Study Protocol and Statistical Analysis Plan Cover Page

Title: Translating Intensive Arm Rehabilitation in Stroke to a Telerehabilitation Format

Date most recently updated &approved by IRB: October 27, 2020

Clinical Trials ID: NCT02665052

UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

Date: Tuesday, November 17, 2020 12:05:16 PM

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HP-00060526

View: v2_Introduction Page

Introduction Page

1 * Abbreviated Title:
TeleBATRAC

2 * Full Title:
Translating Intensive Arm Rehabilitation in Stroke to a Telerehabilitation Format

3

* Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

HP-00060526

View: v2_Research Team Information

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Susan Conroy

CITI Training: ID00005518

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Susan Conroy

CITI Training: ID00005518

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

	Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View	Michael Dimyan	no	no	Research Team Member	no	ID00008911
View	Linda Horn	no	no	Research Team Member	no	ID00005742
View	Min Zhan	no	no	Statistician	no	ID00008648
View	Erica Cikanek	no	no	Research Team Member	no	
View	Linda Keldsen	yes	yes	Research Team Member	no	ID00000777
View	Steven Berger	no	no	Research Team Member	no	
View	Christopher Bever	yes	no	Sub-Investigator	no	ID00002902

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

HP-00060526 View: v2_Resources

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
The principal investigator, Dr. Conroy has 60% of her time assigned to this study. The co-PI, Dr. Bever, has 10% of his time assigned to this study.

2 * Describe the facilities where research procedures are conducted:
This proposed project will be carried out at the VA Maryland Health Care System (VAMHCS), specifically the Baltimore VA Medical Center, the Baltimore VA Annex and VA leased spaced at the University of Maryland Allied Health Building (100 Penn St). These locations have the facilities to successfully support this project.

Recruitment will be conducted within the VAMHCS through the inpatient medicine and rehabilitation services, the stroke and rehabilitation clinics, and the physical and occupational department, An office suite on the 2nd floor of the Baltimore VA Annex will be the location for conducting patient screening, and informed consent. Lab-based interventions and training will occur in the Human Motor Performance Laboratory physically located on the opposite wing of the 2nd floor Annex hall to ensure blinding of the evaluator. Robot-assisted bimanual arm evaluations will be conducted on the VA robot maintained in VA leased spaced at the University of Maryland.

The MyHealtheVet (MHV) registration and training will occur at the Baltimore VA Medical Center at the MyHealtheVet Education center located on the 2nd floor.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
Every reasonable safety measure will be used to protect a participant's well-being. We do not anticipate the need for medical/psychological resources for this study. However, in the case of any medical emergency, the VAMHCS-Annex emergency plan is to call 911. Physicians are a part of the MERCE (Maryland Exercise and Robotics Center of Excellence)center at the Annex and have office hours there on Mondays, Wednesdays and Fridays when most study interventions occur.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
All persons assisting with the research will have access to the protocol through the CICERO website. Prior to the commencement of the study, the research team members will have an introductory meeting with the PI where they will be educated about the protocol, procedures and duties. In addition, regular study meetings will be organized where the team members will be updated about any changes in duties, functions, and responsibilities. Individualized training of study team members will be completed by the study coordinator as needed. Study team members will also complete all necessary institutional training sessions necessary for compliance with policies and procedures.Study team members involved in the MyHealtheVet Secure Messaging research communication will have additional training through the VAMHCS MyHealtheVet Education center.

ID: VIEW4DF83CB976400
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ○ Multi-Site
- ● **Single Site**

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

○ Yes ● **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

○ Yes ● **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

○ Yes ● **No**

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

○ Yes ○ No

6 * Institution(s) where the research activities will be performed:

- ☐ University of Maryland, Baltimore
- ☐ University of Maryland, Upper Chesapeake Kaufman Cancer Center
- ☑ **VAMHCS**
- ☐ UMB School of Medicine
- ☐ Marlene and Stewart Greenebaum Cancer Center
- ☐ University Physicians Inc.
- ☐ Shock Trauma Center
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☐ Private Practice in the State of Maryland
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)

- [ ] National Study Center for Trauma and EMS
- [ ] Univ of MD Cardiology Physicians at Westminster
- [ ] Nursing Homes in Maryland
- [ ] University of Maryland Biotechnology Institute
- [ ] Department of Health and Mental Hygiene (DHMH)
- [ ] Capitol Region PG Hospital
- [ ] Mount Washington Pediatric Hospital
- [ ] Maryland Proton Treatment Center
- [ ] Other Sites
- [x] **University of Maryland Medical System (Select below)**

* UMMS Sites:

- [ ] University of Maryland Medical Center
- [ ] UMMC Midtown Campus (formerly Maryland General Hospital)
- [ ] UM St. Joseph Medical Center
- [ ] UM Baltimore Washington Medical Center
- [ ] UM Charles Regional Medical Center
- [ ] UM Shore Medical Center at Easton
- [ ] UM Shore Medical Center at Chestertown
- [ ] UM Shore Medical Center at Dorchester
- [ ] UM Shore Emergency Center at Queenstown
- [ ] UM Shore Regional Health
- [x] **University of Maryland Rehabilitation & Orthopaedic Institute (formerly Kernan Hospital)**
- [ ] UM Upper Chesapeake Health
- [ ] UM Upper Chesapeake Medical Center
- [ ] UM Harford Memorial Hospital
- [ ] University of Maryland Community Medical Group

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

HP-00060526 View: v2_Funding Information

Funding Information

1 * Indicate who is funding the study:

- [x] **Federal**
- [ ] Industry
- [ ] Department / Division / Internal
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [x] **Device**
- [x] **Staff**
- [x] **Participant Compensation**
- [x] **Procedures**
- [ ] Other

3 Please discuss any additional information regarding funding below:

This VA-funded Merit Grant supports the effort of the PI's and Co-Investigators, research staff, and supplies. It also provides a small stipend to participants for transportation.

ID: VIEW4DF85DF452400
Name: v2_Funding Information

HP-00060526 View: v2_DHHS Funded Study

DHHS Funded Study

You indicated that this is a Federally funded study.

1 * Is this study sponsored by a Department of Health and Human Services (DHHS) agency?

◯ Yes ● **No**

2 You may upload any grant documents here:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4DF87B9560800
Name: v2_DHHS Funded Study

HP-00060526 View: v2_Federal Agency Sponsor Information

Federal Agency Sponsor Contact Information

You indicated that this is a Federally funded study.

1

* Agency Name:
Department of Veterans Affairs

* Address 1:
810 Vermont Ave NW

Address 2:

* City:
Washington

* State:
DC

* Zip Code:
20005

* Contact Person:
Trisha Doru

* Phone Number:
(202) 461-1755

Grant Number 1 (if applicable):
- OR - Check here if Grant 1 is not assigned a number. ☑

If Grant 1 has no number, please provide the following information:
Title of Grant 1:
Translating Intensive Arm Rehabilitation in Stroke to a Telerehabilitation Format
PI of Grant 1:
Christopher Bever

Grant Number 2 (if applicable):
- OR - Check here if Grant 2 is not assigned a number. ☐

If Grant 2 has no number, please provide the following information:
Title of Grant 2:

PI of Grant 2:

Grant Number 3 (if applicable):
- OR - Check here if Grant 3 is not assigned a number ☐

If Grant 3 has no number, please provide the following information:
Title of Grant 3:

PI of Grant 3:

Grant Number 4 (if applicable):
- OR - Check here if Grant 4 is not assigned a number. ☐

If Grant 4 has no number, please provide the following information:
Title of Grant 4:

PI of Grant 4:

ID: VIEW4DF8584874400
Name: v2_Federal Agency Sponsor Information

HP-00060526

View: v2_Research Protocol

Research Protocol

1 * Do you have a research protocol to upload?

- (●) **Yes**
- ( ) No, I do not have a research protocol and will use the CICERO application to enter my study information

2 If Yes, upload the research protocol:

Name	Created	Modified Date
MyHealtheVet_Secure Messaging Pilot and Qualitative Study_tracked changes(0.02)	10/17/2018 10:10 AM	11/26/2018 4:25 PM
MyHealtheVet_Secure Messaging Pilot and Qualitative Study (0.04)	10/17/2018 10:09 AM	11/26/2018 4:25 PM

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

HP-00060526 View: v2_Risk Level

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- (●) **Minimal - The probability & magnitude of harm/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/tests.**
- ( ) Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

HP-00060526

View: v2_Type of Research

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- [ ] Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- [ ] Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- [x] **Use of device(s) whose use is specified in the protocol**
- [x] **Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).**
- [ ] Sample (Specimen) Collection and/or Analysis (including genetic analysis).
- [x] **Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).**
- [ ] None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
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.

● **Yes** ○ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

HP-00060526

View: v2_Lay Summary

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

Stroke is the primary cause of adult long-term disability and upper extremity dysfunction is a significant contributor to this disability. The upper extremity is one of the most commonly affected areas and adequate function is essential for independence in activities of daily living. Rehabilitation focusing on repetitive task specific training using robotic devices has been shown to improve motor recovery of the arm. Our previous laboratory based investigations of robot-assisted arm therapy combined with real-world "hands on" exercise activities led to additional improvements in arm and hand use in patients with chronic stroke deficits.

We now propose to adapt our lab based robot intervention with a more portable, less costly, non-robotic repetitive training device to test the efficacy of a home based tele-rehabilitation approach using the existing VA MyHealtheVet web-based communication platform. The long-range goal is to improve access, lower costs, and translate our laboratory findings of repetitive exercise into a home setting format to improve routine management of chronic stroke related arm hemiparesis and quality of life for Veterans and others with stroke.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

HP-00060526 View: v2_Justification, Objective, & Research Design

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

Stroke is the primary cause of adult long-term disability and its incidence is predicted to rise with the increasing age of our Veteran and general population. The upper extremity is an important target for rehabilitation as it has far reaching consequences for independence in activities of daily living (ADL) and health-related quality of life. More than 55% of stroke survivors have residual arm deficits six months post onset. Interventions emphasizing intensity of repetition and task specificity are key factors in promoting motor recovery. Our investigations utilizing robot-assisted therapy to provide this intensity of practice have resulted in positive effects on reduction of impairment in Veterans with moderate to severe deficits many months post stroke.

An expansion of our work with this same population suggests that intensive robot-assisted reaching combined with a brief period of task specific (Transition to Task Training (TTT)) leads to greater gains than robot-assisted training alone. Given our focus on the moderate to severely affected population and the need to find low cost interventions to maximize function in this later stage of recovery we propose to adapt the lab-based BATRAC (Bilateral Arm Training with Rhythmic Auditory Cueing) training protocol developed and studied at the University of Maryland into a home-based model using a telerehabilitation platform. We have selected the BATRAC because it is a low-cost mechanical device that closely mimics the arm actions of the planar MIT-Manus robot with the same elemental features of intensive repetition, progression and feedback. Differences in the BATRAC include the use of both arms and the lack of a motorized/powered assist mode .We will add TTT since our preliminary results using it combined with robot-assisted therapy showed gains in paretic hand use based on the Hand section of the Stroke Impact Scale. We will also use the VA approved telehealth website MyHealtheVet for secure messaging and asynchronous communication between participant and research staff. We propose to assess the MyHealtheVet utility as a part of a pilot sub-study (see below).

Our specific Primary Study aim is to determine the value of providing home-based BATRAC telerehabilitation to Veterans compared to usual care using outcomes for impairment, activity and participation consistent with the International Classification of Function. This result will provide a useful telerehabilitation prototype for further testing. Our secondary aim is to determine the value of home-based BATRAC telerehabilitation compared to the established lab-based training without telerehabilitation that is one-on-one with a therapist. This result will provide evidence of the value of telerehabilitation and potential for remote use of the therapist.

Our hypothesis:
1) Home-based BATRAC telerehabilitation + TTT will be more efficacious than usual customary care and lead to greater functional improvement for persons with chronic upper extremity stroke deficits.
2) Home-based BATRAC telerehabilitation + TTT will be at least as effective as lab-based BATRAC + TTT.

A delayed entry group will act initially as our usual customary care control and provide the main comparison between BATRAC + TTT telerehabilitation and customary care.

MyHealtheVet SECURE MESSAGING PILOT STUDY:
Current VA policies provide for use of the secure messaging aspect of My HealtheVet (MHV) for clinical purposes, including communication between patients and multiple members of their clinical care teams. Current guidance restricts its use for most VA research. At present, VA staff use the My HealtheVet patient portal and secure messaging for clinical communication with patients and are able to send attachments; Patients could also use this function to share study related materials. The secure message could also include individual survey questions or links (for example to an on-line survey) that study participants could cut and paste into an internet browser. It may be more convenient for study participants to link directly to a given website to complete a task, rather than complete a paper form and return it by standard post. Thus, potential advantages to research include reduced expense and staff effort if appointment reminders and study visit materials could be sent electronically. Efficiency could also be increased, as materials could be shared with study participants more quickly by electronic communication than by mailing by standard post. Finally, the ability to communicate with study participants interested in electronic communication by secure messaging would demonstrate responsiveness to participants' preferences.

The VA Maryland Health Care System (VAMHCS) desires to test secure messaging in My HealtheVet (MHV) for communication with research participants in in the IRB approved (HP-60526), VA Funded Stroke Rehabilitation Trial "Translating Intensive Arm Rehabilitation in Stroke to a Telerehabilitation Format" aka TeleBATRAC. We are working collaboratively with the Veterans and Consumers Health Informatics Office, VHA Office of Analytics, VA Office of Connected Care, and the Office of Research and Development. We aim to assess potential and specific concerns articulated by our national collaborations, which have included: Secure Messaging triage team naming conventions, procedures for the registration, authentication and secure messaging Opt-In for veteran and non-veteran research participants, association with the study triage team, training of study participants and research triage team recipients, informed consent (to include visibility of secure messaging research communication and data to clinical management teams), management of messages and retention of data, ease of message reassignment, the identification of unintended consequences, and development and collection of data and information to inform future VA research policy and guidance.

