has or will a Federal Certificate of Confidentiality be obtained for this research study?

No

5.10

Question has been moved to 5.17

5.11

Question has been moved to 5.16

!Section: Section 5 - Potential Risks and Benefit

[reviewer notes-.]

5.12 Does participation in this research study offer the potential for direct benefit to the research subjects?

Not Applicable - This is a Coordinating Center Application

Describe the benefit:

5.13 Describe the data and safety monitoring plan associated with this study. If the research study involves multiple sites, the plan must address both a local and central review process.

A data safety and monitoring plan will be implemented by having regularly scheduled (at least every 6 months) telephone conference calls for this multi-site study to ensure that there is no change in the benefit/risk ratio during the study and that confidentiality of research data is maintained. In addition, the principal investigator of the coordinating center and the executive committee for the project will discuss the study (e.g. study goals, progress, modifications, documentation, recruitment, retention, data analysis, and confidentiality) and address any issues or concerns. These meetings will be overseen by the principal investigator or designee. Minutes will be kept on file for these meetings. Any instances of adverse effects will be reported immediately using the standard forms and/or procedures set forth by the Institutional Review Board. In addition, investigators and/or coordinators may periodically review study documentation and/or consent forms to ensure that subject's confidentiality is maintained.

[reviewer notes-.]

Section 5 - Potential Risks and Benefits of Study Participation

5.15

What precautions will be used to maintain the confidentiality of the research data during collection, transmission and storage? It is important that you indicate the data security measures for all data types.

Go to the A-Z Guidance, download the Data Security Assessment Form, complete, and upload using the Add button below. Depending on the data type, you may need to consult with your data manager to address some of the sections. Email irb@pitt.edu if you have any questions.

Upload Data Security Form:

Name Modified Date
DSE 2/9/2018 11:29 AM

Address what precautions will be used to maintain the confidentiality of the research data collected in paper format if applicable:
Paper-based records will be kept in a secure location and only accessible to personnel involved in the study. Computer based files will only be made available to personnel involved with this multi-site project through the use of access privileges and passwords. Participant's identity on forms will be indicated by a case number rather than by their name, and the code linking their name to the number will be maintained separately with limited access to associated research staff. To maintain the confidentiality of all data that is transferred to the coordinating center from participating centers, only coded data will be transferred. Questionnaires, images and video may be shared with the coordinating center and collaborators for the purposes of data analysis, further developing the training programs and for the training of clinicians.

Participants may record themselves performing wheelchair skills tasks. Every effort will be

made to avoid recording identifiable features. Participants will have the option to re-record or not upload any videos that show images they do not wish to share. As the videos will focus on wheelchair skills tasks, the presence of identifiable images should be limited to parts of the wheelchair and/or body positioning. Participants will upload the videos into Qualtrics, with access limited to research staff.

5.15.1

Does your research study require a data security review? Answer Yes if any of the following conditions are met:

- Identifiable or 'coded data will be collected, stored, or transmitted using any of the following technologies: mobile app, web-based site or survey, wearable device, text messaging, electronic audio, photographic, or video recording or conferencing **and/ or**
- The!RBrequested a data security review during their review of the study

* Yes

'Coded: Identifying information (such as name) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a code (number, letter, symbol, or any combination) and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens

5.16

If the subject withdraws from the study, describe what, if anything, will happen to the subject's research data or biological specimens.

No subjects will be enrolled under this protocol. If a participant from any of the participating centers withdraws from the study, any information collected prior to the date the subject formally withdrew may continue to be used.

5.17

Following the required data retention period, describe the procedures utilized to protect subject confidentiality. (e.g., destruction of research records; removal of identifiers; destruction of linkage code information; secured long-term retention)

Following the required d'ata retention period, the linkage code information will be destroyed. The coded data collected will be retained for an indefinite period of time and will be stored in a secure manner.

!section: Section 6 - Costs and Payment

[reviewer notes-.)

