Complete Research Protocol (HRP-503)

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Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 19, 20, 22, 23, 24, 25, 31, and 32 do not apply.*
    - *For exempt research: Sections 31 and 32 do not apply.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response:

Intervention Group:

Control Group:

Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

A Functional Upper Limb Training and Assessment Tool to Enhance Efficacy and Scalability of Rehabilitation in Ecological Environments

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

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Rehabilitation Sciences

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VERSION:

Include the version date or number.

Response:June 14, 2019

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response:

This protocol is funded by NIH grant 1 R21 HD09224301

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

Location: PI's office in a locking cabinet

Address: 522 Kimball Tower

Department: Rehabilitation Science

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research.

Response:

Our overarching goal is to develop novel portable technology, affordable for home use and capable of quantifying quality of movement with the purpose of providing to provide objective feedback on performance

of upper limb motor tasks to individuals with residual deficits following chronic conditions such as stroke. We assert that smartphones combined with 3 dimensional printed objects can be used to create rehabilitation and assessment to that may be used in home environments. This creates a home-rehabilitation system that will promote self-management of upper limb rehabilitation efforts across the lifespan in chronic conditions such as stroke.

Aim 1: Develop and validate a novel in-home rehabilitation system using 3D printing technologies, smart devices and machine learning algorithms.

Aim 2: Examine performance changes in trained ADLs when augmenting 3D printed objects with smart technology to provide quantitative feedback on performance.

1.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response:

Aim 1 hypothesis- Smartphone measurements provide a valid assessment of upper limb kinematics

Aim 2 hypothesis: We hypothesize that characteristics of performance including time to complete the task and normalized jerk score (smoothness/quality of movement) will improve with this home based training

2.0 Scientific Endpoints

2.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response:

Aim 1- *We will validate that data from a smartphone can be modeled to accurately identify human performance including task events, movement status detection, and performance-quality evaluation.*

Aim 2- We will examine kinematics of movement as well as time to completion of defined acts of daily living.

2.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response: Significance: Developing portable technology, affordable for home use, capable of quantifying quality of movement and providing user feedback on motor performance is significant as it advances the present standard of care in home-based rehabilitation for millions of individuals with motor deficits (1-4). The population in the US is aging, (5) and with increased age there is diminished motor control (6-9) in addition to higher risk for neurological insult such as stroke (10). Over 700,000 new cases of stroke occur each year (11,12). This number is projected to increase with the aging of the baby boomer generation. Rehabilitation services aimed at reducing limitation and improving functional mobility often focus on the early stages of recovery with specialized inpatient rehabilitation units for stroke (13). Despite evidence that improvements can still be made several years post stroke (14) rehabilitation options in chronic stages of stroke are not well established. Only 10-15% of stroke survivors had a follow-up with a physical therapist one year after their stroke (15) Written home exercise programs are commonly prescribed at the end of formal therapies. However, as practice is a key component to improvement (16), participation is imperative for a home exercise program to lead to motor performance benefits (17). Regaining as much upper limb function as possible is important, as even mild impairments are associated with limitations in daily function and lower health-related quality of life (18). Hence, developing approaches to better support clients with their home program is important. The proposed portable measurement system will have the potential to promote participation and refine practice by providing them with feedback.

Creating automated systems that measure and give feedback on quality of movement will promote a more proactive approach to maximizing function across the lifespan of individuals with chronic conditions. With a robust body of research underscoring the importance of practice, (19-22) providing adequate practice in rehabilitation across the lifespan is central to efficacious interventions (19,23). Providing feedback can promote participation, refine practice and give individuals a better understanding of their abilities to then set goals for themselves (17,24,25) As demonstrated by previous research, exercise programs that include feedback from a

person through a home visit, telephone call or clinic appointment have resulted in better outcomes compared to programs without feedback (17,25) This feedback informs the participant of their progress to more specifically direct their rehabilitation efforts and potentially motivate them to continue. Feedback can encourage better self-management of ongoing rehabilitation. Herein it is proposed that coupling three-dimensional (3D) printing with smart technology provides a scalable option to provide feedback in long-term rehabilitation. Embedding smartphones in 3D printed objects tailored to the individual's mobility needs harnesses the sensors and networking functions of smartphones to quantify quality of movement and provide timely feedback to the user. This offers a vast improvement compared to the typical written home program issued at discharge. With a static written home exercise program, patients have a limited capacity to evaluate their motor performance and no encouragement to refine their movement. As individuals with motor deficits following neurological insult are able to make improvements beyond the acute phase, (16,21,26) it is necessary to provide better options for home rehabilitation.

