Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

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

Principal Investigator: ***Susan Conroy, PT, DSc.PT 410-637-3213***
VA Facility: ***Baltimore (512)***

STUDY No: HP-00060526: PATIENT CONSENT FORM

SPONSOR: VA Rehabilitation Research and Development

You are invited to participate in a research study. This study, called TeleBATRAC, is investigating a home arm exercise program using the Internet. If you are eligible and wish to participate, please note that you are a volunteer and may ask questions at any time. The research will take place at the VA Maryland Health Care System (VAMHCS), conducted by VAMHCS researchers and staff at the Baltimore VA Annex located on 209 West Fayette Street, Baltimore, MD 21201, and at VA-leased space at the University of Maryland Allied Health Building, 100 Penn Street, Baltimore, MD 21201.

PURPOSE OF STUDY:

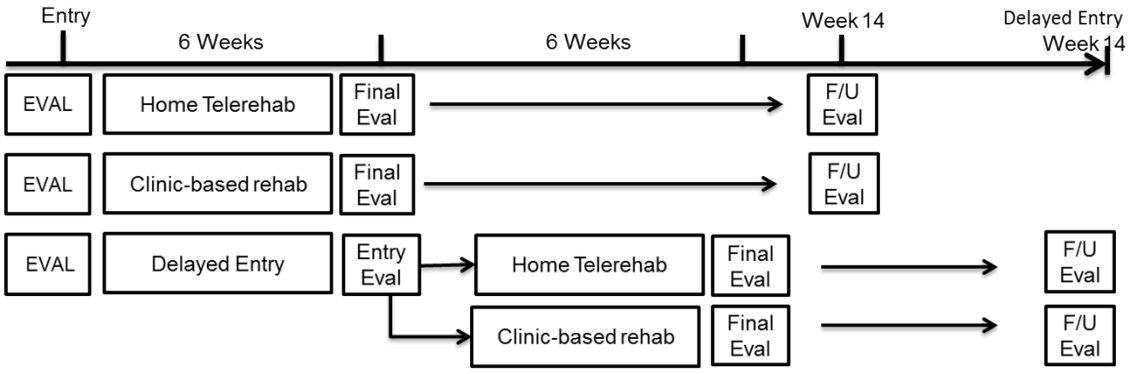
Stroke rehabilitation studies investigating recovery of arm use with a specific portable repetitive exercise device called the Bilateral Arm Training with Rhythmic Auditory Cueing (BATRAC) have shown to benefit people several months after stroke. The purpose of this study is to determine if a home program using the BATRAC can be successfully combined with traditional exercise and the VA's MyHealth*e*Vet website for remote "telerehabilitation" of arm weakness after stroke. The MyHealth*e*Vet website will allow for exercise video access and secure messaging to a therapist. We will compare this home-based telerehabilitation exercise program to the same exercise provided here at the VA and to a group that does not exercise for the first 6 weeks of the study. The BATRAC is available in the marketplace as an FDA-approved exercise device called the "Tailwind." It was developed and studied with patients with stroke at the University of Maryland and is NOT an investigational device.

You may qualify for this study if you had a stroke at least 6 months ago and continue to have weakness in your arm. You also have an identified person (caregiver) that will assist with your exercise program, if needed. The VAMHCS will be the primary location for this study, and you will be one of 98 participants asked to take part.

PROCEDURES:

This is a single blind randomized controlled trial. This means our study evaluator will not know, and will be "blinded," to your exercise group assignment and cannot be told which treatment you are getting. However, you, the therapist, and the study doctor will know. Please be aware that this study requires a large amount of time and effort. If you agree to participate, you may be asked to make about 24 visits to the VA. This entire study will take about 5–7 months.

There are three exercise groups assigned at random. This means the group you get will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what treatment you get. There are three exercise groups you can be randomly assigned to: (1) a home-based telerehabilitation group, (2) a clinic-based rehabilitation group, or (3) a delayed-entry group. The first two groups will start training immediately after the consent and baseline process. The delayed-entry group will wait 6 weeks before starting their randomly assigned exercise training. The figure below shows how the study will be conducted.