MyHealtheVet Secure Messaging Pilot Aims and Hypotheses
Aim 1: To develop and pilot test a Home-based stroke rehabilitation program using the MHV patient portal and secure messaging as the communication delivery system.

Aim 2: To assess for differences in eHealth literacy and self-efficacy between the Delayed Entry Usual Care and the Home-based rehabilitation group using MHV secure messaging.

Hypothesis 1: Home-based MHV stroke survivor & caregivers' intervention group Web-Based Learning Self-Efficacy Scores will meet or exceed the Delayed Entry Usual Care group.

Hypothesis 2: Home-based MHV stroke survivors and caregivers' intervention group eHEALS Health Literacy Scale will meet or exceed the Delayed Entry Usual Care group scores.

Aim 3: Determine efficacy of the two (2) one-hour structured MHV training on stroke survivors and caregivers Web-Based Learning Self-Efficacy Scores (WBLSES) and eHEALS scales.

Hypothesis 1: Home-based MHV stroke survivors and caregivers' intervention group WBLSES will exceed the baseline scores at the end of the clinical trial demonstrating improved comfort and skill in using the MHV patient portal.

Hypothesis 2: Home-based MHV stroke survivors and caregivers intervention group eHEALS Health Literacy Scale will exceed the baseline scores at the end of the clinical trial demonstrating improved comfort and skill in using secure messaging for health care management.

Aim 4: Determine efficacy of stroke survivors and caregivers use of the MHV patient portal and Secure Messaging for communication with research team.

Hypothesis 1: Home-Based MHV stroke survivors and caregivers intervention group WBLSES and eHeals literacy scores will increase from baseline demonstrating improved comfort and skill in the use of the MHV patient portal and secure messaging for health care management.

Hypothesis 2: Home-Based MHV stroke survivors and caregivers secure messaging volume will increase over the 18 week period of the study demonstrating improved comfort and skill in the use of secure messaging and enhanced self-efficacy for self-regulated stroke rehabilitation.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

This is a longitudinal, single blind, randomized controlled trial with three parallel 6 week intervention arms conducted over a three-year time period :
1) Home-based BATRAC Telerehab (HBT) + TTT, 2) Lab-based BATRAC (LBB) + TTT, and 3) Delayed Entry Usual Care group that will serve as a control for the initial six weeks of enrollment and NOT receive an active study intervention before randomizing to one of the two active interventions. This strategy will ease recruitment needs, reduce attrition from the delayed entry group, and spread the training schedule more equally across the three years. In order to have a better understanding of general function in the chronic stage of recovery for this moderately to severely impaired cohort we will conduct weekly phone calls to the delayed entry group during the 6 week control period and record general activity (household or community) and monitor amount and intensity of arm use. After serving as a control, this group will be randomized to one of the two active interventions.

After obtaining informed consent, and completing baseline testing, participants will be randomized to one of the above three study arms. Participants and their caregivers will be provided the option at the time of consent to participate in the VA MyHealtheVet Secure Messaging Pilot Study. Those consenting to this option will be enrolled in the pilot upon randomized to the Delayed Entry UC Group or the Home-based Telerehabilitation (HBT+TTT) group. Those randomized to the lab-based training (LBT+TTT) will NOT be enrolled in the pilot.

Overall study randomization will be stratified based on the participant's baseline Fugl-Meyer (FM) score to prevent selection bias and generate intervention groups with similar impairment levels. Low baseline scores will fall into the range of 19-29 out of 66 max, and high scores in the range of 30-50 out of a 66 max. To account for a 15% attrition rate, we will randomize 78 subjects to achieve an effective sample size of 66 (22 per group). Based on our prior study, we anticipate 73% will be in the low FM group, and 27% in the high FM group. This gives us about 57 subjects in the low FM group and the remaining 21 subjects in the high FM group. To reduce the potential imbalance among different intervention groups, we will block randomize separately for subjects in each baseline FM stratum. To randomly allocate about 57 subjects (yielding to an effective sample size of 48) in the low FM stratum and 21 subjects (yielding to an effective sample size of 18) in the high FM stratum to the HBT+TTT (H), LBB+TTT (L) and delayed entry UC groups with equal proportion, the Biostatistician will generate a permuted block randomization schedule with a block size of 6, using a statistical software, SAS (SAS Institute Inc., NC, USA). This randomization schedule will link each subject sequence number in this stratum with an intervention group.

Each patient will be enrolled in the study for 18 training sessions (spread over a maximum of 9 weeks to allow for missed visits due to transportation/weather or minor illness) to complete the intervention as described below. Participants will be asked to return for a retention follow-up after 8 weeks of no training for a maximal study commitment of 17 weeks for those immediately randomized and 23 weeks for those enrolled in the delayed entry group. All repeated outcome measures will be conducted at the VA Annex by a study evaluator blinded to the intervention assignment and will occur at baseline, training completion, and at the 8 week retention follow-up. Additionally, all participants in the Home-based BATRAC telerehabilitation group will be provided with a VA's MyHealtheVet website account (www.myhealth.va.gov) to access the already established educational features and resources about stroke, exercise and caregiver support. Every effort will be made for MyHealtheVet Secure Messaging Pilot study participant appointments to be coordinated with the Primary Study appointments to avoid undue travel.

Intervention and Training
1) Home-based BATRAC telerehabilitation: The BATRAC training platform will be used in conjunction with the VA MyHealtheVet website. This group will have an upgraded MyHealtheVet account to access the Secure Messaging Option for VA approved electronic messaging to the study therapist. Training in use will take place at the Baltimore VA MyHealtheVet Educational Office (2nd floor). MyHealtheVet allows for asynchronous communication with the study therapist, and will store performance information entered by the participant and caregiver related to arm exercise duration, repetitions completed and distances reached. This account can be securely linked and is VA approved for use on any home device (computer, cell phone or tablet) with internet. A MyHealtheVet training visit at the VA and a home visit to verify access, and use with be completed with participants in this group as well as their identified caregivers.

Participants and caregivers consenting to the option of videoconferencing with the study team via the VA's "VA Video Connect" app, in addition to the VA's MyHealtheVet website described above, will be trained for approximately 5 to 10 minutes on how to use this app when they receive training on how to use the MyHealtheVet website. The "VA Video Connect" app uses encryption to ensure a secure and private session, and it allows quick and easy health care access from any mobile or web-based device; more information on this app is at https://mobile.va.gov/app/va-video-connect. Adding the option for videoconferencing communications via the VA's "VA Video Connect" app would allow for an additional means of communication for participants randomized to the home-based telerehabilitation group--besides just phone calls and asynchronous private messages sent back and forth on the MyHealtheVet website. Videoconferencing communications also would allow for these participants and study team members to, in real time, ensure that participants are completing rehabilitation interventions at home properly.

Participants and caregivers consenting to the option of taking part in the VA MyHealtheVet Secure Messaging Pilot study will be seen for baseline Standard Evaluations (eHeals, Web-based Self-Efficacy & MoCA, Post-training Interviews) following randomization and prior to initiation of the study intervention. Those randomized to the Home-based telerehabilitation will receiving training in the appropriate use of MHV secure messaging for research communication and will be interviewed immediately after training to ensure that they feel confident in their ability to use the MHV portal and secure messaging to communicate with the research team via the BAL-RESEARCH-TELEBATRAC STUDY_RES secure messaging mail group link (see uploaded Interview Form in Section 5.0)

During the pilot, a designated member of the research team will train, and re-train if necessary, on the importance of directing clinical messages to one of their clinical teams and research messages to the research team at the BAL-RESEARCH-TELEBATRAC STUDY_RES secure messaging mail group. Reinforcement to direct all research communications to the research team (BAL-RESEARCH-TELEBATRAC STUDY_RES) will also be provided. The Veteran study participant's knowledge will be reassessed to ensure understanding of how to submit research related secure messages to the BAL-RESEARCH-TELEBATRAC STUDY_RES secure messaging mail group and non-urgent clinical communications to their health care provider(s) using a questionnaire and misdirected communication will be tracked and re-directed.

The VA MyHealtheVet website will allow for asynchronous communication with the participant and therapist to promote personalized prescription of the BATRAC arm exercise. All telerehab interventions will occur at home with entry into the MyHealtheVet by the participant and/or caregiver on their preferred electronic device or on a VA provided touchscreen tablet. The individualized BATRAC exercise protocol will be the same for both groups, however the Home Telerehabiliation group will use this asynchronous communication to guide their exercise program.

BATRAC training will consist of 45 minutes of high intensity bilateral reaching and rest periods (see Lab-based BATRAC training details below) followed by 15 minutes of video guided transition to task training (TTT). These videos will be linked from the VA MyHealtheVet site to study specific youtube videos of the study therapist demonstrating the exercise. The initial training will occur in the lab setting with the therapist for BATRAC instruction and TTT exercise training. The participant and caregiver will have the opportunity ask questions and develop proficiency during this training session. For the TTT, each functional task will be presented via the MyHealtheVet Secure Messaging (SM) and linked by a URL to an instructive youtube video clip of exercise sequencing, and level of difficulty. After completion of each exercise session the participant will complete a study report form attached to the SM. This information will be available for off-line assessment of performance by the research therapist. In cases of participant non-adherence, the therapist can contact the participant via phone to review exercise barriers and motivate the individual to participate. If necessary, the therapist could change the exercise parameters and send changes within the My HealtheVet SM.

2) Lab-based BATRAC + TTT training: Participants randomized to this group will receive 60 minutes of training in the lab (45 minutes using BATRAC and 15 minutes of TTT). BATRAC for high intensity bilateral reaching and retrieving actions (pushing handles away and pulling them back) on a constrained linear track to their maximum arm extension ability. The track can be set at different angles in the work space. The training protocol is the same for both groups and will consist of four, 5-minute periods interspersed with 5-minute rest periods to avoid fatigue. An auditory metronome is set initially at the participant's preferred speed and for periods 1 and 3 participants move both arms simultaneously (in-phase). In periods 2 and 4 participants move both arms in alternating (antiphase) movements. For the proposed study a fifth bout of simultaneous arm movements will be included to reach the 45 minute training goal. Progression of the auditory cue frequency, direction of travel (pushing/pulling or in a diagonal) and distance of reach will be progressed every 3 sessions based on performance. If a progression cannot be sustained for the five-minute bouts by the end of the session, adjustments towards the previous level are made. This training will be followed by 15 minutes of transition to task training (TTT) with supervision and support as needed by the therapist.

Transition to Task Training (TTT): Each participant will receive 45 minutes of their randomized BATRAC intervention followed by 15 minutes of TTT. This training is functionally based in four domains of real-world tasks and include: homemaking, hygiene, feeding, and dressing. Two goal directed functional tasks are selected from the four domains every two weeks and prescribed to the individual based on severity level, general interests and goal. The task design is progressive in nature and difficulty is added by changing the parameters (movement amplitude) and demand (resistance) for increased generalization to real life challenges. Assist by the therapist or caregiver is provided to prevent compensatory movements from being re-enforced. For the home-based training, the caregiver will be instructed to provide this assistance through the initial personal training as well as have access to a set of videos for each of the tasks.

Delayed Entry Usual Care: Participants randomized to this group will initially serve as a control and not receive any study interventions except for the protocol study

evaluations in the same time intervals as those receiving active interventions and weekly phone calls to record general activity level. During this time frame, this group may participate in the MyHealtheVet Secure Messaging Pilot to receive the pilot pre and post evaluations and interviews Every effort will be made for MyHealtheVet Secure Messaging Pilot appointments to be coordinated with the Primary Study appointments to avoid undue travel. After serving as a control, this group will be entered into their delayed active intervention group of either lab-based BATRAC + TTT training, or Lab-based Robot+ TTT.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

Expanding the continuum of care to home has significant barriers due to limited opportunity for education, and limited access to rehabilitation professionals which may lead to poor adherence to the rehabilitation program. These barriers can potentially be addressed using modern telemedicine technologies already established at the VA for aspects of healthcare management on their MyHealtheVet website. This will act as a resource for support and involvement of the caregiver in the exercise program. The benefit of family involvement in recovery of upper extremity motor function has yet to be fully investigated. A qualitative study by Galvin et al. found that family members of stroke survivors were willing to participate in unsupervised exercises but indicated a lack of confidence in assisting with the exercises as one of the barriers (Galvin 2009). Additionally, a recent study by Harris et al. found caregiver involvement to be a significant determining factor in improved arm function over and above initial severity of motor impairment and exercise intensity (Harris 2010). Although there are a growing number of studies evaluating various telerehabilitation interventions in stroke, reports using this potentially promising technology for comprehensive home-based upper limb rehabilitation are limited.

In this project, we seek to objectively assess the impact of a comprehensive patient-centered, home-based upper limb telerehabilitation program augmented with an VA approved asynchronous on-line communication website. Results of the study will provide information on the use of this modern technology to improve care in Veterans with stroke related upper extremity neuromuscular impairments.

Our most recent preliminary robot assisted arm training study addressing moderate to severe chronic upper extremity deficits suggested intensive reaching combined with a brief period of task specific training or transition to task training (TTT) leads to greater gains than robot-assisted training alone. An earlier change was seen in the course of the intervention with an overall improvement in time to complete tasks for the Wolf Motor Function Test (WMFT). The mean WMFT time change was 9.4 seconds (±SD 10.3) from baseline. This magnitude of change is similar to that reported in the literature for the EXCITE constraint-induced movement trial (Wolf 2006) and representative of a clinically important difference (Lin 2009). Additionally, an analysis of participants' self-reported hand function using the Stroke Impact Scale (SIS) hand domain showed significant within group changes not seen in the robot only group as well as significant between group differences.