Preliminary Work and Pilot Data: Focus groups held with individuals with stroke and local clinicians substantiate the need for better long-term options to promote home-based therapeutic practice. Individuals with stroke have positive comments when assessing this system: "I could see what I had to do to improve the graphs… after a couple of times I could see what worked and what didn't… I would use this, I don't know that I would call it fun, but it makes it interesting to do rather than sitting with an inanimate object like clay or an elastic strap". Clinicians echo the need to engage individuals in rehabilitation in chronic stages of stroke. While time measurements are commonly provided as feedback to participants in clinical settings, this metric does not provide the user with information on quality of movement. With the portable devices, we can calculate a normalized jerk score, which is dimensionless, allowing comparisons of movements that vary in duration and/or amplitude (27,28) In a small sample of young and older adults as well as individuals with stroke we examined normalized cumulative jerk. In three separate tasks young adults show minimal variability in performance compared to older adults and individuals with stroke. In addition, young adults demonstrate minimal variability across repetitions while individuals with stroke demonstrate a greater change across trials (29). Interestingly, when individuals with stroke are familiarized with the concept of smoothness, they are able to decrease their normalized jerk score. Recording normalized jerk over time and across activities is a promising way to assess change in impairment (30-33) and has been used to demonstrate change in motor performance pre/postinterventions. An extended record of this assessment via a portable measuring device would provide information to the individual with stroke and healthcare providers.

2.2 Include complete citations or references.

1. Response: Roger, V. L., Go, A. S., Lloyd-Jones, D. M., Benjamin, E. J., Berry, J. D., Borden, W. B., . . . Stroke Stat, S. Heart Disease and Stroke Statistics-2012 Update A Report From the American Heart Association. Circulation 125, E2-E220, doi:10.1161/CIR.0b013e31823ac046 (2012).

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3.0 Study Design

3.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response:

Aim 1: Develop and validate a novel in-home rehabilitation system using 3D printing technologies, smart devices and machine learning algorithms.

Part 1.1 Augment Smart Devices for Rehabilitation Use Through 3D Printing:

The instrumented physical devices offer customization of on-demand functional objects enhanced by 3D printing augmentation and smart devices properly located for sensing movement and

providing feedback. 3D printed objects can be personalized and adaptive to individual needs. Such design philosophy enables users with specific conditions (e.g., hand size, diminished strength) to experience fewer obstacles and achieve better outcomes. For example, a 3D printed mug design is flexible in handle size, body design, weight, and inside design. As shown in Fig. 5a, multiple slots were designed inside the mug to arrange for different types of smartphones. The same methodology is applied to augment smartphones into other functional rehabilitation objects, such as bowls and keys. Our team has considerable experiences on 3D printing design and fabrication.

Part 1.2 Develop a Smartphone App for Analyzing Sensors Data and Providing User Feedback

Sensor Data Analysis: The kinematic computation engine is implemented in the embedded smartphone, which primarily focuses on sensor data analysis and user feedback realization. In sensor data analysis, the collected acceleration and angular velocity data from a smartphone are used for task events counting (e.g. repetition, time), status detection (still/moving), and performance-quality evaluation (kinematic features extraction). The core part of the computation engine is a robust algorithm to detect and classify the occurrence of task events. To this end, we propose an occurrence-detection method to identify, index and classify the sensor patterns of task events. First, we will investigate a new presentation

method to characterize cross-channel sensor data. We can form a set of signal shape primitives to represent three channel signals. Then we can build the interval coincidence graph, representing the primitives in the motion sensor signal recordings. The thickness of edges shows higher coincidence between the primitives. Primitives with high coincidence are clustered. Our team has preliminarily evaluated this approach on human activity monitoring application. In addition, other existing machine learning methods will be compared with proposed approach for exercise activity recognition.