If you agree to participate in this study, you will receive baseline evaluations for the first month (4 weeks), followed by either 6 weeks of your randomized exercise or 6 weeks of weekly phone calls if you are initially assigned to the delay group. Home-based telerehabilitation and clinic-based rehabilitation will include exercise sessions 3 times /week for a total of 18 training sessions. This training will be spread over a maximum of 9 weeks, to allow for missed visits due

to transportation/weather or minor illness. You will be asked to return for a follow-up after 8 weeks of no training. Please note that if you are initially randomized to the delayed entry group, you will have a slightly longer maximum study commitment: 4 weeks of baseline + 6 weeks of delay + max. 9 weeks of intervention + 8 weeks of retention = 27 weeks.

The research related procedures performed include:

- 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 related to your stroke. A depression survey called the Center for Epidemiologic Studies Depression Scale, and a cognitive screening called the Montreal Cognitive Assessment will also be conducted at this time. The doctor will promptly notify you and refer you to a specialist if your depression or cognitive test indicate need for concern. This evaluation should take approximately 30–40 minutes.

- Robotic Evaluation of Arm Function: The KinArm robot is an arm robot specifically designed to test motor skill and coordination of both your arms at the same time. It will be used to evaluate your arm function. This evaluation will occur once at the start of the study, and once at the end of the study by a trained study staff member. This VA-owned robot is located at VA-leased space at the University of Maryland Allied Health Building.

- Non-robotic Evaluations of Arm Function and Use: **These will be performed at the VA by an evaluator that is not supposed to know your treatment assignment.** Each evaluation visit will take approximately 90 minutes to complete. You will need to attend three baseline visits with him/her approximately one week apart in the first month. You will also need to be seen by this evaluator at a final evaluation visit (on Week 6–9), and after an 8-week time period of no training (at a visit called the retention evaluation visit).

- Questionnaires and surveys about your activity, arm use, self-efficacy, satisfaction, and learning.

The specific non-robotic research evaluations are as follows:

- Wolf Motor Function Test: This includes 15 timed arm/hand tasks and two strength activities designed to measure the capabilities of your stroke-affected arm. Time to administer this test is approximately 25 minutes.

- Fugl-Meyer Upper Extremity Motor Performance: This is an examination of your ability to move your arm and hand for specific tests including reflexes, sensation, and movement quality. Time to administer this test is approximately 25 minutes.

- The Action Research Arm Test is an evaluation of your ability to handle objects and complete gross and fine-motor tasks with your left or right hand. Time to administer is 7–10 minutes.

- Stroke Impact Scale (Questionnaire): This is a structured interview consisting of 50 questions about your physical activity, activities of daily living, mobility, and hand function after your stroke. Time to administer is approximately 10 minutes.

- Motor Activity Log-28 (Questionnaire): This is a structured interview about the quality and amount of arm movement you have throughout your day. It includes activities ranging from eating to dressing to housework. This interview will be conducted with you and with your designated caregiver. Time to administer is approximately 15 minutes.

- Strength: Strength grip will be tested using a force-measuring device called a dynamometer, and manual muscle testing of the upper extremity. Time to administer is approximately 10 minutes.

Questionnaires and surveys include:

- Telerehabilitation Satisfaction Survey (for the home-based telerehabilitation group, and the clinic-based group): This is a 12- to 17-question survey of participant satisfaction with the intervention. It includes questions related to ease of use, and general satisfaction. Time to administer is approximately 5–10 minutes.

- Self-efficacy questionnaires about your exercise expectations and barriers to exercise: Time to administer the two questionnaires is approximately 10 minutes.

- Home Activity Questionnaire (for the delayed-entry group only): This is a 10-question survey of activities completed in the past week using your stroke-affected arm, also to

record general household activities and community outings. Time to administer is approximately 5 minutes.