BATRAC Outcomes: There are several published laboratory studies of using BATRAC in chronic stroke with patients with a range of severity consistent with our proposed population. All but one have used the proposed scheduling protocol and have demonstrated significant immediate pre-post changes in the primary variable of WMFT timing. The mean improvement from these studies were 4.0 (Whitall 2000), 3.3 (Luft 2004), and 2.6 seconds (Whitall 2011). All of these exceed the clinically important difference of 1.5 to 2 seconds derived by Lin et al for chronic stroke patients. Where retention was assessed, the gains did not disappear. Even the one modified study schedule (8 sessions x 2.25 hours over 2 weeks), by a different research group, demonstrated a significant increase of paretic arm use. Recent submitted data, where we have been more aggressive in progressing parameters have shown an improvement of 7.4 ±7.6 seconds (p=.004) on the WMFT time.

Relevant to choosing BATRAC as a potentially viable and motivating treatment, an RCT that compared BATRAC to Dose-Matched Therapeutic Exercises (DMTE) found similar significant changes in the WMFT time immediately after training and 4-months later (Whitall 2011). However, on a 5 point Lickert scale, satisfaction with BATRAC was significantly higher than with DMTE after training (4.4 vs. 3.8, p=.003) and remained slightly higher but not significant after the retention period (4.1 vs. 3.8). Furthermore, the BATRAC group showed a greater change on the SIS total score after the retention period (although not immediately after training). Taken together, these data give us confidence that BATRAC can improve the ability to perform tasks faster in a clinically meaningful and durable way and that it is likely to be tolerated well.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

Despite success in impairment reduction in chronic stroke, there is a gap between improvement in impairment or basic function and the use of the hemiparetic arm in activities of daily living. Our recent work in patients with moderate to severe chronic upper extremity impairment suggests that intensive robot-assisted reaching combined with a brief period of task specific functional training leads to greater gains of hand use than robot-assisted training alone. Robots are not easily accessible, therefore, another strategy to maximize training intensity in this later stage of recovery may be to convert an established lab-based repetitive and intense training protocol into a home-based model using a telerehabilitation platform. Given our focus on the moderate to severely affected population and the need to find a low cost technology for a home-based approach, the best choice for interfacing with a telerehabilitation platform is the BATRAC system.
Home-based therapy programs for functional recovery following a stroke have been shown to facilitate improvement in activities of daily living (ADL) and recovery for the lower extremity, however, a focused review of upper extremity specific interventions (Coupar 2012) showed insufficient evidence for its application. Further research is therefore needed regarding upper extremity home-based therapy programs as the majority of studies utilized mixed interventions, had a small sample size, and focused on individuals with mild to moderate stroke deficits.

MyHealtheVet SECURE MESSAGING PILOT STUDY:
Current VA policies provide for use of the secure messaging aspect of My HealtheVet (MHV) for clinical purposes, including communication between patients and multiple members of their clinical care teams. Current guidance restricts its use for most VA research. At present, VA staff use the My HealtheVet patient portal and secure messaging for clinical communication with patients and are able to send attachments; Patients could also use this function to share study related materials. The secure message could also include individual survey questions or links (for example to an on-line survey) that study participants could cut and paste into an internet browser. It may be more convenient for study participants to link directly to a given website to complete a task, rather than complete a paper form and return it by standard post. Thus, potential advantages to research include reduced expense and staff effort if appointment reminders and study visit materials could be sent electronically. Efficiency could also be increased, as materials could be shared with study participants more quickly by electronic communication than by mailing by standard post. Finally, the ability to communicate with study participants interested in electronic communication by secure messaging would demonstrate responsiveness to participants' preferences.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

HP-00060526 View: v2_Supporting Literature

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

Home-based therapy programs for functional recovery following a stroke have been shown to facilitate improvement in activities of daily living (ADL) and recovery for the lower extremity, however, a more focused review of upper extremity specific interventions showed insufficient evidence for clinical application. Further research is therefore needed regarding upper extremity home-based therapy programs as the majority of studies utilized mixed interventions, had a small sample size, and focused on individuals with mild to moderate stroke deficits .

2 If available, upload your applicable literature search:

Name	Created	Modified Date
Localization_Impaired_Kinesthesia_Kenzie2016(0.01)	3/21/2017 10:05 AM	3/21/2017 10:05 AM
Novel_Robotic-Task_Bimanual_Assesment_Lowrey2014(0.01)	3/21/2017 10:03 AM	3/21/2017 10:03 AM
References_MyHealtheVet SECURE MESSAGING PILOT STUDY(0.01)	10/3/2016 11:45 AM	10/3/2016 11:45 AM
References from Grant Submission(0.01)	10/1/2015 1:39 PM	10/1/2015 1:39 PM
Coupar et al. 2012_Home Based Therapy_Cochrane Review(0.01)	7/10/2014 11:53 AM	7/10/2014 11:53 AM
Duncan et. al 2011_Body Weight Support TM_NEJM(0.01)	7/10/2014 11:52 AM	7/10/2014 11:52 AM
Fearon et al. 2012_Early Supported Discharge_Cochrane Review(0.01)	7/10/2014 11:51 AM	7/10/2014 11:51 AM

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

HP-00060526 View: v2_Study Procedures

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

A) General Medical Evaluation: A general neurological evaluation will be conducted at baseline by a neurologist to confirm clinical diagnosis of stroke and review medical records relating to the index stroke. It also includes a review of questionnaires specific to depression and neurocognitive function (Center for Epidemiologic Studies Depression Scale [CESD] and Montreal Cognitive Assessment [MoCA]). Clinical suspicion or evidence on the CESD and MoCA of dementia, depression, severe aphasia,, or other major neuro-cognitive deficits that may interfere with the conduct of the study preclude further evaluation and initiate prompt referral to psychiatry or other specialist for evaluation.

B) Evaluations of Arm Function and Use: These will be performed at the VA by an evaluator blinded to treatment allocation and will occur three times at baseline, at final training (week 6-9), and after an 8 week no training retention period.

C) Questionnaires about arm use and participation will also be completed. The research evaluations are as follows below.

Wolf Motor Function Test (activity): This is a measurement tool of functional capability of the affected UE in terms of performance time, quality of movement, and ability to hold a weight. It examines functional use and speed of movement for general arm motions and fine hand control based on fifteen timed activities and two strength activities. This measure was sensitive to within group changes for our previous study and is selected to capture potential changes in hand function related to the TTT training. It has high inter-rater reliability, internal consistency, and test-retest reliability. Time to administer this test is approximately 25 minutes.

Fugl-Meyer Upper Extremity Motor Performance (global upper limb impairment): This is an impairment level measure of the UE specific to patients post stroke. It provides a direct-observational assessment of graded tasks of volitional arm and hand movement with a maximum perfect score of 66. Impairments related to reflexes, sensation, and abnormal synergies are examined while speed or functional use is not emphasized. This measure is selected to capture the impact of potential UE impairment improvements resulting from the intensive training using the BATRAC. It has been shown to be valid and reliable and have high inter-rater reliability and test/retest reliability. It is a recommended tool for evaluating changes in motor impairment following stroke. Time to administer is approximately 25 minutes.

The Action Research Arm Test (arm function) is an evaluative measure assessing specific changes in limb function among individuals who have hemiplegia (Lyle, 1981). It assesses the ability to handle objects differing in size, weight and shape and is considered an arm-specific measure of activity limitation (Platz, Pinkowski, Kim, di Bella, & Johnson, 2005). It is included as a secondary outcome for comparison to other studies and because we expect it to have neither floor nor ceiling problems in the target study population. Time to administer is 7-10 minutes.

Stroke Impact Scale (participation): This is a patient-based self-report structured interview consisting of eight domains examining the physical, mental, and emotional changes that occur as a result of stroke which contribute to a change in quality of life. The SIS has been tested and found to be reliable, valid, and sensitive to change in the stroke population. The short version of this questionnaire contains 50 questions and is designed to assess changes in impairments, disabilities, and handicap following stroke. It has four physical domains which assess the physical, ADL, mobility, and hand function abilities post stroke. These domains can be analyzed separately or summed together to create a physical dimension score. The hand domain score had the most robust changes in our previous study and showed significance (p=0.05) that differentiated the two interventions. However, as a self-report measure it captures the perceived performance of arm use in daily life and as such has limitations related to recall and objective quantification of each activity. To address this limitation, we propose to include accelerometers as an index of actual arm. Time to administer is approximately 10 minutes.

Motor Activity Log-28 (participation): This is a structured self-report interview which is unique in its inclusion of the patient's perception of quality of movement in addition to the amount of use. It has been used in constraint induced studies of arm rehabilitation and examines the daily use of the hemiparetic arm after stroke asking the patient to rate how well (quality of movement) and how much (amount of use) their hemiparetic arm is used to accomplish specific activities of daily living. It encompasses a broad range of activities ranging from eating to dressing to housework. To avoid potential frustration in our moderately to severely impaired participants, we will follow procedures consistent with the EXCITE trial and administer the assessment only at baseline and at the completion of treatment. This interview will be conducted in person for all participants as well as the designated caregiver. It has been found to be reliable and valid. Time to administer is approximately 15 minutes.

Strength (impairment): Isometric grip strength using a hydraulic hand dynamometer and manual muscle testing of upper extremity. The hand-held dynamometer has been validated for use with patients with stroke. Time to administer is approximately 10 minutes.

Robotic Bimanual Coordination Evaluation: The KinArm robot, a clinical arm robot designed to assess post-stroke sensorimotor deficits and quantify bilateral arm movements will be used to examine arm kinesthesia and bimanual impairment. The robot evaluation will be performed in a seated position with each arm supported by the robot exoskeleton. Participants will be prompted by a visual target or be moved by the robot to mirror-match arm positions within a horizontal plane of motion. The robot will record and store all movement data. Safety will be ensured with a study staff member present at all times. The robot also has an emergency stop system built in for quick termination of any testing if necessary. This evaluation will occur one time at baseline and one time post-training. Time to administer 30-40 minutes.

Telerehabilitation Study Satisfaction Surveys (Home-based Tele rehabilitation Group and Clinic-based Group) :
Home-based Telerehabilitation Group: This is a 17 question survey of participant satisfaction with the telerehabilition format. 10 questions use a 5-point Lickert scale to address ease of use, convenience, understanding of information provided and general satisfaction. There are 6 open-ended questions for participant comments. Time to administer is approximately 10 minutes.

Clinic-based Group: This is an 12 question survey of participant satisfaction with the clinic-based training format. 5 questions use a 5-point Lickert scale to address ease of use, convenience, understanding of information provided and general satisfaction. There are 6 open-ended questions for participant comments. Time to administer is approximately 5-10 minutes.

Home Activity Questionnaire (for Delayed-Entry group only): This is a 10 question survey of activities completed in the week that incorporated the affected arm. Also to record general household activities and community outings. Time to administer is approximately 5 minutes.

MyHealtheVet Training (for the home group only): Training and education about registration and use of MyHealtheVet secure messaging to communicate with the study team will be completed if randomized to the home group. This will take approximately 15 minutes.

VA Video Connect Training: (for the home group only): Training and education about use of the VA's "VA Video Connect" videoconferencing app to communicate with the study team will be completed if the participant is randomized to the home group AND consent for this optional app usage is obtained. This will take approximately 5 to 10 minutes.

Accelerometer Measures of Arm Use (activity): Accelerometers are a low cost, portable method of providing a more objective index of paretic arm use in daily life as compared to the self-report measures listed above. This data will complement the self-report measures and further add to the understanding of UE activity level in the

chronic phase of recovery and potential carry-over of study gains to functional use in the participant's home environment. The aim of including these small, light-weight affordable accelerometers is two-fold: (1) a more accurate record of use and (2) a more objective account of potential study gain carry-over to the real-world environment. Analysis will include examinations of duration of arm activity, the ratio of impaired to unimpaired use, correlations to clinical scales, and rehabilitation efficacy.

For this proposal, we selected tri-axial wireless digital accelerometers based on several factors including their low cost, small size, reliability, versatility of settings for sampling frequency and epoch duration adjustable by the research team, and overall data accessibility. Participants will wear two monitors (one on each wrist) over a 4-day time period. The monitors will be placed and removed by the research staff to avoid error. We will examine duration of arm activity and take a ratio of the non-paretic to paretic arm use as our outcome measure of interest. Reporting a ratio of paretic to non-paretic arm use will provide important information about the amount of use and incorporation of the stroke affected arm in daily activities as well as quantify change in motor capabilities and/or potential decreased learned non-use related to our intervention. We will also explore data further through consultation and advanced processing using new graphical methods developed in Dr. Lang's lab at Washington University (Lang 2013). Of particular interest is their quantification of real-world bilateral arm use given our bilateral training paradigm with the BATRAC.

MyHealtheVet SECURE MESSAGING PILOT STUDY Additional PROCEDURES
Questionnaires :
1. eHealth Literacy Scale (eHeals): This is an 8-item questionnaire that measures your perceived ability and comfort using information technology for health. It will be used to gain an understanding of your electronic health literacy at the beginning and again at the end of the study. It should take approximately 5 minutes to complete.

2. Web-Based Learning Self-Efficacy Scale (WBLSES): This is an 8 to 12 item questionnaire used to rate your confidence using electronic tools for web-based online learning. Questions ask you to rate your opinion the MyHealtheVet instructions used, availability of assistance, amount of time available to complete the items, encouragement, physical conditions and computer navigation methods. It will be given at the outset of the study and again at the end of the study. It should take approximately 5 minutes to complete.