User Feedback Interface: The sensor data analysis results serve as the source of user feedback. Our focus groups and pilot data demonstrate user feedback is important in rehabilitation it motivates participation and encourages better self-management of the rehabilitation program. User

feedback in our system has two categories including instant user feedback and post-training feedback. Instant feedback is primarily acoustic and/or visual. For example, when a user is pouring water from a cup, the sound of water flowing will vary in different stages of pouring, providing an immersive experience for rehabilitation. Feedback such as applause, fireworks sound, or smiling faces are designed as rewards for achieving preset goals or reaching milestones. Post-training feedback emphasizes quantitative performance measurements at the end of the task training.

Measurements include time to complete the task, normalized jerk score, total path length, and number of repetitions. We have developed an App on a smartphone to visualize the statistical results, and users can see their rehab performance across multiple trials. We adopted a two-layer feedback report design including a basic report and detailed report. Users are provided with a basic report with the performance trend graphed. If the user clicks on a specific trial, then the detailed report of performance metrics for that trial will appear.

Validation: We will validate that data from a smartphone can be modeled to accurately identify task events (repetition and time), movement status detection (moving or still), and performance-quality evaluation (kinematic measures. In a study (N=15 young adults) we will examine the ability of the smartphone to accurately identify the above listed components for the ADLs listed in Table 1. Each participant will be asked to perform five

repetitions of each activity in three different testing sessions. We will qualify the performance of our activity recognition algorithms using accuracy and area under the receiver-operator characteristic (ROC) curve (AUC). We will perform an evaluation with random hold out and cross-validation as well as leave-one-person-out evaluation. Particularly, we will compute sensitivity, specificity, and F-measure values. Then we will generate a learning curve that plots classification accuracy as a function of training set size and will add data collection time until the curve plateaus. Our previous research work has shown that it is critical to collect enough

sensor training data in building robust models. Similarly, we will consider recruiting new participants until the curve plateaus. The data collection for this study will take place in the Rehabilitation Lab at the University at Buffalo. The controlled environment will allow us to measure motion accuracy and thus calculate gold standard numbers for jerk score, task completion, total path length, and other qualitative metrics (i.e., the number of repetitions).

Aim 2: Examine performance changes in trained ADLs when augmenting 3D printed objects with smart technology to provide quantitative feedback on performance. Study Design: A single-subject experimental design with a multiple baseline, multiple probe testing setup is well suited to stroke rehabilitation research. With inherent variability between motor performance of individuals with stroke, there is an advantage to having participants serve as their own control. The level of stability of motor performance will be established during baseline by three different assessments (described in "Assessments" below). Each participant will have a varying length of the baseline period to establish that the intervention, rather than time, is the primary reason for any observed change in performance. For the intervention, all participants will be asked to complete a six-week in home training program as described in "Training Intervention" below. A follow-up phase, using the same assessments as in the baseline, will be repeated for the purpose of assessing carry-over post intervention. Training Intervention: Training will focus on upper extremity ADLs and manipulating or transporting the 3D printed objects instrumented with a smartphone, the smartphone will be supplied for the length of the training program (Table 1 in attached grant proposal). Participants will be cued to start their rehabilitation program by setting an alarm on the smartphone. The smartphone will be placed either in (e.g., the bowl) or on (e.g., the key) the 3D printed device. During the initial assessment, rehabilitation professionals will work with participants to determine which tasks can be completed safely. Task modifications will be made as necessary to protect joint integrity and balance. Similar to previous research in stroke, training will be tailored to the participant's ability. The majority of training ADLs give participants the opportunity to perform them in a seated position. However, some participants may prefer to stand as this position is more functional for many of the ADLs. Participants will be asked to complete a minimum of 10 repetitions of each task they are training once a day/ five days per week for six weeks. These common ADLs include general arm movement (horizontal transport), forearm pronation and supination (pouring) and fine motor (key). Participants will receive auditory feedback on count or speed of movement in real time. Feedback will be given as described previously. The goal is to perform tasks more smoothly and in less time than the previous session. If participants have increased pain with training, they will be asked to stop doing the training tasks and contact the PI.