MyHealth*e*Vet (for the home-based telerehabilitation group only):

For the home-based telerehabilitation group, secure messages are exchanged as part of the study over the VA's MyHealth*e*Vet website to communicate treatment activities and recommendations between you and the study team. You will receive training and education in how to register and use the system by the study team if randomized to this group. This will take approximately 15 minutes.

If you are randomized to the home-based telerehabilitation group, you also will have the **option** to videoconference with the study team via the VA's "VA Video Connect" app. VA Video Connect 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. You can learn more about VA Video Connect at https://mobile.va.gov/app/va-video-connect. If you choose to use this app, you will receive training and education on how to use it. This training will take approximately 5 to 10 minutes.

Please check the box below indicating whether or not you choose to communicate with the study team via VA Video Connect.

_____ Yes, I agree to communicate with the study team via the VA's "VA Video Connect" app—in addition to the VA's MyHealth*e*Vet website—if I am randomized to the home-based telerehabilitation group. I understand this is an **optional** part of the study, and using this app has no bearing on my enrollment or randomization in this study. I also understand that I may withdraw consent to participate in this aspect of the study at any time.

_____ No, I am not interested in communicating with the study team via the VA's "VA Video Connect" app if I am randomized to the home-based telerehabilitation group. I understand that refusing this option has no bearing on my enrollment or randomization in this study.

Subject Initials _____ Date_____

Home Activity Monitoring with Accelerometers:

Accelerometers are portable sensors that can be worn on your wrist to record your arm activity. We will ask you to wear these watch band-type devices for approximately 4 days at the start of the study, and then again at the end of the study. This information will complement the questionnaires and further add to the understanding of the level of your arm activity after a stroke.

FUTURE RESEARCH:

After completing this study, you may be eligible to participate in future IRB-approved research projects for persons who have had a stroke. Please check the box below indicating whether or not you agree to be contacted for future research studies. Even if you agree to be re-contacted now, you may still change your mind about this in the future.

_____ Yes, I may be re-contacted to learn about future research studies.

_____ No, I may not be re-contacted to receive this information

Subject Initials _____ Date_____

[OPTIONAL] MyHealth*e*Vet SECURE MESSAGING PILOT AND QUALITATIVE STUDY:

The VA Maryland Health Care System (VAMHCS) would like to gather information about the use of MyHealth*e*Vet (MHV) secure messaging for research communication in the TeleBATRAC main study. Secure messaging is used clinically at the VA for patient and provider communication, but it has not been fully evaluated for research communication.

You have the **option** of participating in the MyHealth*e*Vet Secure Messaging Pilot and Qualitative Study. If you are interested in participating, and if you are randomized to the home telerehabilitation group or the delayed entry group in the primary study, you will be asked to complete additional questionnaires at the beginning and end of the study. These questionnaires

will add an additional 30 minutes to your pre- and post-study assessments and include the eHealth Literacy Scale, Web-Based Learning Self-Efficacy Scale, and Montreal Cognitive Assessment, as well as a brief MyHealth*e*Vet interview. At the end of the study, you will be asked to complete a brief background questionnaire about your previous experience with the MyHealth*e*Vet patient portal and a one-hour face-to-face interview. **This data collection is optional, and you can opt to participate or refuse. Your participation in this pilot study does not affect your participation in the primary study.**

Questionnaires and interviews for the MyHealth*e*Vet Secure Messaging Pilot and Qualitative Study are as follows:

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 MyHealth*e*Vet 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 onset of the study and again at the end of the study. It should take approximately 5 minutes to complete.

3. Background Questionnaire: This is an 8- to 12- item questionnaire used to gather your prior experience with the MyHealth*e*Vet patient portal and its tools prior to participating in this pilot study. It should take approximately 5 minutes to complete.

4. Interview: The MyHealth*e*Vet interview 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. An additional one-hour interview at the end of the study will focus on your overall experiences and perspectives on MyHealth*e*Vet use.

RISKS:

- The MyHealth*e*Vet Secure Messaging Pilot and Qualitative Study has a risk of frustration and/or irritation with completing the questionnaires and interviews. You can skip any question that you find uncomfortable.
- 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.