3. Montreal Cognitive Assessment (MoCA): The Montreal Cognitive Assessment is a 30-point screening instrument that has been validated to detect mild cognitive impairments or deficits in attention, memory, learning and visuospatial functions that may be due to neurological deficits consistent with stroke. The MoCA will be used to gain a general baseline of study participant's cognitive functioning and should take no more than 20 minutes to complete.

4. Interview: Post-training interviews will be completed after you receive instruction in using the MHV website for access to the secure messaging portal and mail group. This interview will be completed after your initial instruction and at any follow-up training. Questions will focus on your experience with the training and confidence using the site.

Qualitative Study Additional Procedures

1. Background Questionnaire: There are two versions of the background questionnaire; one designed for a study participant and one for staff and lab personnel employed by the VA Maryland Health Care System or University of Maryland. This is an 8-12 item questionnaire used to gather the study participants', staffs' or lab personnels' prior experience with the My HealtheVet patient portal and its tools prior to using it and or being involved in the design and implementation in the My HealtheVet Secure Messaging Pilot Study. It should take approximately 5 minutes to complete.

2. Interview: a) A face-to-face semi-structured interview will be conducted after completion of the My HealtheVet Secure Messaging Pilot and Qualitative Study for first time participants, and after for returning study participants enrolling in the Qualitative Study focusing on your overall experiences and perspectives on My HealtheVet use; b) staff, students, and laboratory personnel enrolled in the Qualitative Study will complete a face-to-face semi-structured interview examining their experiences and perspectives of the four features of the My HealtheVet patient portal and Secure Messaging. The interview is expected to take approximately one-hour to complete.

3. Focus Group: A face-to-face semi-structured focus group may be conducted with VA Maryland Health Care System and University of Maryland staff, students and laboratory personnel, if the option is elected by members of this group. The focus group interview process will be used to elicit observations and experiences that may only come to light as a result of sharing experiences in an open forum. The focus group is expected to take approximately one-hour to complete.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):
N/A

3 * Describe the duration of an individual participant's participation in the study:
Each patient will be enrolled in the study and seen for baseline evaluations in the 1st month followed by 6 weeks of randomized intervention 3 times/week for 18 training sessions. This training time will be spread over a maximum of 9 weeks to allow for missed visits due to transportation/weather or minor illness. Participants will be asked to return for a retention follow-up after 8 weeks of no training. Maximal study time commitment will be 21 weeks.

Participants initially randomized to the 6 weeks delayed entry group will have a potential maximum study commitment of 27 weeks (4 week baseline + 6 week delay + max 9 weeks of intervention + 8 week retention).

4 * Describe the amount of time it will take to complete the entire study:
This study will be 3 years in length.

5 * Describe any additional participant requirements:
N/A

ID: VIEW4E0280585B400
Name: v2_Study Procedures

HP-00060526 View: v2_Sample Size and Data Analysis

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:

A sample size analysis was conducted for comparison of the home-based BATRAC group and the usual care group (Aim 1), with nominal power set at 80% and a two-sided alpha of 0.025. This sample size of 22 per group provides 80% power to detect a between group difference in change of the WMFT time score after training if we assume that the mean changes are 0 and 7.4 for the usual care group and the home-based BATRAC group, and SD=7.6. The mean change and SD estimates were based on our preliminary data sets from a progressive BATRAC group. Our current study has an attrition rate of 15% so we anticipate recruiting 78 participants to have 66 complete the study.

We also conducted power analysis for testing Aim 2, that home-based BATRAC telerehabilitation+TTT would be at least as effective as lab-based BATRAC+TTT, based on a non-inferiority test. The null hypothesis is delta<= dNI and the alternative hypothesis is delta > dNI, where delta is the difference in change of WMFT time scores between the home-based BATRAC group and the lab-based BATRAC group, and dNI is the non-inferiority margin. We selected 4.5 as the non-inferiority margin based on clinical meaning for this population in the chronic stage of recovery. With the sample size of 33 subjects per group (22 plus 11 from the delayed entry of the usually care group), assuming the home-based and lab-based BATRAC groups are equally efficacious, based on a one-sided T test with alpha=0.025, we have 66% power to reject the null hypothesis. Although this is under-powered for the non-inferiority test, this is only a secondary comparison. The sample size required to achieve 80% power for the non-inferiority test is 46 per group, using a 0.025 significance level and this number exceeds our recruitment ability.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:

Co-I/Biostatistician Min Zhan will actively participate in planning and conducting data analysis. Descriptive analyses including constructing graphical displays of the data and frequency distributions will be performed. Non-normally distributed data will be transformed to normality or categorized, whichever is more appropriate. Robust or nonparametric analysis will be performed as required. Patient characteristics (including age, race, gender, time since stroke, pre-stroke handedness), impairment severity (baseline FM score) as well as comorbidities (cardiac history, and diabetes) will be compared between intervention groups.

Aim #1 Analysis of Home-based BATRAC Telerehabilitation + TTT
The goal of this aim is to determine the efficacy of home-based BATRAC compared to usual customary stroke care for Veterans with chronic upper extremity stroke deficits. The primary outcome will be the change in the WMFT score from baseline to completion of the six-week intervention. We will use intention-to-treat (ITT) analysis and include all subjects who are randomized in the analysis. The primary analysis will be a two sample T test with a significance level of 0.025.

Alternative analysis for Aim 1: As an alternative analysis, we will compare our primary outcome measures adjusting for imbalanced baseline covariates, by using a linear regression model. As secondary analyses, we will examine outcome measures on multiple levels of the International Classification of Function including impairment, activity level and participation to provide an extensive examination of abilities. To assess the time trend of WMFT score in the home-based BATRAC group and in the usual care group, we will use linear mixed models that are similar to 2-way ANOVA with treatment group (2) X time (2) with repeated measures on the last factor. The independent variables will include time at which the outcome was measured i.e., pre (average of 3 time points), post training (~6 weeks) and after retention (~14weeks), treatment group (Home-based BATRAC Telerehab + TTT, and Usual Care), baseline FM group (the stratification variable), and the possible interaction terms between treatment group and time and possible interaction terms between treatment group and baseline FM group. If the interaction terms are not statistically significant, they will be removed from the model. We can also include imbalanced baseline covariates into the linear mixed models.

Aim #2 Analysis of Home-based BATRAC Telerehab. + TTT compared to lab-based BATRAC + TTT.
The goal of this aim is to determine whether HBT + TTT is non-inferior to LBB + TTT. The primary outcome is the change in WMFT score (WMFT score at post intervention – WMFT score at baseline). The non-inferiority analysis for the null hypothesis of delta<= dNI will be carried out as below, where delta is the difference of the change in WMFT score, defined as (WMFT change in the HBT + TTT group) - (WFMT change in the LBB+TTT group), and dNI is the non-inferiority margin (4.5 is selected based on clinical meaning). A 95% confidence interval for the difference delta will be constructed. If the upper bound of the confidence interval is less than the non-inferiority margin of 4.5, we would reject the null hypothesis and conclude that the HBT + TTT is either at least as efficacious as LBB + TTT, or the degree of inferiority is acceptable (no more than the non-inferiority margin). This will provide information on the value of adding the telerehabilitation component as well as the potential of remote therapy for the TTT exercises compared to one-on-one therapy.

Alternative Interpretations of Aim #2: If the upper bound of the 95% confidence interval is equal to or greater than the non-inferiority margin of 4.5, we do not have enough evidence to reject the null hypothesis that HBT + TTT is inferior to LBB+TTT. However, the results from this trial will help us to design a larger non-inferiority trial at the next step.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

HP-00060526

View: v2_Sharing of Results

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:

Typically the research evaluations will not be shared with the participant. If a medical problem is revealed during the medical examination and screening, the participant will be informed and study staff will make appropriate efforts to facilitate follow-up with the participant's primary care physician.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

HP-00060526 View: v2_Research with Medical Devices

Research with Medical Devices

You indicated on the "Type of Research" page that your study involves the evaluation of device(s) for safety or effectiveness or use of a HUD.

1 * List all devices to be used in this study:

	Device Name	FDA Approved?	Labeled	IDE Number	IDE Holder
View	BATRAC-commercial name is Tailwind	yes	yes	10028009	no

2 * Attach the device labeling or device manual for the devices being used in this study:

Name	Created	Modified Date
Tailwind Brochure(0.01)	10/1/2015 2:43 PM	10/1/2015 2:43 PM

3 * Are you requesting a nonsignificant device risk determination by the IRB? (*Applicable if the FDA has not issued an IDE and the device does not qualify to be IDE exempt.)*

○ Yes ● **No**

4 If yes, please provide the rationale for how the device(s) used in the study meet the following criteria:

- Is NOT intended as an implant, is NOT purported or represented to be for use supporting or sustaining human life, and is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health.
- DOES NOT present a potential for serious risk to the health, safety, or welfare of a subject.

5 * Do you have a plan regarding access controls for essential and appropriate research personnel?

● **Yes** ○ No

6 * Will you have procedures for verifying physical access of the device?

○ Yes ● **No**

7 * Will the storage of the study device be in a secure environment and include locks on doors and controlled access?

● **Yes** ○ No

8 * Will there be an establishment of equipment control both in to and out of the research site?

● **Yes** ○ No

9 * Will there be a development of Security Incident Procedures to report any privacy breaches?

○ Yes ● **No**

10 If applicable, do you have data backup, storage, and emergency mode procedures?

● **Yes** ○ No

11 If applicable, will the storage of the device be at the appropriate temperature, with a storage and temperature log?

● **Yes** ○ No

ID: VIEW4E0514D4C8C00
Name: v2_Research with Medical Devices

HP-00060526

View: v2_Psychological/Behavioral/Educational Methods and Procedures

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 * Select all behavioral methods and procedures which apply to this study:

- [x] **Surveys/questionnaires**
- [x] **Key informant or semi-structured individual interviews**
- [ ] Focus groups or semi-structured group discussions
- [ ] Audio or video recording/photographing
- [ ] Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)
- [ ] Individual or group behavioral observations
- [ ] Psychosocial or behavioral interventions
- [ ] Neuropsychological or psychophysiological testing
- [ ] Deception
- [ ] Other psychosocial or behavioral procedures

ID: VIEW4E09416F57800
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

HP-00060526 View: v2_Surveys/Questionnaires

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:

Montreal Cognitive Assessment (MoCA)
Web-Based Learning Self-Efficacy Scale
eHealth Literacy Scale
Stroke Impact Scale
Motor Activity Log-28
Telerehabilitation Satisfaction Surveys
Center for Epidemiologic Studies Depression Scale (CES-D)
Caregiver Burden Survey
Barriers to Self-Efficacy Scale (BARS)
Multidimensional Outcome Expectation Scale
Home group exercise tracking form
Research Provider Background Questionnaire
Research Study Participant Background Questionnaire
VA Video Connect Satisfaction Survey

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
VA Video Connect Satisfaction Survey.docx(0.01)	1/25/2019 4:14 PM	1/25/2019 4:14 PM
RESEARCH Study Participant Questionnaire IRB 10-17-18.docx(0.01)	10/17/2018 2:00 PM	10/17/2018 2:00 PM
RESEARCH PROVIDER Questionnaire IRB 10-17-18.docx(0.01)	10/17/2018 1:59 PM	10/17/2018 1:59 PM
Home group exercise tracking form(0.01)	1/23/2018 10:04 AM	1/23/2018 10:04 AM
Barriers Self-Efficacy Scale (BARS)(0.01)	3/28/2017 9:09 AM	3/28/2017 9:09 AM
Multidimensional Outcome Expectation (MOEES)(0.01)	3/28/2017 9:07 AM	3/28/2017 9:07 AM
Telerehabilitation Satisfaction_home-based(0.01)	3/27/2017 2:36 PM	3/27/2017 2:36 PM
Telerehabilitation Satisfaction_clinic-based(0.01)	3/27/2017 2:33 PM	3/27/2017 2:33 PM
Caregiver Burden Survey(0.01)	3/21/2017 3:02 PM	3/21/2017 3:02 PM
CESD(0.01)	3/21/2017 2:30 PM	3/21/2017 2:30 PM
Montreal Cognitive Assessment (0.01)	9/28/2016 12:25 PM	9/28/2016 12:25 PM
Web-Based Learning Self-Efficacy Scale(0.01)	9/28/2016 12:19 PM	9/28/2016 12:19 PM
eHealth Literacy Scale(0.01)	9/28/2016 12:15 PM	9/28/2016 12:15 PM
Motor Activity Log-28(0.01)	10/2/2015 9:34 AM	10/2/2015 9:34 AM
Stroke Impact Scale(0.01)	10/2/2015 9:33 AM	10/2/2015 9:33 AM

3 * What is the total length of time that each survey is expected to take?

Stroke Impact Scale: 10 minutes
Motor Activity Log-28: 15 minutes
Telerehabilitation Satisfaction Surveys:10 minutes
eHealth Literacy Scale: 5 minutes
Web-Based Learning Self-Efficacy Scale: 5 minutes
Montreal Cognitive Assessment: 20 minutes
CESD: 5 minutes
Caregiver Burden survey: 5 minutes
Multidimensional Outcome Expectation for Exercise Scale: 5 minutes
Research Provider Background Questionnaire: 5 minutes
Research Study Participant Background Questionnaire: 5 minutes
Barriers Self-Efficacy Scale Scale: 5 minutes
Home group exercise tracking form: 5 minutes
VA Video Connect Satisfaction Survey: 10 minutes

4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

○ Yes ● **No**

5 * Do any questions elicit information related to the potential for harm to self or others?

◯ Yes ● **No**

5.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

HP-00060526 View: v2_Interviews

Interviews

You indicated that this study involves key informant or semi-structured individual interviews.