4.0 Local Number of Subjects

4.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response:

We expect about 45 people in this research study. Fifteen young adults (18-30) who have not experienced a stroke will be recruited. It is possible that we would need to recruit more than the anticipated 15 participants. Possibly 10 more. Our previous research has shown that it is critical to collect enough sensor training data in building robust models. Similarly, we will consider recruiting new participants until the curve plateaus. Twenty adults who have experienced a stroke are expected to participate in the study.

4.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response:

It is possible that approximately 25% of individuals with stroke will not qualify for the study. We anticipate that advertisements for the study emphasizing study criteria will keep the screening failure rate low.

4.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response:

The enrollment at The University at Buffalo is over 29,000. It is likely that we can find 15 adults between the ages of 18-30 from the campus community to participate in the study

Erie County has the highest rate of stroke in New York State (BCBS statistics). It is likely that we can recruit 20 participants for the proposed study.

5.0 Inclusion and Exclusion Criteria

*5.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Aim 1 and Aim 2: Inclusion Criteria

Both older adults and individuals with stroke need to be: 1) living in the community as an independent ambulator with or without an assistive device (orthosis, walker, cane, etc.). 2) able to hear well enough, with or without a hearing aid, to participate in a conversation

Aim 1 Criteria: adults: age 18-30 in good health

Aim 2 Criteria in individuals with stroke must: 1.) have had no more than one non-cerebellar stroke. 2.) be 6+ months post stroke 3.) be 18 years or older

5.2 Describe the criteria that define who will be ***excluded*** *from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Exclusion Criteria: 1.) Presence of cognitive impairment that would affect ability to participate as determined by the Mattis Dementia Scale (minimum of 124/144). 2) Acute or chronic pain that would interfere with participation in testing or training. 3) Severely limited range of motion or contractures of the arms or hands. 4) Absence or severely impaired proprioception of upper limbs. 5) Musculoskeletal or circulatory conditions affecting the lower limb (vascular disease, tendonitis, cellulitis, Raynauds syndrome, severe osteoarthritis or rheumatoid arthritis, other orthopedic surgeries involving the lower limbs). 6) Severe spasticity interfering with function (3 or greater on the Modified Ashworth Scale). 7) Recent treatment (within 3 months) for spasticity including botulinum toxin injections or spasticity medications including intrathecal baclofen. 8) Hospitalization within 3 months of participation

Exclusion Criteria specifically for Aim 2- Participants in Aim 2 will need to score greater than 42 on the Berg Balance Scale indicating they are not at a higher risk for falls.

5.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☐ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

5.4 Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

*In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response:

Participants with stroke involved in the intervention will need to be fluent in English to efficiently interact with the written/verbal feedback based on the Smartphone. Non-English speaking participants will be excluded in this initial study of the software guiding the gait rehabilitation program.

6.0 Vulnerable Populations

*If the research involves special populations that are considered vulnerable, **describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

*6.1 For research that involves **pregnant women,** safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response: It is possible that one of our participants may be pregnant. There is no reason to anticipate that the procedures used in this study would harm a pregnancy.

☐ **N/A**: This research does not involve pregnant women.

*6.2 For research that involves **neonates of uncertain viability or non-viable neonates,** safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

*6.3 For research that involves **prisoners**, safeguards include:*

NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

6.4 *For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

6.5 *For research that involves **cognitively impaired adults**, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

6.6 *Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable.* ***Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response:

Flyers, advertisements and letters will be used to recruit participants. Participants will have the choice to contact the PI to participate in the study, thereby avoiding coercion or undue influence.

7.0 Eligibility Screening

7.1 *Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

Response:

The PI or research assistants will be responsible for screening potential participants. Participants will be asked a series of questions over the phone (see phone scripts and questionnaires for young adults and individuals with stroke). When participants arrive for their first scheduled session, they will complete a cognitive assessment (Mattis Dementia Rating Scale- Dementia Rating Scale–2™ (DRS-2™) http://www4.parinc.com/Products/Product.aspx?ProductID=DRS-2, this trademark assessment will be purchased for the study information on the

assessment is found at the given website), The Montreal Cognitive assessment may also be used. A movement screen (range of motion and proprioception) and assessments for spasticity (Modified Ashworth Scale) will also be conducted prior to starting the testing. If the individual demonstrates severe limitations in movement, they will not complete the testing session. They will be paid for coming to the testing session on South Campus.

☐ **N/A:** There is no screening as part of this protocol.