Please check the box below indicating whether or not you agree to participate in these additional activities for the MyHealth*e*Vet Secure Messaging Pilot and Qualitative Study.

_____ Yes, I agree to participate in the MyHealth*e*Vet Secure Messaging Pilot and Qualitative Study. I understand this is an **optional** part of the study and enrolling has no bearing on enrollment or randomization. I agree to complete additional questionnaires and an interview. I also understand that the study team will make every effort to coordinate the MyHealth*e*Vet Secure Messaging Pilot and Qualitative Study appointments with the primary study appointments to avoid undue travel. I also understand that I may withdraw consent to participate in this aspect of the study at any time.

_____ No, I am not interested in participating in the MyHealth*e*Vet Secure Messaging Pilot and Qualitative Study. I understand that refusing this option has no bearing on enrollment or randomization in the primary study.

Subject Initials _____ Date:_____

[OPTIONAL] RETURNING STUDY PARTICIPANTS—QUALITATIVE STUDY OF FOUR FEATURES OF THE MyHealth*e*Vet SECURE MESSAGING PILOT:

You have indicated a willingness to be notified about additional research studies. The VA Maryland Health Care System (VAMHCS) would like to gather information about your experience and perspective using four features of the MyHealth*e*Vet personal health record

during your previous participation in the MyHealth*e*Vet secure messaging pilot. Your experience and perspective could have important ramifications on the design and implementation of future studies using this communication technology for home-based telerehabilitation. This area of research has not been previously addressed, and your experience will provide valuable insight into the use of information communication technology in telerehabilitation research.

You have the **option** of participating in the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot. To participate in this Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot, you must have (1) been randomized to either (A) the home-based telerehabilitation group or (B) the delayed entry group, and (2) agreed to be contacted about participation in other research studies following your participation in the primary study. If you are interested in participating, you will be asked to complete an 8- to 12-item questionnaire, and to participate in a one-hour face-to-face interview. **This data collection is optional, and you can opt to participate or refuse. Your participation in this pilot study does not affect your participation in the primary study.**

RISKS:

- The Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot has a risk of frustration and/or irritation with completing the questionnaires and interviews. You can skip any question that you find uncomfortable.
- 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.

Please check the box below indicating whether or not you agree to participate in these additional activities for the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot.

_____ Yes, I agree to participate in the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot. I agree to complete a questionnaire and a one-hour face-to-face interview. I also understand that the study team will make every effort to coordinate the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot appointments with regularly-scheduled VA appointments or at a time convenient for me to avoid undue travel.

I also understand that I may withdraw consent to participate in this aspect of the study at any time.

_____ No, I am not interested in participating in the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot. I understand that refusing this option has no bearing on my prior participation in the parent study.

_____ N/A, I am not a returning study participant, so this section about the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot does not apply to me.

Subject Initials _____ Date:_____

[OPTIONAL] MyHealth*e*Vet TRIAGE TEAM MEMBERS—QUALITATIVE STUDY OF FOUR FEATURES OF THE MyHealth*e*Vet SECURE MESSAGING PILOT:

The VA Maryland Health Care System (VAMHCS) would like to gather information about your experience and perspective using four features of the My Health*e*Vet personal health record in the MyHealth*e*Vet Secure Messaging Pilot. Your experience and perspective could have important ramifications on the design and implementation of future studies using this communication technology for home-based telerehabilitation. This area of research has not been previously addressed, and your experience will provide valuable insight into the use of information communication technology in telerehabilitation research.

If you are interested in participating, you will be asked to complete an 8- to 12-item background questionnaire about your prior use of the MyHealth*e*Vet patient portal, and to participate in a one-hour face-to-face interview. **This data collection is optional, and if you are an employee or student, 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**.

RISKS:

- The Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot has a risk of frustration and/or irritation with completing the questionnaires and interviews. You can skip any question that you find uncomfortable.
- 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.

Please check the box below indicating whether or not you agree to participate in these activities for the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot.