1 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

◯ Yes ● **No**

2 * Upload a copy of the interview script or guide that will be used to guide the interviews:

Name	Created	Modified Date
UNSTRUCTURED FOCUS GROUP 10-17-18.docx(0.01)	10/17/2018 2:31 PM	10/17/2018 2:31 PM
Study Participant Interview IRB 10-17-18.docx(0.01)	10/17/2018 2:31 PM	10/17/2018 2:31 PM
Staff, Student, Lab Personnel Interview IRB 10-17-18.docx(0.01)	10/17/2018 2:31 PM	10/17/2018 2:31 PM
Secure Messaging Pilot_Research Team Interview(0.01)	9/28/2016 12:42 PM	9/28/2016 12:42 PM
Secure Messaging Pilot_Subject Interview(0.01)	9/28/2016 12:37 PM	9/28/2016 12:37 PM
Delayed Entry_Weekly Interview(0.02)	10/2/2015 10:18 AM	11/10/2015 10:23 AM

3 * What is the individual duration of each interview and what is the entire duration of the interviews?

DELAYED ENTRY WEEKLY INTERVIEW: Participants randomized to the Delayed Entry Control will be called weekly at an agreed upon time for a brief phone interview about their general activity level and functional use of their arm. The duration of each phone interview will not exceed 15 minutes and the interviews will be conducted 1x/week over the 6 week delayed entry time period.

SECURE MESSAGING PILOT INTERVIEW: Participants randomized to the Home-Based Tele-rehabilitation group and enrolled in the Secure Messaging Pilot study will receive this interview with questions specific to the MyHealtheVet web-based training. This interview should take approximately 15 minutes to complete.

RESEARCH TEAM INTERVIEW: Research team members involved in the secure messaging management of research communications will be given a brief interview of confidence with using the tool. This should take approximately 5 minutes to complete.

STAFF, STUDENT, LAB PERSONNEL INTERVIEW: Staff, student or laboratory personnel involved in the design, implementation and use of the My HealtheVet (MHV) Secure Messaging Pilot Study will be interviewed to gather their individual experiences and perspectives using four features of the MHV patient portal. The face-to-face interview should take approximately one hour.

STUDY PARTICIPANT INTERVIEW: First-time and returning participants randomized to the Home-Based Tele-rehabilitation or Delayed Entry group will be interviewed to gather their experiences and perspectives of the four features of the My HealtheVet Secure Messaging Pilot study. The face-to-face interview should take approximately one hour.

Unstructured Focus Group: Staff, student or laboratory personnel involved in the design, implementation and use of the My HealtheVet (MHV) Secure Messaging Pilot Study will be offered the opportunity to participate in an unstructured focus group to gather their experiences and perspectives of using MHV patient portal and secure messaging for research. This activity is expected to take one hour.

4 * How will the interview responses be recorded and by whom?

The Delayed Entry_Weekly Interview, Secure Messaging Pilot_Subject Interview and Secure Messaging Pilot_Research Team interviews will be recorded on paper by research staff using the designated study forms. These document will be stored according to VA policy with the participant's research documents. The research team interview forms will be de-identified and stored within the study documents binder in a locked cabinet in the PI's office.

The Staff, Student, Lab Personnel Interview, Study Participant Interview, and Unstructured Focus Group will be voice recorded on a password-protected computer and secured behind a firewall in a database within a VA Server. The computer and data will be in a secure location, such as a locked office and locked cabinet. All data will be de-identified and not retrievable by subject name or other personally identifiable information.

5 * Do any questions elicit information related to the potential for harm to self or others?

◯ Yes ● **No**

5.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E0947A633C00
Name: v2_Interviews

HP-00060526 View: v2_Data Collection / Record Review

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)

- [ ] Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
- [x] **Prospective (data is not yet in existence and/or collected)**

2 * Will this study involve adding data to a registry or database for future use?

○ Yes ● **No**

3 * Will the data be released to anyone not listed as an investigator on the protocol?

○ Yes ● **No**

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

HP-00060526 View: v2_Prospective Data

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)

- [x] **Medical records**
- [x] **Medical images**
- [ ] Commercial (for profit) entity
- [ ] Publicly available records
- [ ] Schools
- [x] **Other**

1.1 If Other, please specify:
Arm activity monitors, functional assessments and other training data related to the proposed interventions.

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.
Name
Date of Birth
Social Security # (for VA forms only)

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0E25B643800
Name: v2_Prospective Data

HP-00060526 View: v2_Clinical Trial Registration

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?

● **Yes** ○ No

2 * Has this trial been registered?

● **Yes** ○ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

HP-00060526

View: v2_Clinical Trial Registration Information

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
(●) **Yes** ( ) No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
( ) Yes ( ) No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT02665052

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

HP-00060526 View: v2_Participant Selection

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
250

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
98

Worldwide - the number being enrolled total at all sites (including local enrollment):
98

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [ ] 0 to 27 days (newborn infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] **18 years and older (Adult)**
- [ ] 89 years and older

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect

- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

◯ Yes ● **No**

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

HP-00060526 View: v2_Vulnerable Populations

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [x] **Employees or Lab Personnel**
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [x] **Pregnant Women/Fetuses**
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [ ] None of the above

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

HP-00060526

View: v2_Vulnerable Populations - Employees or Lab Personnel

Vulnerable Populations - Employees or Lab Personnel

You indicated that employees or lab personnel are included in this study.

1 * Describe how you will ensure participtionin this research will not affect employment and prevent undue influence:

Potentially vulnerable participants include University of Maryland and/or VA employees, students or lab personnel. This data collection is optional and if you are an employee, student or lab personnel your employment status or academic standing at the VA Maryland Health Care System or University of Maryland Will not be affected by your participation or non-participation in the study.

ID: VIEW4E0E5192BA800
Name: v2_Vulnerable Populations - Employees or Lab Personnel

HP-00060526

View: v2_Vulnerable Populations - Pregnant Women / Fetuses

Vulnerable Populations - Pregnant Women/Fetuses

You indicated that pregnant women are included in this study.

1 * Describe how you will prevent undue influence:
A recent trend toward an increased stroke incidence earlier in the lifespan (Mozaffarian, Kissela 2012) may result in more of our stroke participants being women of child bearing potential. We are not specifically targeting this population, however, pregnant women will be included as pregnancy will not affect the ability to use the device, increase risk or affect the scientific design. Pregnancy will be ascertained and documented during the screening process through verbal asking. If a participant becomes pregnant during the course of the study we will just ask for the participant to notify us. It will be the participant's choice to continue or withdraw from the study.

2

* What risk to subjects is presented by this research? ***If the research does not fall under one of the categories below, it will require submission to OHRP prior to any IRB approval. Please consult the HRPO staff for further guidance.***

- ○ Greater than minimal risk with prospect of direct benefit ONLY to fetus
- ○ Greater than minimal risk with prospect of direct benefit to pregnant woman only OR to both pregnant woman and fetus
- ○ Minimal risk to pregnant woman and fetus without the prospect of direct benefit, but the research proposes the development of important biomedical knowledge which cannot be obtained by any other means
- ● **Minimal risk with prospect of direct benefit to pregnant woman only OR to both pregnant woman and fetus**
- ○ Minimal risk with prospect of direct benefit ONLY to fetus
- ○ None of the Above

Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.

3 * If scientifically appropriate, provide information about preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, that have been conducted and provide data for assessing potential risks to pregnant women and fetuses: (*if not scientifically appropriate, enter "N/A".*)
N/A

4 * Explain why the identified risks are the least possible for achieving the objectives of the research:
We are not specifically targeting this population, however, pregnant women will not be excluded as pregnancy will not affect the ability to use the device, increase risk or affect the scientific design. This exercise protocol is not aerobic in nature, and the reaching activity is not designed to be strenuous. The device provides support and when not using the device the participant's caregiver or therapist will assist.

5 * Explain how each individual providing consent will be fully informed and kept fully informed regarding the reasonably foreseeable impact of the research on the fetus:
Pregnancy will be ascertained and documented during the screening process through verbal asking. If a participant becomes pregnant during the course of the study we

will ask her to notify us. At that time it will be the participant's choice to continue or withdraw.

This research should not pose any risk to the fetus or mother, and may have potential benefit on future care if the mother is able to use her arms better for activities of daily living.

6 * Will inducements, monetary or otherwise, be offered to terminate a pregnancy?

○ Yes ● **No**

7 * Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?

○ Yes ● **No**

8 * Will individuals engaged in the research have any part in determining the viability of a neonate?

○ Yes ● **No**

ID: VIEW4E0E5195C0000
Name: v2_Vulnerable Populations - Pregnant Women / Fetuses

HP-00060526 View: v2_Eligibility

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?

◯ Yes ● **No**

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE.** The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
There are no items to display		

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Age 18 years or older.
View	2	Have a clinically defined unilateral hemiparetic stroke with radiologic exclusion of other diagnosis.
View	3	Stroke onset of at least 6 months prior to enrollment.
View	4	Present with moderate to severe arm impairment based on a Fugl-Meyer score ranging from 19-50 out of 66.
View	5	No previous experience using the BATRAC.
View	6	Ability to use and interact with the tele-rehabilitation platform according to study protocol.
View	7	Have an identified individual/caregiver to perform the TTT exercises if randomized to the Home Telerehabilitation group.

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Musculoskeletal diagnosis or significant arm pain that would interfere with positioning and use of the intervention (BATRAC) devices.
View	2	Cognitive impairment such that the participant is unable to understand the study requirements to answer the Evaluation to Sign Consent Form tool accurately.
View	3	Absence of a working telephone line or cell phone for telerehabilition set-up if randomized to this group.
View	4	Enrollment in a concurrent rehabilitation study or actively receiving therapy for their stroke affected (study) arm.
View	5	Having received a botulinum toxin injection to the stroke affected (study) arm within 3 months of enrollment.

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00060526_6 v5-2-2017-1493727589921(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

HP-00060526 View: v2_Recruitment

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):

Some participants with stroke will be recruited by referrals from VA OT/PT clinicians or from IRB approved flyers and word of mouth. Initial interactions will consist of a phone call from a research staff member stating that we are contacting the individual based on their expressed interest in the study. Other participants will be recruited from the Univeristy of Maryland Rehabilitation & Orthopaedic Institute Stroke Registry (UMROI) Stroke and Pepper Center registries which are approved by UMB IRB. Other participants will be recruited using specialized searches on VA CPRS. The UMROI Stroke Registry, Pepper Center Registry and VA CPRS will all be used to identify and conduct preliminary screening of potential participants. Initial interactions will consist of a phone call from a research staff member stating that we are contacting the individual based on their prior willingness to be contacted about new research studies and asking if they would be interested at this time in learning about our new project. If they are interested in learning more about the study, the caller will briefly outline the study and describe the initial visit.
If still interested the caller will inquire about available times that the potential participant could come to the Baltimore VA Annex, and subsequently schedule an appointment for the initial visit and informed consent. During this initial phone contact, research staff will NOT request the veteran's social security number.

We will attempt to enroll as many Veteran participants as possible in this VA-funded human research study. However, we do anticipate recruitment of at least some non-veterans, assuming that recruitment of Veterans-only may prevent timely completion of this 3-year randomized controlled study. Also, we may need to recruit non-veterans to expand the range of deficit severity in the stroke group, to better define future applicability of upper extremity telerehabilitation in the larger stroke population. Scientifically we expect that results obtained from any non-veteran stroke survivors will be similar to that potentially gained from veterans who have had a stroke, should be similar to that of healthy Veterans.

Study participants who indicated that they would be willing to be contacted about future research will be contacted about participation in the Qualitative Study examining the study participants experience and perspectives using four features of the My HealtheVet patient portal and Secure Messaging.

Employees, students and laboratory staff who may be employees of the VA Maryland Health Care System and University of Maryland who participated in the design, implementation and use of the My HealtheVet Secure Messaging Pilot Study will be recruited for participation in the Qualitative Study examining the experiences and perspectives of the users.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):

Participants will be informed that they have an absolute right to withdraw from the study at any time for any reason. It will be emphasized upon withdrawal that they will not lose eligibility for medical care or services at the VA or University of Maryland Medical Center, nor will they lose eligibility to participate in any future research studies. Informed consent will follow institutionally approved guidelines, including protection of confidential information relating to medical history and other information gathered to determine eligibility criteria.

Participants will be provided information at the time of consent that the MyHealtheVet SECURE MESSAGING PILOT STUDY is optional and he/she can opt-in to receive the associated pilot questionnaires and interviews, and that refusing this option has no bearing on enrollment or randomization.

Returning participants will be informed at the time of consent that their participation is entirely voluntary and they may withdraw at any time and their participation will not affect their participation in the parent study.

Staff, students and laboratory personnel will be information that their participation is voluntary and they may withdraw for any reason and that their participation or non-participation will not have any impact on their employment status or academic standing at the VA Maryland Health Care System or University of Maryland.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] **PI**
- [x] **Study Staff**
- [x] **Third Party**

3.1 If you are using a third party, specify Third Party Recruiters:

GRECC recruitment hotline (410) 605-7000 ext 54573

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
Recruitment Letter Study Participant 11_26_18_mod20.doc(0.03)	10/17/2018 3:11 PM	11/26/2018 4:23 PM
Recruitment Letter Staff 11_26_18_mod20.doc(0.03)	10/17/2018 3:11 PM	11/26/2018 4:23 PM
Recruitment Flyer-Staff 10-17-18.docx(0.01)	10/17/2018 3:12 PM	10/17/2018 3:12 PM
Recruitment Flyer patients 10-17-18.docx(0.01)	10/17/2018 3:11 PM	10/17/2018 3:11 PM
Participant Screening Tool_v.3(0.01)	1/16/2018 12:49 PM	1/16/2018 12:49 PM
Participant Screening Tool_v.2(0.02)	11/10/2015 11:16 AM	12/11/2015 12:18 PM

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

HP-00060526 View: v2_Advertising

Advertising

1 * Will you be using advertisements to recruit potential participants?