8.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

8.1 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response:

Recruitment strategies for young adults will consist of flyers posted on UB campuses. Recruitment for individuals with stroke will be extensive including distribution of flyers through organizations such as Meals on Wheels, the Program of All-Inclusive Care for the Elderly (PACE), stroke support groups, senior centers and clinical facilities in the greater Buffalo region. In addition, advertisements will be placed in local papers and flyers at community centers. Final versions of the newspaper advertisements will be submitted to as an amendment to the IRB for approval prior to the printed ad. We will also ask the Buffalo Research Registry for a list of potential participants to contact and determine if they are interested in participating and if they are a good fit.

8.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response: Participants will self-select to respond to one of the advertisements for the study. They need to choose to contact the researchers to participate in the study. The settings for the phone conversation and data collection will be private areas.

8.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response:

Flyers, advertisements, and follow up phone conversations- see phone scripts will be used to recruit participants. The flyer will be used as the advertisements.

9.0 Procedures Involved

*9.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Approach: Our goal is to develop portable technology capable of cueing a home training program, collecting data on upper limb motor performance and providing user feedback on performance.

Response: *Aim 1:Participants will be asked to come to Kimball Tower three times within a two week time span to demonstrate consistency of motor performance. An infrared motion monitor system will be used to track their movement and compare kinematics produced by the smartphone with kinematics produced from the infrared motion monitor system. Participants may be video taped during data collection to further assess mobility.*

Aim 2

Wolf Motor Function Test (WMFT): examines functional abilities. It is a valid and reliable outcome measure following stroke

9-Hole Peg Test: a timed test of manual dexterity which involves lifting/placing/removing 9 pegs into/out of holes. It is both valid and reliable in measuring arm function after stroke.

Grip assessment: Grip strength is measured with a hand dynamometer.

Berg Balance Scale: A 14-item scale designed to measure balance

All clinical assessments are recommended Outcome Measures by the APTA for stroke (http://www.neuropt.org/professionalresources/neurology-section-outcome-measures-recommendations/stroke)

Use of smartphone and 3D printed objects will be in home over a 11- week span. Five of these weeks the participants will perform a limited number of task trials without feedback to act as a probe for performance quality. The other 6 weeks, participants will be asked to perform their exercise program 5/7 days and the in home exercise program may take up to an hour to complete.

User Feedback Measures: User Interaction Satisfaction: We will ask participants to rate the effectiveness of the information displays in supporting a set of key needs. The Questionnaire for User Interaction Satisfaction (QUIS) is a validated usability assessment tool applied in numerous studies of interface design (80-82, information on online assessment found at http://www.lap.umd.edu/QUIS/index.html), including assessment of health information interfaces (83-85). This licensed, online questionnaire will be supplemented with context specific questions related to the display. Comments and Debriefing: Participant will be interviewed to obtain additional feedback on their overall experience during the test. A semi-structured interview will be used in which broad questions are formulated and the conversation progresses. Findings from these components will be used to make iterative improvements as necessary to the system to support future research and implementation

Caregiver Feedback Measures: Caregivers of participants will be given the opportunity to provide their feedback on mRehab and the participant's use of the mRehab system. A semi-structured interview will be used to gain feedback on how much assistance caregiver's provided for 1) setting up mRehab, 2) providing motivation to use mRehab, 3) assisting the participant in using mRehab and 4) suggestions for improving mRehab.

9.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

Aim 1:

The controlled environment will allow us to measure motion accuracy and thus calculate gold standard numbers for jerk score, task completion, total path length, and other qualitative metrics (i.e., the number of repetitions). Video assessments will allow us to review motor behavior and further assess mobility.

Aim 2:

Clinical Assessments used to determine mobility of the more affected limb:

Wolf Motor Function Test (WMFT): examines functional abilities. It is a valid and reliable outcome measure following stroke

9-Hole Peg Test: a timed test of manual dexterity which involves lifting/placing/removing 9 pegs into/out of holes. It is both valid and reliable in measuring arm function after stroke.

Grip assessment: Grip strength is measured with a hand dynamometer.

Modified Ashworth Scale: Assesses spasticity

Probes: Perform the ADLs from the training program without feedback.