_____ Yes, I agree to participate in the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot. I agree to complete a questionnaire and a one-hour face-to-face interview. I understand that I may withdraw consent to participate in this study at any time.

_____ No, I am not interested in participating in the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot.

_____ N/A, I am not a MyHealth*e*Vet triage team member, so this section about the Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot does not apply to me.

Subject Initials: _____ Date:_____

[OPTIONAL] MyHealth*e*Vet TRIAGE TEAM MEMBERS—FOCUS GROUP:

If you are interested in participating, you will be asked to complete an 8- to 12-item background questionnaire about your prior use of the MyHealth*e*Vet patient portal (unless already completed), and to participate in a one-hour focus group to elicit observations and experiences that may only come to light as a result of the sharing of experiences in an open forum. **This data collection is optional, and if you are an employee or student, 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**.

Participant Name: _____ Date:_____

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

Principal Investigator: ***Susan Conroy, PT, DSc.PT 410-637-3213***
VA Facility: ***Baltimore (512)***

RISKS:

- The Optional Focus Group Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot has a risk of frustration and/or irritation with completing a focus group, and you may only participate to the degree that you feel comfortable. There is also a risk of inconvenience and interruption to your schedule.
- 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.
- Anonymity cannot be assured if all MyHealth*e*Vet triage team members elect to participate in a focus group. The members will be aware of the statements attributed to each other. Use of any statements made in the group will be deidentified if later used as part of a publication for research, and, if possible, will be used in such a way that comments represent a conclusion rather than direct attributions.

Please check the box below indicating whether or not you agree to participate in these activities for the Optional Focus Group Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot.

_____ Yes, I agree to participate in the Optional Focus Group Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot. I understand that I may withdraw consent to participate in this aspect of the study at any time.

_____ No, I am not interested in participating in the Optional Focus Group Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot.

_____ N/A, I am not a MyHealth*e*Vet triage team member, so this section about the Optional Focus Group Qualitative Study of Four Features of the MyHealth*e*Vet Secure Messaging Pilot does not apply to me.

Subject Initials _____ Date:_____

Participant Name: _____ Date:_____

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

Principal Investigator: ***Susan Conroy, PT, DSc.PT 410-637-3213***
VA Facility: ***Baltimore (512)***

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to:

- Keep study appointments and notify the study team if you need to reschedule.
- Discontinue any current arm exercise programs you are participating in to avoid any potential interference of your activities with the study results.
- Notify us of any emergent medical problems that will affect continuing with the training or overall study.
- Notify us if you become pregnant over the course of the study.

POTENTIAL RISKS/DISCOMFORTS:

There are no major risks or discomforts that you are likely to experience as a participant in this research. Additionally, pregnancy will not affect the ability to use the device, increase risk, or affect the scientific design. Below are some potential minor risks or discomforts that may occur:

1. There is a small risk of muscle strain or pull in the assessment of strength and coordination. You will be instructed to perform within your 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. You will be informed that you can skip any question that is uncomfortable.

4. Training involves repetitive arm motions which may cause muscle soreness, and joint irritation to your shoulder and elbow. This is a relatively rare occurrence, and is more likely in the early stages of training when you are unused to the exercise. The risk is reduced by providing regular opportunities to rest within the training protocol. You will be asked about joint and muscular pain after each session and told to rest the affected area and report back if pain persists. Therapy sessions will be suspended if pain worsens, and you will be asked to seek a medical evaluation before resuming research activities.

5. There is a small risk that your privacy/confidentiality may be compromised. There is a potential risk to your confidentiality related to the use of MyHealth*e*Vet secure messaging. Secure messages are electronically stamped by the VA system and include your name, date of birth, and last four digits of your 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 your identifiable information. Several procedures are in place to minimize this risk. All research activities will be conducted in a private setting. 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 PI's office. Only the PI and research team will have access to this information on an as-needed basis. Only these research codes will be used for data collection and training records. Electronic data, including digital video and secure messages, will be password-protected and kept within the VA firewall in approved computers and servers. There are no foreseeable psychological, social, or legal risks for this study.