● **Yes** ○ No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

HP-00060526 View: v2_Advertising Detail

Advertising Detail

You indicated that you will be using advertisements to recruit potential participants.

1.1 * Select the mode(s) of advertising (check all that apply):

- [ ] Radio
- [ ] Internet
- [ ] Print
- [ ] Television
- [x] **Other**

1.1.1 If Other, specify:
Hand-out

1.2 * Provide exact text of all proposed advertisement(s):
TeleBATRAC Study

Telerehabilitation & Bilateral Arm
Training with Rhythmic Cueing

Baltimore VA Medical Center — Annex

What is the goal of the TeleBATRAC study?

Isolating and removing barriers to access post-stroke rehabilitation services is critical for stroke survivors to reach their highest level of functioning. This study plans to investigate a home arm exercise program using the BATRAC arm exerciser, “hands-on” task specific training and the internet to increase access.

Specifically, participants will use the VA My HealtheVet secure electronic messaging system to communicate record and manage their arm rehabilitation.

Who is eligible?

To be eligible for the TeleBATRAC study, you must:
• be 18 years of age or older
• have had a stroke 6 months before starting the TeleBATRAC study
• have weakness in one of your arms
• ability to use the VA My HealtheVet patient portal
• have a willing individual/caregiver

What happens if I join this study?

If you are eligible for this study, you will undergo a medical evaluation and arm evaluations.

These evaluations will be performed three times over a 14-week period:

• Before training,
• After 6 weeks of training, and
• Once more at Week 14 in the study

Once enrolled, you will be randomly assigned to one of three therapy groups:

1) VA research clinic-based training
2) Home tele-rehabilitation training
3) Delayed entry (waiting 6 weeks before training)

Assignment to one of these groups is random, like the flip of a coin.

We ask that you be willing to participate in any of the three groups.

Where do I go for this study?

The active training location will depend on your random assignment and will last 1 hour, for 3 times a week for 6 weeks.

If you are initially in the delayed
entry group, you will receive weekly phone calls for 6 weeks. Then, you will be randomly entered into the active clinic-based or home tele-rehabilitation group for 6 weeks of training.

Evaluation procedures will take place at Baltimore VA Medical Center Annex and the University of Maryland, Baltimore.

This study has been approved by the Veterans Affairs Maryland Health Care System (VAMHCS) Research and Development Committee, and by the University of Maryland, Baltimore (UMB) Human Research Protections Office.

Study #: HP-00060526

For more information, please call or complete and mail this form in a sealed envelope to:

TeleBATRAC Study
Baltimore VA Annex
209 West Fayette Street
2nd Floor — Robotics
Baltimore, MD 21201
(410) 637-3230 (office)
(443) 206-3304 (recruitment)

Name: _____

Address: _____

_____

_____

Phone #: _____

Reason for Study Interest:

I have had a stroke.

I am a caregiver.

Other: _____

For more information, please call:
TeleBATRAC Study Recruitment Line:
(443) 206-3304

TeleBATRAC Study Principal Investigator:
Susan Conroy, PT, DSc.PT
VA Maryland Health Care System, Baltimore Medical Center

VA My HealtheVet Patient Portal:
www.myhealth.va.gov

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
TeleBATRAC_Hand-Out_v10_20190201.doc(0.01)	2/1/2019 12:13 PM	2/1/2019 12:13 PM

ID: VIEW4E0BCE82B8C00
Name: v2_Advertising Detail

HP-00060526 View: v2_Research Related Risks

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

The risks of participating include the physical risks associated with the assessments and repetitive training, and the personal risks related to the questionnaires and the risk of potential loss of privacy/confidentiality .

1. There is a small risk of muscle strain or pulled muscles in the assessment measures of strength and coordination. Participants will be instructed to perform within their level of comfort.

2. There is a risk of injury by the robot. The possible injuries from this malfunctioning robot include bumps, bruises, fingers jammed, pinching or lacerations. The risk of injury is minimized by continuous oversight by a qualified staff member trained in the use of the robot during all evaluations. The robot design is specific to evaluations of neurologically impaired people and includes an emergency stop to immediately terminate all robot forces if there is any potential for injury.

3. There is a risk of frustration and/or irritation with completing the questionnaires. Participants will be informed that they can skip any question that is uncomfortable for them.

4. Training involves repetitive arm activities which have a potential to cause muscle soreness, and joint irritation of the shoulder and elbow. This is a relatively rare occurrence, but it is more likely in the early stages of training when subjects are unused to the exercise activities. The risk is reduced by providing regular opportunities to rest within the BATRAC training protocol. Participants will also be questioned about joint and muscular pain at the end of the sessions and told to rest the affected area and report back if pain persists. Therapy sessions will be suspended for persistent pain and the participant will be referred for a medical evaluation.

5. There is a small risk that subject privacy/confidentiality may be compromised. Several procedures are in place to minimize this risk. Participants are provided privacy during research interactions with the research team. The PI and research team will keep identifiers linking names to research codes in a secure file locked in a cabinet in the locked research space or the Co-PI's office. Only the Co-PI's and research team will have access to this information on an as-needed basis. Only the research codes will be used for data collection and training records. Any identifiable patient information will be kept within the VA firewall in approved computers and servers. There are no foreseeable psychological, social, or legal risks for this study.

6. There is a potential confidentiality risk related to the use of the My HealtheVet Secure Messaging. Secure messages are electronically stamped by the VA system and include name, date of birth, and last four digits of the social security number. These messages are stored securely in the VA system and may be reviewed by study staff. They may also be counted by the VA as part of VHA Support Service Center (VSSC) Reports. The information retrieved for the VSSC reports will not include identifiable information.

7. The MyHealtheVet SECURE MESSAGING PILOT STUDY has a confidentiality risk related to a risk of frustration and/or irritation with completing the questionnaires and interviews.There is a minimal risk that a breach of confidentiality could occur. Loss of confidentiality will be minimized by storing data in a secure location, such as a locked office and locked cabinet, and electronic and voice recorded data will be password-protected and secured behind a firewall in a database within a VA server.

8. For medical emergencies that occur at the Baltimore VA Medical Center Annex and in the VA leased spaced at the University of Maryland an AED is available on site and the 911 emergency medical system would be activated by the research team.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

HP-00060526

View: v2_Potential Benefits and Alternatives

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:

The participant may or may not benefit from taking part in this study. There is no guarantee that the participant will receive direct benefit from this study. A potential benefit of participation is the development of new arm exercise therapies for stroke survivors and defining those who can successfully use this new telerehabilitation approach.

2 * Describe the importance of the knowledge expected to result from the study:

As our adult population ages the number of strokes and resulting long-term disability is predicted to rise exponentially. The opportunity to define the appropriate use of home telerehabilitation to restore arm function has far reaching implications for the improvement of independence in ADL's and quality of life. If this proposed Home-based Telerehabilition format proves to have better efficacy than usual customary care then this will be an incentive to continue development for broader community home use. If proven as effective as standard lab/clinic based BATRAC rehabilitation,this may lead to deployment and integration into communities lacking specialized stroke care. The proposed model of home-based tele-rehabilitation may also be extended to other neurological conditions with upper extremity dysfunction such as Brain Injury, Parkinson's disease or Multiple Sclerosis. These benefits outweigh the minimal risks that may arise from study participation.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:

The risks are minimized based on the selection of the BATRAC as the rehabilitation tool. This device is not mechanized and has been carefully studied in the lab based setting to be safe and effective. It is now available commercially (Tailwind) for home and clinical use. The Home-based TeleBATRAC format has been carefully considered to include access to training, help tools, and a secure asynchronous link to a therapist should any issues arise. This intervention should not pose any risk greater than that encountered with traditional home therapy exercise activities. The risks are reasonable in relationship to the benefit of objectively defining appropriate candidates and appropriate protocols for Home-based telerehabilitation to restore upper extremity abilities after stroke.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.

There are no alternatives to participation in this study. Participation is voluntary and the alternative is not to participate.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

HP-00060526

View: v2_Withdrawal of Participants

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:

Participants may be withdrawn from the research without their prior agreement under the following circumstances:
-poor attendance leading to insufficient training
-participation in other exercise protocols or activities that would confound study results
-emergent medical problems that preclude continuing with the training protocol

2 * Describe procedures for orderly termination:

Orderly termination of the study will occur at the conclusion of the retention evaluation. At that time, the participant will be informed of any interim results to indicate how they have performed during the course of the study if they request such information. In the event the participant requests an early termination, the study PI or research staff will discuss the reasons and provide any interim study feedback on the participant's progress if available.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:

When participants withdraw a note will be placed in their study file indicating the reason for withdrawal. In rare cases, if a participant is unable to complete all planned procedures, but it is determined this will not compromise the scientific integrity of the study then a note will be made to file explaining the circumstances.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

HP-00060526 View: v2_Privacy of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***

Privacy will be ensured during the consenting process by having the potential participant meet with the study personnel in a private office or other private setting to review consent forms and discuss study procedures. All study related activities will take place in private environments. Questionnaires and physical testing will take place in private rooms when possible. Only trained staff will conduct these meetings and the participant's identity will not extend beyond the research team. Once enrolled, provision to protect the privacy interests of participants include the assignment of a study code which only the PI and research staff have access to.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:

Screening and consent activities with participants will be conducted in the Baltimore VAMC, or VA Annex, in a private examination/interview area, or in a another private office area away from public traffic where only the member(s) of the study research team may see or overhear the participant.

3 * Describe potential environmental stressors that may be associated with the research:

This research will not introduce new environmental stressors to the participant.

4 * Will this study have a site based in the European Union?

○ Yes ● **No**

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?

○ Yes ● **No**

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

HP-00060526 View: v2_Confidentiality of Data

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

- (●) **Yes**
- ( ) No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

The data collected will be used for research purposes only.
All research data with identifiers are kept in locked cabinets, and all digital data on research computers are protected by network firewalls and passwords. Electronic data will be stored on VA servers and hardcopies in a locked file in a locked room.
All research subjects are assigned a unique identifying number and all data processing is done utilizing this number rather than name, social security number, birth date or other specific individual identifying information. Analysis will primarily be in the form of averaged group results.

3 * How will such data be secured?

A master file with the names and numbers of the research subjects will be maintained by the PI and kept in a locked file cabinet in a locked area at the VA Annex. All data from tests and training will be de-identified and recorded into electronic file formats that will be stored behind the firewall and password protected network. Transmission of any electronic data will utilize file encryption. No data will be stored on a hard drive. All data will be stored on a server and backed up daily on the rehab\\oitbalfpcrsch02.v05.

The VA MyHealtheVet website provides for VA approved secure messaging and all entries are stored at the VA website and not on the mobile device. This web application is available within and outside the VA and meets VA requirements for use as a telehealth tool.

Digital recording of the protocol arm exercises will be conducted with a VA issued recording device and uploaded and stored with other electronic sensitive study information on on our VA server site: rehab\\vhabalrsch2.

As per current VA policy, all data, including the investigator's research records and any participant identifiers will be retained in accordance with the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1), and will not be destroyed. If at a later date the VA policy changes data will be destroyed using the most current approved methods available.

4 * Who will have access to research data?

Only the PI and his research team will have access to the research data.

5 * Will study data or test results be recorded in the participant's medical records?

- ( ) Yes
- (●) **No**

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research and VA research cannot be deleted)***

- ( ) Yes
- (●) **No**

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 Do you plan to obtain a Certificate of Confidentiality?

- ( ) Yes
- (●) **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date

There are no items to display

8 * Discuss any other potential confidentiality issues related to this study:

No research data will be removed from the VA protected environment. All access to data will be terminated when a staff member leaves employment or is no longer a member of the research team. If there is a loss of data, unauthorized access to sensitive data, or non-compliance with security controls it will be immediately reported to the PI, and the appropriate VAMHCS Privacy Office and Information Security Personnel. The VA Research Compliance Office and IRB will also be notified.

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

HP-00060526 View: v2_Monitoring Plan Selection

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ● **Data Safety Monitoring by a Committee**
- ○ Data Safety Monitoring by an Individual
- ○ There is no data safety monitoring plan in place

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

HP-00060526 View: v2_Monitoring Plan - Committee

Monitoring Plan - Committee

You indicated that the monitoring will be done by a Committee.

1 * Will the Committee be Internal or External?

- (●) **Internal DSMB**
- ( ) External DSMB

2 * What data will be reviewed?

- [x] **Adverse Events**
- [x] **Enrollment Numbers**
- [ ] Patient Charts/Clinical Summaries
- [ ] Laboratory Tests
- [ ] Medical Compliance
- [ ] Procedure Reports
- [ ] Raw Data
- [ ] Outcomes (Primary, Secondary)
- [ ] Preliminary Analyses
- [ ] Other

2.1 If Other, specify:

3 * What will be the frequency of the review?

- ( ) Annually
- (●) **Bi-Annually**
- ( ) Other

3.1 If Other, specify:

4 * Safety monitoring results will be reported to:

- [x] **IRB**
- [ ] GCRC
- [ ] Sponsor
- [x] **Other**

4.1 If Other, specify:
VA Research & Development Committee/Compliance Office

ID: VIEW4E1B025761800
Name: v2_Monitoring Plan - Committee

HP-00060526

View: v2_Monitoring Plan - Internal DSMB

Monitoring Plan - Internal DSMB

You indicated that the monitoring committee will be an internal DSMB.