Performance will be assessed by examining data collected from the smartphone:

Participants will be asked to complete only two repetitions of the training tasks without receiving feedback on three separate days during each baseline week and each follow-up week to determine baseline performance and in follow-up retention of task learning.

Performance Measures: We will examine the following measurements of movement and task performance for comparison between the baseline and training intervention periods:

Task completion time: Measured from the start to the end of the task. Normalized jerk score (NJS)/smoothness: Using the acceleration readings from the inertial measurement unit embedded in the smartphone, the normalized jerk score can be computed.

Usability: Participants will evaluate the usability of the system based on ease of use and interpretability of the feedback. Usage metrics will be recorded to track how often and for how long they use the system at home. Also, a post-survey study will be used to collect quantitative participant feedback for UI improvement.

User Feedback Measures: User Interaction Satisfaction: We will ask participants to rate the effectiveness of the information displays in supporting a set of key needs. The Questionnaire for User Interaction Satisfaction (QUIS) is a validated usability assessment tool applied in numerous studies of interface design, including assessment of health information interface. This licensed, online questionnaire will be supplemented with context specific questions related to the display. Semistructured interviews will also be used.

Caregiver Feedback Measures: Caregivers will be given the option of participating in a semi-structured interview to assess their feedback on how much assistance the caregiver provided for 1) setting up mRehab, 2) providing motivation to use mRehab, 3) assisting the participant in using mRehab and 4) suggestions for improving mRehab.

9.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response:

List of instruments used in study:

Questionnaires for young adults and adults with stroke

Mattis Dementia Rating Scale- Licensed manual with scoring software

http://www4.parinc.com/Products/Product.aspx?ProductID=DRS-2

Montreal Cognitive Assessment

Clinical Assessments:

Wolf Motor Function Test

9-hole peg test

Modified Ashworth Scale

Grip Strength- measured with hand dynamometer; *the hand dynamometer is an instrument used to measure the strength of the hand and forearm muscles by asking the participant to squeeze the dynamometer with as much force as possible.*

Berg Balance Scale

The Questionnaire for User Interaction Satisfaction (QUIS)- licensed online assessment , *http://www.lap.umd.edu/QUIS/index.html*

Semi-structured interview for participants

Semi-structured interview for caregivers

A modification will be submitted to upload the QUIS and Mattis Dementia Rating Scale after funding is received for the project and the license and the test is purchased.

9.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response: Not applicable

*9.5 Indicate whether or not **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 physician) and if so, describe how these will be shared.*

Response:

9.6 If participants ask about their performance, we could inform them of their performance on the clinical assessments. *Indicate whether or not **study***

results will be shared with subjects or others, and if so, describe how these will be shared.

Response:

Data from the study will be analyzed and will be presented in professional journals and conferences.

10.0 Study Timelines

10.1 Describe the anticipated duration needed to enroll all study subjects.

Response:

It is anticipated that all participants will be enrolled within two years of the start of the study.

10.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response:

Aim 1: Participants will come to Kimball Tower on South Campus three times for approximately 1 hour each session.

Aim 2: Participants with stroke will be asked to come to Kimball Tower a total of 4 times (2 pre-tests and 2 post-tests) and participate in a 10 week in-home technology guided exercise program. Pre and post testing will be done in the two weeks pre and post the exercise program. The caregiver feedback measures would obtain information from caregivers in one session lasting 5-30 minutes depending on the amount of feedback the caregiver provides. We could conduct the interview over the phone on or near the last day of the testing session or the caregiver can do it in person during the participant's 3rd or 4th testing sessions.

10.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response:

It is anticipated that data collection and analyses will be completed in 2-2.5 years.

11.0 Setting

11.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response: Data collection will be done on the South Campus of UB in Kimball Tower. The building is handicap accessible and is open to the public during normal working hours. Parking spaces are reserved for participants and in addition handicapped parking is available next to Kimball Tower. The lab is located on the fifth floor of Kimball Tower. The de-identified data from the in-home exercise program will be collected through the smartphone. De-identified data will be uploaded to Amazon Simple Storage Service (Amazon S3). Security measures have been taken so that only members of the research team are able to access de-identified data on Amazon S3. If internet is not available to upload the data, data will remain stored on the phone.