6. There may be risks in this study which are not yet known.

POTENTIAL BENEFITS:

- You may or may not benefit from taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study.
- A potential benefit oy your participation is the development of a new home telerehabilitation program for survivors of stroke.
- There is a potential benefit in defining those who can successfully use this new telerehabilitation approach after stroke.

ALTERNATIVES TO PARTICIPATION:

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at the VA Maryland Health Care System (VAMHCS) will not be affected.

COSTS TO PARTICIPANTS:

It will not cost you anything to take part in this study. You will not be charged for any treatments or procedures that are performed for research purposes in this study. If you usually pay co-

payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

PAYMENT TO PARTICIPANTS:
You will be reimbursed $10 for each study visit completed at the VA. In the event you do not complete the study, you will receive $10 per session attended to be paid on the last day of your participation. You will receive a voucher from the study team at the Baltimore VA Annex to be redeemed at the Baltimore VA Medical Center cashier's office at 10 North Greene Street, Baltimore, MD 21201 as follows:

- BASELINE: At the completion of the entire baseline testing phase, a voucher for your consent and baseline evaluation visits 1–4 and robot evaluation visit 5 will be distributed in the amount of $50.

- TRAINING:
  A) If you are randomized to the clinic-based rehabilitation group, you will receive additional vouchers for travel to/from the VA for intervention visits 1–18. This voucher will be issued at the final training evaluation visit in the amount of $180 if all appointments are kept.
  B) If you are randomized to the home-based telerehabilitation group, you will NOT NEED TO TRAVEL to the VA for your exercise visits, so you will NOT be reimbursed for sessions 1–18.

- EVALUATION: At the retention visit, a voucher for the final arm and robot evaluation visits, and for the retention arm evaluation visits will be given in the amount of $30.

In summary, if you are immediately enrolled in the clinic-based group and keep all your appointments, you will receive $260. If you are immediately enrolled in the home-based group and keep all your evaluation visits, you will receive $80. If you are in the delayed intervention group, you will receive payment for the intervention described above after the delay, and one additional evaluation reimbursement of $10 for your delayed retention evaluation.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY:

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA Maryland Health Care System (VAMHCS) will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY OR AFTER HOURS:
Dr. Christopher Bever, Jr. at 202-443-5734

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS:

- The study will involve use of confidential information. Study personnel will have access to the information, and it will be coded to protect your identity. The investigators will use the codes with all research data in electronic format (including any digital video), and all other files with confidential information will be stored in locked file cabinets within locked office or lab space at the VA Annex. Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.
- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research." However, if your information is disclosed to other entities, the VAMHCS no longer has

control of that information. Please see the HIPAA Authorization for this study for further details.

- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. The Veterans Health Administration (VHA) and its Offices may inspect your research records. Your research records will be stored in a locked file cabinet at the VA Maryland Health Care System (VAMHCS) Annex.
- We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the VAMHCS Office of Research Compliance and other representatives of this organization including the VA Office of Research & Development (ORD), VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP).
- Study monitors, auditors, and the IRB will be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access**.**

If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

RIGHT TO WITHDRAW:
Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, **Susan Conroy, PT, DSc.PT at 410-637-3213.**

- There are no adverse consequences (physical, social, economic, legal, or psychological) of your decision to withdraw from the research.

- If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.
- You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff, or if the principal investigator decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is, in fact, IRB-approved and is being conducted at the VAMHCS, you may contact Susan Conroy, PT, DSc.PT at 410-637-3213 or the study recruitment line at 443-206-3304. Additional information can be found at the ClinicalTrials.gov website (www.clinicaltrials.gov).

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland Baltimore. The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the UMB Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Office of Academic Affairs Regulatory Compliance
Human Research Protections Office
620 West Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Human and Animal Research Protections Officer (HARPO)**.** The contact information for the HARPO is:

VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56582
Room 3D-158

The VAMHCS Human and Animal Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

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

Principal Investigator: ***Susan Conroy, PT, DSc.PT 410-637-3213***
VA Facility: ***Baltimore (512)***

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____