1 * List Internal DSMB Members:

	Name
View	Internal DSMB members are listed in the GRECC I-SMB plan uploaded in Additional Documents.

2 * Confirm that no financial or other conflicts of interest exists for the above individuals.

● **Yes** ○ No

3 * Will there be an interim efficacy analysis?

○ Yes ● **No**

3.1 If Yes, when?

4 * Briefly describe the DSM review process itself. Will it be an open or closed review to the investigator? Blinded/unblinded data? How will confidentiality of individual participant data be maintained?

The GRECC I-SMB meets twice a year. This will be an open review, but investigators are not allowed to vote on their own protocols. No PHI will be revealed when SAEs are reviewed. Aggregate data will be presented.

5 * What are the criteria defined in the protocol to be used for decision making regarding continuation, modification, or termination of study?

Failure to follow good clinical practice, investigator noncompliance, and/or failure to meet enrollment goals may be grounds for suspension or termination of a study.

ID: VIEW4E1B0261D9400
Name: v2_Monitoring Plan - Internal DSMB

HP-00060526

View: v2_Research Related Costs

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

- ☑ **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- ☑ **Investigational or Study Device**
- ☐ Investigational or Study Drug
- ☐ Investigational Procedure(s)

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- ☑ **Participant**
- ☐ Sponsor
- ☐ UM
- ☐ Other
- ☐ There will be no uncovered research-related costs

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

Participants will be paid $10 per visit for costs related to transportation to attend study evaluation and intervention sessions. They will not have to pay for parking. If transportation costs exceed this amount then the participant will be responsible for the difference.

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

HP-00060526 View: v2_Compensation for Research-Related Injury

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

◯ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date

There are no items to display

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

◯ Yes ● **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

HP-00060526 View: v2_Payment to Participants

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

● **Yes** ○ No

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HP-00060526 View: v2_Payment Detail

Payment/Reimbursement Detail

You indicated that participants will receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research.

1 * Payment/reimbursement to participants will be for: (check all that apply)

- [x] **Travel**
- [ ] Parking
- [ ] Meals
- [ ] Lodging
- [ ] Time and effort
- [ ] Other

1.1 If Other, specify:

2 * What is the total dollar value of the payments/reimbursements over the duration of the study? ***Total payment(s) for participation in research of $600 or more is required to be reported on an IRS Form 1099.***
Maximum of $270 @ $10/ visit (may vary slightly if visits are missed).

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?
The VA requires that we issue vouchers for participants to redeem at the VA cashier's office. Vouchers will be issued from the study team at the Baltimore VA Annex to be redeemed by the participant t the Baltimore VA Medical Center cashiers office at 10 North Greene St. Baltimore, MD 21201. Reimbursement is $10 for each study visit completed at the VA. In the event a participant does not complete the study, he/she will receive $10 per VA visit up until the last day of participation. Payment is as follows:

1) Baseline-At the completion of the entire baseline testing phase, a voucher for the consent and baseline evaluation visits 1-4 and the robot evaluation visit 5 will be issued in the amount of $50.
2) Final Evaluations-At the retention visit a voucher for the final arm and final robot evaluation and retention evaluation visits will be issued in the amount of $30.
3) Study Interventions
-If the participant is randomized to the clinic-based rehabilitation group, he/she will receive vouchers for travel to/from the VA for intervention visits 1-18. This will be issued at the final training evaluation visit in the amount of $180 if all appointments are kept.
-If the participant is randomized to the home-based telerehabilitation group he/she will NOT NEED TO TRAVEL to the VA for intervention visits so will NOT be reimbursed for sessions 1-18.

In summary, if a participant is immediately enrolled in the clinic-based group and keeps all appointments he/she will receive $260. If a participant is immediately enrolled in the home-based group and keeps all the evaluation appointments he/she will receive $80. If a participant is in the delayed intervention group, he/she will receive payment for their delayed randomized intervention described above and one additional evaluation reimbursement of $10 for their delayed retention evaluation.

4 * Method(s) of payment/reimbursement to be Used:

- [ ] Cash
- [ ] Check
- [ ] Money Order
- [ ] Gift Certificate/Gift Card
- [x] **Other**

4.1 If Other, specify:
Vouchers for redemption at the Baltimore VA cashier desk.

ID: VIEW4E1C54A6ACC00
Name: v2_Payment Detail

HP-00060526 View: v2_HIPAA

HIPAA (Health Insurance Portability and Accountability Act)

1 * HIPAA applies to the University of Maryland School of Medicine, the University of Maryland School of Dentistry and the VA. Are you affiliated with, or will be accessing data from, any of these places? ● **Yes** ○ No

2 If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA? ● **Yes** ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

HP-00060526 View: v2_Protected Health Information

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [x] **Address (if more specific than Zip Code)**
- [x] **Dates**
- [x] **Ages over age 89**
- [x] **Telephone numbers**
- [ ] Fax numbers
- [ ] Email addresses
- [x] **Social Security numbers**
- [ ] Medical record numbers
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including fingerprints and voiceprints
- [x] **Full-face photographic images and any comparable images**
- [ ] Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
- [ ] None

2 * Why is the PHI necessary for this research?
If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).
We are required to enter the real, full social security number, date of birth, and name to enroll participants into the VA medical CPRS system. This information will be recorded on VA Form 1010-EZ which is submitted to the VA for entry into CPRS by authorized VA personnel and stored in their chart. We do not retain a copy of this form, but we do store the last four of the SS# in the participant's files.

3 * What is the source(s) of the PHI?
The source of the PHI would be from patient report and medical records.

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).
The PHI collected for the conduct of this study will not be used for another study or for any other purpose that has not been approved.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [x] **Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")***
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

HP-00060526 View: v2_Waiver/Alteration of Authorization

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
The PI and study personnel will take every reasonable step to protect PHI. All PHI will be stored in locked room within a locked file cabinet. Only authorized study personnel who have completed HIPAA, Privacy and Information Security, and CITI training will have access to PHI. Research compliance officers of the VA R&D conduct routine audits to ensure proper usage and destruction of PHI. Full social security numbers are only used to enroll participants into the VA medical CPRS system. The full social secruity numbers are not retained or stored within participant files. Because of these measures taken, our research does not present more than a minimal risk to the privacy of individuals.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
We will protect this information from improper use by removing the subject's name, date of birth, and contact information from all research data collection and data storage files. The file for decoding the numeric identifers will be kept in a locked file within a locked office. Only selected information from medical records will be recorded onto coded files in order to characterize the nature and history of stroke and the research encounters during the study, to protect individual identities.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
All data, including the investigator's research records and any participant identifiers will be retained until the maximum retention period is reached as defined by the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1). When the maximum retention period is reached, the data will be destroyed using the most current electronic data destruction methodologies that are available at the time of data destruction.

4 * Why could the research not practicably be done without access to and use of this PHI?
The PHI are needed to establish that potential participants meet basic entry requirements i.e. history of stroke, time since stroke, and presence of upper extremity deficits. Not everyone who has had a stroke can be considered for this BATRAC rehabilitation. It is necessary to evaluate the basic clinical and demographic information to see if subjects are initially eligible, medically safe, and appropriate in terms of deficit severity for the BATRAC training. The waiver is the alternative to an in-person evaluation to see if subjects' are medically eligible and safe to enter; a process that would increase participant burden.

5 * Why could the research not practicably be done without the waiver or alteration?
Traditional recruitment methods (flyers, physician referrals) offer limited consistency in the identification of appropriate candidates for our study given our specific time range post-stroke and type and level of deficit. A waiver would gain us access to the Univeristy of Maryland Rehabilitation & Orthopaedic Institute Stroke Registry, the Pepper Center Registry and specified searches within VA CPRS, giving us access to potential participants to meet our recruitment aims in an efficient and timely manner without undo burden on the potential candidates.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
● **Yes** ○ No

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.
This research is being conducted at the Baltimore VA Medical Center.Therefore, some of the study personnel are VA employees and will have access to PHI. The VA R&D may also choose to audit our records and may require access to PHI.

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

HP-00060526 View: v2_Informed Consent Process

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [ ] Not applicable (study may qualify as exempt)
- [x] **Request to Waive Consent/Parental Permission (Consent is not being obtained)**
- [ ] Request to Alter Consent (Some Elements of Consent Waived)
- [ ] Request to Waive Documentation of Consent (Verbal/Oral Consent)
- [x] **Written Consent Form**
- [ ] Electronic Consent

2 * Describe the Informed Consent process in detail:

Those interested in the study and with no apparent exclusionary criterion at the time of initial screening are scheduled to come in to hear about the study in detail and carefully go over the consent form with trained staff at the at the VA Medical Healthcare System (VAMHCS), specifically the Baltimore VA Annex, Baltimore VA Medical Center.

A trained research staff member will obtain consent, and upon signing the document, the subject will be provided with a copy. Family members and/or caregivers are encouraged to accompany the study candidate through all processes of the informed consent. In addition to standardized screening tests and examinations, a custom questionnaire assessing patients' comprehension of our consent form and study is then administered (see Additional Documents). Candidates are required to get questions correct to indicate adequate comprehension to sign the study consent and to enter.

In keeping with the privacy requirements, a) social security numbers of subjects will only be asked for in person for required registry in the VA CPRS system, b) research staff will restrict contacts with subjects to the procedures and data elements outlined in the IRB approved protocol and c) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G. In addition, in case of patients who are veterans, guidelines put forth in the Department of Veterans Affairs memo dated 7/10/06 will be followed.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

(●) **Yes** ( ) No

4 * Describe who will obtain Informed Consent:

The PI or research team members who have been trained to obtain informed consent.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*

N/A

6 * Describe the setting for consent:

In a private interview or conference room in the VA Medical Healthcare System (VAMHCS), specifically the Baltimore VA Annex or Baltimore VA Medical Center.

7 * Describe the provisions for assessing participant understanding:

A brief questionnaire "Ability to Give Informed Consent" is administered after the consent process to verify that the participant understands key information given during the consent process.

8 * Describe the consideration for ongoing consent:

At each encounter for testing or training, the participant will be reminded of what the study asks them to do and whether they wish to continue with the protocol.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

HP-00060526 View: v2_Waiver/Alteration of Consent Process

Waiver or Alteration Consent Process

You indicated that a waiver/alteration of consent is requested.

1 * Explain why the research involves no more than minimal risks to the subjects:
This request for waiver of informed consent is for recruitment purposes only, as required by the VA for studies that also obtain a waiver of HIPAA authorization for recruitment purposes. We will view information to determine eligibility but no research procedures will be conducted until such time that the participant agrees to take part in the study and signs the informed consent document. The recruitment process involves no more than minimal risk to the individual.

2 * Explain why a waiver or alteration of the consent process would not adversely affect the rights and welfare of the subjects:
This waiver request is for recruitment purposes only as required by the VA. If it is determined that the individual would be eligible to take part in the study, they will be approached and given the opportunity to agree and sign the informed consent document or they can decline participation.

3 * Informed consent is always required unless there is reason to grant a waiver or alteration of the consent process. Explain why you cannot carry out the research unless you are granted a waiver or alteration of the consent process:
This waiver request is for recruitment purposes only as required by the VA. If it is determined that the individual would be eligible to take part in the study, they will be approached and given the opportunity to agree and sign the informed consent document or they can decline participation.

4 If the research involves using identifiable private information or identifiable biospecimens, please explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

5 In some cases there will be additional pertinent information during the study that should be given to the participating subjects. For those subjects who have not been given informed consent because there is a waiver or alteration of the consent process, explain how the subjects will receive this additional important information. If applicable, please explain why a subject would not receive additional pertinent information.
N/A. Individuals who would be eligible to take part in the study will be given the opportunity to agree and sign the informed consent document or to decline participation.

6 If you are requesting an alteration of the consent process please explain why this request is necessary for the conduct of the research study. Please identify specifically what is being altered or changed in the consent process.
N/A

ID: VIEW4E1C73B344800
Name: v2_Waiver/Alteration of Consent Process

HP-00060526

View: v2_Consent Forms - Draft

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
VA_ICF_Patient-Mod_24_clean.docx(0.01)	2/1/2019 12:15 PM	2/1/2019 12:15 PM
VA_ICF_Caregiver-Mod_24_trackedchanges.docx(0.01)	2/1/2019 12:15 PM	2/1/2019 12:15 PM
VA_ICF_Caregiver-Mod_24_clean.docx(0.01)	2/1/2019 12:15 PM	2/1/2019 12:15 PM
VA_ICF_Patient-Mod_24_trackedchanges.docx(0.01)	2/1/2019 12:15 PM	2/1/2019 12:15 PM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
VA_ICF_Patient-Mod_23_clean.docx(0.01)	1/15/2019 12:09 PM	1/15/2019 12:09 PM
VA_ICF_Caregiver-Mod_23_clean.docx(0.01)	1/15/2019 12:09 PM	1/15/2019 12:09 PM
VA_ICF_Patient-Mod_23_trackedchanges_SC.docx(0.02)	1/14/2019 12:20 PM	1/15/2019 12:09 PM
VA_ICF_Caregiver-Mod_23_trackedchanges.docx(0.02)	1/14/2019 12:20 PM	1/15/2019 12:08 PM
VA_ICF_Patient-tracked changes(0.02)	11/9/2018 11:34 AM	11/26/2018 1:03 PM
VA_ICF_Patient-clean(0.03)	11/9/2018 11:34 AM	11/26/2018 1:03 PM
VA_ICF_Caregiver_tracked changes(0.01)	11/9/2018 12:07 PM	11/9/2018 12:07 PM
VA_ICF_Caregiver_clean(0.01)	11/9/2018 12:06 PM	11/9/2018 12:06 PM
VA ICF-Patient(0.01)	10/17/2018 10:14 AM	10/17/2018 10:14 AM
VA ICF-Patient (Changes Tracked)(0.01)	10/17/2018 10:13 AM	10/17/2018 10:13 AM
VA ICF-Caregiver (Changes Tracked)(0.01)	10/16/2018 3:05 PM	10/16/2018 3:05 PM
VA ICF-Caregiver(0.01)	10/16/2018 3:04 PM	10/16/2018 3:04 PM

2 Upload any HIPAA authorization forms here:

VA_HIPPA(0.01)	2/5/2018 3:02 PM	2/5/2018 3:02 PM
VA_HIPAA_past version(0.03)	11/16/2015 10:15 AM	1/16/2018 1:02 PM

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates: http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

HP-00060526

View: v2_Organization Review Requirements (other than IRB)

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

Veterans Administration Hospital

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● **No**
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ○ Yes ● **No**

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ● **Yes** ○ No
* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ● **Yes** ○ No
* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ● **Yes** ○ No

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

HP-00060526 View: v2_Use of Non-Veterans

VA-Specific Criteria

1 * What is the relevance of this research to the mission of VA and the Veteran population that it serves*?