6.1

Will research subjects or their insurance providers be charged for any of the procedures (e.g., screening procedures, research procedures, follow-up procedures) performed for the purpose of this research study? *

No

[reviewer notes-.J

6.2 **Will subjects be compensated in any way for their participation in this research study?**

Yes

6.2.1

Describe the amount of payment or other remuneration offered for complete participation in this research study.

For complete participation, Trainers may receive $255 or $345, depending on their participation history.

For complete participation, Trainees will receive $75.

6.2.2 **Describe the amount and term of payment or other remuneration that will be provided for partial completion of this research study.**

Participants will be compensated for each portion of the study that they complete.

Trainers will be paid $30 for completing baseline questionnaires and reviewing online material. They will be paid $60 for practicing the skills in pairs and sending videos for remote review. Trainers will also receive $30 for completing the post-training questionnaires and providing feedback on the training program(s). If a participant has completed the above listed activities as part of the study "Remote Training Coordinating Center" (PRO15120300), they will receive $30 for completing the wheelchair skill modules and the pre-/post-confidence questionnaire.

Trainers will receive $75 for providing wheelchair skills training to a WSTP Trainee. They may provide training to up to 3 Trainees. For complete participation, they may receive $255 or $345, depending on their participation history.

WSTP Trainees will receive $10 for completing baseline questionnaires. They will be paid $60 for attending wheelchair skills training sessions and for sending videos for remote review. They will receive $15 for completing the follow up questionnaires. For complete participation, Trainees will receive $75.

!Section: Section 7 - Qualifications and Source(s) of Supporij

[reviewer notes,]

7.1

Summarize the qualifications and expertise of the principal investigator and listed co-investigators to perform the procedures outlined in this research study.

Michael Boninger, M.D. is a Professor and Chair of the Department of Physical Medicine and Rehabilitation at the University of Pittsburgh. Dr. Boninger works as a physician researcher for the Department of Veterans Affairs and is the Senior Associate Medical Director of the Human Engineering Research Laboratories a VA Center of Excellence. Dr. Boninger has over 100 peer-reviewed journal publications and numerous book chapters and extended abstracts. He has lectured internationally on biomechanics of repetitive strain injury, assistive technology, and wheelchair propulsion.

Jonathan Pearlman, PhD is an assistant professor in the Department of Rehabilitation Science and Technology and a biomedical engineer at the Department of Veterans Affairs. Dr. Pearlman is the Associate Director of Engineering at the Human Engineering Research Laboratories. Dr. Pearlman received his BS in mechanical engineering from the University of California at Berkeley, M.Sc. in mechanical engineering from Cornell University with a focus in biomechanics and PhD in Rehabilitation Science and Technology at the University of Pittsburgh. Dr. Pearlman is lead or co-author on twenty-four peer-reviewed journal articles and book chapters, and has seven patents awarded or pending.

Lynn A. Worobey, PhD, is a staff member in the Department of Physical Medicine and Rehabilitation. She received her BS in bioengineering from Worcester Polytechnic Institute in 2008. She completed her PhD in bioengineering and a Certificate of Rehabilitation Technology from the University of Pittsburgh in 2013. She was the recipient of a National Science Foundation Graduate Student Research Fellowship during her doctoral work. Her background is in biomechanics and injury prevention. She will be responsible for assisting in the development of clinical protocols, monitoring and participating in study implementation, subject recruitment and data management. Dr. Worobey has been the lead author or co-author on over 25 manuscripts and abstracts related to wheelchairs and mobility.

Karen Greenwald RN, BSN is an experienced clinical research coordinator previously involved in a multi-centered NIH grant with GenIMS (Genetic and Inflammatory Markers of Sepsis) Pneumonia research study in CCM. She completed her BSN at California University of PA and is certified through the Association of Certified Research Professionals ACRP as a Certified Clinical Research Coordinator CCRC. Ms Greenwald serves as the Lead Coordinator on the Spinal Cord Injury Model System research as well as numerous research studies in the Department. She is responsible for assisting in the development of clinical protocols, monitoring and participating in study implementation, subject recruitment, and data management.

M. Lee Tempest, BS received his degree in Psychology from Kent State. His current position in PMR is as a data coordinator for this project. He has been working with individuals with disabilities for more than 5 years.

[reviewer notes,]

7.2 **Indicate all sources of support for this research study.**

*

Selections

Federal: Upload a copy of the entire grant application **(including the cover sheet)** if our site is the awardee institution; for federal contracts, upload a copy of the research plan

!Section: Section 7 - Qualifications and Source(s) of Supporij

If Federal support, provide the sponsor information:

	Federal sponsor	Grant Title	Grant number	Awardee institution	Federal grant application
View	2D ED	Collaboration on Mobility Training (COMIT)	g QDP00	University of Pittsburgh	COMIT Grant .(_Q_,_Q1l

For projects not supported by a federal grant, upload the research plan that was submitted for funding:

Name Modified Date

If Industry support, provide the sponsor information and level of support:

If Foundation support, provide the sponsor information:

If Other support, provide the support information and level of support:

[reviewer notes,]

7.3

Is this study funded in part or whole by a PHS Agency?

No

Does any investigator* involved in this study (select all that apply):

Name

0 **A.** Have equity in a **publicly-traded entity** that either sponsors** this research or owns the technology being evaluated or developed that exceeds a **5% ownership interest** or a current value of **$10,000?**

B. Have equity in a **non-publicly-traded entity** that either sponsors this research or owns the technology being evaluated or developed?

C. Receive salary, consulting fees, honoraria, royalties or other remuneration from an entity that either sponsors this research or owns the technology being evaluated or developed that is expected to exceed **$10,000** during the past or next 12 months?

D. Have rights as either the author or inventor of **intellectual property** being evaluated or developed in this research that is the subject of an issued patent or has been optioned or licensed to an entity?

0 **E.** Have an officer or management position**** with a **Licensed Start-up Company** overseen by the CO! Committee that either sponsors this research or owns the technology. being evaluated or developed?

F. Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?

i;zi **None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.**

!section: Section 7 - Qualifications and Source(s) of Supporg

***Investigator** means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. **The PI is responsible for ensuring thats/he andall other relevant members of the study team review the above questions describing Significant FinancialInterests.**

**through the provision of funds, drugs, devices, or other support for this research

****Such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO).

@ection: Supporting Documentation!

[reviewer notes-)

Supporting Documentation Section

References and Other Attachments

Additional documents: *Please use the Add button to the left to upload additional documents if needed.*

Name	Modified Date	Version

(reviewer notes-)

Clinica/Trials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

"Applicable clinical trials" are required by **federal law** to be registered in ClinicalTrials.gov.

Applicable Clinical Trials (ACTs) are studies that meet the following criteria:

- The study is an interventional study AND
- The study intervention is a drug, biologic, medical device, radiation or genetic AND
- The Study is not Phase 0 or 1 AND
- The study has at least one site in the United States or is conducted under an investigational new drug application or investigational device exemption

NIH Policy

Effective January 18, 2017, revised NIH Policy requires that all clinical trials funded in whole or in part by the NIH be registered and results information posted on ClinicalTrials.gov.

As defined by the NIH, a clinical trial is:

> *A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health related biomedical or behavioral outcomes.*

The NIH Policy extends beyond the Food and Drug Administration Amendment Act (FDAAA 801) requirements in that it requires registration and results reporting of:

- clinical trials of behavioral, surgical and other types of health and medical interventions
- phase 1 studies of drugs and biological products
- small feasibility studies of device products

Failure to submit all required registration and results information requested on ClinicalTrials.gov can jeopardize University grant funding, the future funding of the grantee and subject the University of Pittsburgh to future monetary penalties.

In addition, to promote transparency of the clinical trials process, the International Committee of Medical Journal Editors (ICMJE) has established a policy requiring the entry of clinical trials in a public registry, such as ClinicalTrials.gov, prior to subject enrollment as a condition of consideration for publication of the trial results.

ection: Supporting Documentation!

* Based on the above information, will this study be registered in ClinicalTrials.gov?
No