Reducing the burden of stroke is a priority for the Veterans Affairs (VA) Health System, reflected by the creation of the VA Stroke Quality Enhancement Research Initiative (QUERI). This group has shown that healthcare costs for Veterans after an acute ischemic stroke are 3.4 times greater than cost of average VA veteran healthcare. Due to the physical challenges after stroke, it is difficult for all potential Veteran candidates to participate here at the VA in our study. Therefore, we opened recruitment to the non-Veteran community to provide a meaningful representation of this population with stroke deficits. The enrollment of Veteran and non-Veteran participants will improve the relevance of this study to determine its efficacy and inform policy to advance the VA's commitment and mission to serving and advancing excellence in care for Veterans after stroke.

2 * Describe who will be enrolled in this study:

- ○ Non-veterans will be enrolled in this study
- ○ Only veterans will be enrolled in this study
- ● **Veterans and Non-veterans will be enrolled in this study**

2.1 * If non-veterans will be enrolled in this study, provide a description of non-veterans who will be enrolled (For example: community members, family members/caretakers of Veterans, clinicians/caregivers to Veterans, etc.):

Non-veteran community members, and family members/caretakers of veterans who meet study criteria will be enrolled in this study.

2.2 If non-veterans will be enrolled in this study, provide a substantive justification** for the enrollment of non-veterans in this research:

We make ongoing attempts to enroll veteran stroke survivors in our study. However, to achieve prescribled sample sizes for this research study, we anticipate the need to accept non-veterans as participants. Additionally, because the majority of veterans tend to be males, we often rely on recruiting non-veterans to achieve balance between genders.

2.3 * If this is a VA-funded study, was the use of non-veterans discussed within your merit award proposal?

- ● **Yes**
- ○ No
- ○ N/A

*

http://www.va.gov/about_va/mission.asp

VA Mission Statement
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.

VA Core Values
VA’s five core values underscore the obligations inherent in VA’s mission: Integrity, Commitment, Advocacy, Respect, and Excellence. The core values define “who we are,” our culture, and how we care for Veterans and eligible beneficiaries. Our values are more than just words – they affect outcomes in our daily interactions with Veterans and eligible beneficiaries and with each other. Taking the first letter of each word—Integrity, Commitment, Advocacy, Respect, Excellence—creates a powerful acronym, “I CARE,” that reminds each VA employee of the importance of their role in this Department. These core values come together as five promises we make as individuals and as an organization to those we serve.
Integrity: Act with high moral principle. Adhere to the highest professional standards. Maintain the trust and confidence of all with whom I engage.
Commitment: Work diligently to serve Veterans and other beneficiaries. Be driven by an earnest belief in VA’s mission. Fulfill my individual responsibilities and organizational responsibilities.
Advocacy: Be truly Veteran-centric by identifying, fully considering, and appropriately advancing the interests of Veterans and other beneficiaries.
Respect: Treat all those I serve and with whom I work with dignity and respect. Show respect to earn it.
Excellence: Strive for the highest quality and continuous improvement. Be thoughtful and decisive in leadership, accountable for my actions, willing to admit mistakes, and rigorous in correcting them.

**

a. Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment (38 CFR 17.45, 17.92), but only when there are insufficient Veteran patients suitable for the study. The investigator must justify including non-Veterans and the IRB must review the justification and provide specific approval for recruitment of non-Veterans.
b. Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans’ family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate.
---
e. Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigator.

[VHA Handbook 1200.05 §24]

ID: VIEW4E1C7A737E800
Name: v2_Use of Non-Veterans

HP-00060526 View: v2_VA Prohibited Research

VA Prohibited Research

1 * Is the research planned emergency research in subjects from whom consent can not be prospectively obtained?
○ Yes ● **No**

2 * Does the study involve children **AND** is greater than minimal risk?
○ Yes ● **No**

3 * Will recruitment phone calls involve asking veterans for their Social Security numbers?
○ Yes ● **No**

ID: VIEW4E1C8AF03A400
Name: v2_VA Prohibited Research

HP-00060526 View: v2_Additional VA

Additional VA

1 * For data that is combined, which site is the "Data Coordinating Center"?
VA

2 If VA data will be combined with non-VA data, describe when and how this will occur and where the combined data will be stored.
Upon enrollment of non-veteran participants and for medical clearance, we will seek a faxed copy of that participants medical record. This record is data that was generated by the participants primary care provider. That data will be combined with the participants VA research chart which is stored within the Baltimore VA Annex, RM 224, filing cabinets.

3 If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data collected? (This answer may overlap with Research Related Procedures. If so, please refer to that section.)
This data is collected via participants signed community medical release of information form. This release is faxed to the research participants PCP via VA Stream Print fax number: 410-209-8416. Upon receipt of the participants medical records (electronic form), that data is stored within the VA share drive rehab (\\oitbalfpcrsch02.v05.med.va.gov) and saved under the participants ID number in the TeleBATRAC share folder called faxing info.

4 If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data received and combined with the UM data?
The participants medical records are the only outside data being combined with VAMHCS data. No data will be transmitted and stored with UM.

5 If the UM is the Coordinating Center holding the "combined data", will you only use the combined data set while not on VA time or will you obtain approval from VA ORD/Regional Counsel to do this as an "off-site" VA Research activity.
NA

ID: VIEW8D5931EAC5B1E6E
Name: v2_Additional VA

HP-00060526 View: v2_VA Review Required

VA Maryland Health Care System Review Required

1

Note: Based on the answers provided in your submission, this protocol qualifies as a VA study. Therefore, VAMHCS Research &Development (R&D) Committee approval (in addition to IRB approval) is required prior to engaging in any research activities. **Importantly, you must submit the protocol to the VAMHCS Research Service within 60 days of IRB approval.**

**Details related to the VA submission and approval processes are best obtained by calling or visiting the Baltimore VA Research Office (Fred Ivey @ 410-605-7000 x6582). Despite not being able to submit at VA until after IRB approval is obtained, we strongly encourage immediate consultation with the VA R&D service, allowing time for early familiarization with VA requirements and VA Service clearance for your proposed work.

VA Research Service **Forms** can be accessed using the following link:

https://www.maryland.va.gov/research/human/human_subject_forms.asp

**In addition to the post-IRB VA approval process referenced above, there are also VA-specific items that must be addressed before IRB review. Failure to address the two VA components listed below will prevent your protocol from even receiving a full IRB review.

1. **VA information security and privacy Officer (ISO-PO) Approval:** This must happen before the IRB will move your protocol to full-board review. The ISO-PO approval process is initiated by submitting an ISO-PO checklist (accessible through the VA Forms link above) to the Baltimore VA Research Service. Personnel from the VA Research Office will then work to get the required approval signatures, ensuring that the signed ISO-PO checklist is uploaded as a public comment to your protocol's History Log. Again, your protocol CANNOT move forward to full IRB review without a fully signed ISO-PO checklist in the History Log, so getting that item submitted to the VA Research Service as quickly as possible should be a top priority.

2. **Specification of Research Activity Locations:** VA policy mandates that locations of all research activities (including data coordination, data analysis, and data storage) be clearly specified within appropriate sections of the CICERO protocol and the VA Informed Consent Document. Please ensure that locations of all research activities are clearly specified throughout these documents before submitting the protocol to IRB. This is particularly important for "VA Collaborative Studies" (i.e. those studies involving research activities that occur at both VA and non-VA sites). However, all studies, be they collaborative or not, should make clear delineation of research activity locations and data locations an emphasis.

2 **Questions answered on 'Organizational Review Requirements' page**:

The research will be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments):	**Yes**
The research will utilize VA resources (e.g. equipment, funds, medical records, databases, tissues, etc.):	**Yes**
The research will be conducted on VA property, including space leased to and used by VA:	**Yes**

Questions answered on 'VA Prohibited Research' page:

The research is planned emergency research in subjects from whom consent can not be prospectively obtained:	**No**
The study involves fetuses:	**No**
The study involves in vitro fertilization:	**No**
The research involves work with embryonic stem cells:	**No**
The study involves children AND is greater than minimal risk:	**No**
Recruitment phone calls involve asking veterans for their Social Security numbers:	**No**

If the answers to these questions are wrong, use the Jump To menu to return to the 'Organization Review Requirements' page to change your answers.

3 * **Confirm** - You have read the above information and understand that in addition to this IRB application form (CICERO), you are required to send a submission to the VAMHCS R&D Committee **within 60 days of receiving IRB approval**.

● **Yes** ○ No

ID: VIEW4E1C8F0D7B000
Name: v2_VA Review Required

HP-00060526 View: v2_Summary of Required Reviews (other than IRB)

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	Review Status
Neu Multiple Sclerosis	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

HP-00060526 View: v2_Additional Documents

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
HP-00060526-Mod23-PO_and_ISSO_signed_checklist.pdf(0.01)	1/25/2019 4:15 PM	1/25/2019 4:15 PM
TeleBATRAC_Study_Flowsheet_MHV-20190115.docx(0.02)	12/17/2018 12:19 PM	1/15/2019 2:35 PM
New Informed Consent and HIPAA Quality Checklist - Revised 11.5.2018(0.01)	11/28/2018 2:16 PM	11/28/2018 2:16 PM
16.07.20 I-SMB policy.doc(0.01)	10/15/2018 9:48 AM	10/15/2018 9:48 AM
FINAL MINTUES MERCE Safety Monitoring Board Meeting MINUTES Nov 2017(0.01)	3/5/2018 3:34 PM	3/5/2018 3:34 PM
VA_ISO_PO_Checklist.pdf(0.01)	1/26/2018 12:19 PM	1/26/2018 12:19 PM
VA_ISO_PO_Checklist_edits.docx(0.01)	1/23/2018 3:32 PM	1/23/2018 3:32 PM
MyHealteVet_Forgot User ID Info(0.01)	5/2/2017 8:18 AM	5/2/2017 8:18 AM
MyHealtheVet Patient Handbook(0.01)	5/2/2017 8:16 AM	5/2/2017 8:16 AM
KinArm_ISO_Certificate(0.01)	3/28/2017 8:10 AM	3/28/2017 8:10 AM
KinArm Robot_User Guide(0.01)	3/24/2017 2:14 PM	3/24/2017 2:14 PM
Response_MRSA_Jan.2016(0.01)	1/26/2016 11:49 AM	1/26/2016 11:49 AM
Evaluation to Sign the Informed Consent(0.03)	12/11/2015 2:08 PM	12/15/2015 1:19 PM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

HP-00060526 View: v2_Final Page of Application

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
Neu Multiple Sclerosis	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

HP-00060526

View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Michael Dimyan

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Please add Michael Dimyan as a backup study clinical provider to Christopher Bever. He will perform any medical evaluations that Chris Bever cannot cover. This addition to our team will provide more scheduling flexibility.

Mr. Dimyan is an Assistant Professor in the Department of Neurology, Division of Rehabilitation Adjunct Assistant Professor, Department of Physical Therapy and Rehabilitation Science University of Maryland School of Medicine Staff Neurologist, VA Maryland Health Care system. He is currently PI on multiple NIH/NINDS and a VA R&D funded studies.

HP-00060526 View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Linda Horn

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Horn is a physical therapist and assistant professor at the University of Maryland Department of Physical Therapy and Rehabilitation Science. She has experience in clinical trials and is accomplished in teaching and performing upper extremity evaluations

HP-00060526 View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Min Zhan

2 Research Role:
Statistician

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Min Zhan has 15 plus years' experience providing statistical support for human research studies.

HP-00060526 View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Erica Cikanek

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Ms. Cikanek will complete chart reviews, including data entry and data verification. She has extensive experience in VA policies and procedures and has received human research and study-specific training.

HP-00060526 View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Linda Keldsen

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Ms. Keldsen has 32 years of nursing experience and is a current 3rd year PhD student at UM focusing on the use of health information technology. Ms. Keldsen's research rotations have focused on the use of patient portals, secure messaging and education tools to enhance patient outcomes. She has six years of experience working with the VA MyHealtheVet patient portal and is the current program manager. In this role, she routinely teaches patients how to access and use the features of the MHV patient portal: establishing an account, setting up and sending secure messages and troubleshooting issues arising from their use of the patient portal and secure messaging. She a subject matter expert for the VA medical staff and assisting with issues related to panel management, misdirected messages and other concerns related to secure messaging. She is also adept at pulling data from the My HealtheVet administrative portal and the VHA Support Service Center (VSSC) Reports.

HP-00060526 View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Steven Berger

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Steven Berger is a medical student at the University of Maryland School of Medicine who is pursuing research as part of his academic program.

HP-00060526 View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Christopher Bever

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Wording TBD