11.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

12.0 Community-Based Participatory Research

12.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

12.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

13.0 Resources and Qualifications

*13.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response:

The PI has completed a PhD program, post-doctoral training and has a productive research lab. Key personnel have completed a PhD or advanced graduate degrees in their respective fields and are involved in ongoing scholarship. All research personnel have completed CITI training. Research assistants have been trained in the lab on use of equipment, clinical assessments, and pen and paper assessments. Training includes reading pertinent literature, hands on training and training with more senior research personnel. Research assistants working with participants have completed CPR and First Aid training. Research assistants are responsible for screening potential participants, obtaining verbal consent, collecting data, managing data sets and writing. The PI will regularly communicate with research personnel regarding recruitment, data collection, data management and writing.

Describe other resources available to conduct the research.

13.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response: Key personnel with academic appointments will devote .5-.9 academic months and up to .75 summer months. Personnel with 12 month appointments will devote .3 calendar months. In addition, Graduate (9 month appointment yr 1 and 12 month appointment yr 2) and undergraduate research assistants (total of 30 hours per week) will work on the project.

13.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response: If individuals demonstrate they are at higher risk for falls based upon the clinical assessments, they will be encouraged to consult with their physician and given basic information regarding fall prevention strategies. If a fall were to occur during assessments or training, there are not medical resources on site. If needed, medical resources would need to be called.

13.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: Research personnel working with the participants are trained in the use of clinical assessments, equipment used in the study and are familiarized with the research protocol. This is done through hands on training, reading pertinent literature and working with senior research personnel. In addition, all research personnel have completed CITI training.

14.0 Other Approvals

14.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

Prior to dispersing advertisements through Meals on Wheels, the Program of All-Inclusive Care for the Elderly (PACE), stroke support groups, senior centers, or clinical facilities, permission will be obtained from the organization to do so.

☒ **N/A:** This study does not require any other approvals.

15.0 Provisions to Protect the Privacy Interests of Subjects

15.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response:

Participants will self-select to respond to one of the advertisements for the study. They need to choose to contact the researchers to participate in the study. The settings for the phone conversation will be in private areas. The subjects will be seen in private lab areas for clinical assessment.

15.2 Indicate how the research team is permitted to access any sources of information about the subjects.

NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question ***does apply*** *to records reviews.*

Response: Participants will directly provide personal data to research personnel. Research personnel do not have access to medical or other records for the participant.

16.0 Data Management and Analysis

16.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response:

Aim 1:

Validation of smartphone with motion monitor system. We will look at consistency of motor performance across time.

Aim 2:

A strength of the proposed single-subject study design is the internal validity gained by using repeated measurement from the same individuals and the ability to replicate the effect of the intervention across participants. As is typical with single-subject designs, visual inspection will be used as the first stage of analysis to determine the general stability of performance during the baseline phase and the trend of performance change during the training intervention. Statistical analysis to corroborate the visual analysis will include time-series analysis to infer changes in trend and level across phases.80 The serial dependency in the data for each participant will be accounted for using the autoregressive integrated moving average (ARIMA).80 If a significant positive trend in overall performance during the training intervention is observed, the hypothesis will be accepted. To validate the effect of the training program on the performance measures, the effect on the standardized assessments will be tested. A repeated measures analysis of variance (ANOVA) will be used to assess whether there is a difference within each participant for performance on the Wolf

Motor and 9 hole peg test assessments at the start of baseline, end of baseline, start of follow-up, and end of follow-up. Post hoc pairwise comparisons will be used to assess the differences ΔB = Bend-Bstart, ΔTraining (ΔT) = Fstart-Bend, and ΔF = Fend-Fstart. It is hypothesized that ΔB and ΔF will be 0, indicating stable performance during the baseline and follow-up, and that ΔT > 0. If these results are consistent with the findings from the functional tests, then the results will be considered valid.

16.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response:

Aim 1: In a study (N=15 young adults) we will examine the ability of the smartphone to accurately identify the above listed components for the ADLs listed in Table 1. Each participant will be asked to perform five repetitions of each activity in three different testing sessions. We will qualify the performance of our activity recognition algorithms using accuracy and area under the receiver-operator characteristic (ROC) curve (AUC). We will perform an evaluation with random hold out and cross-validation as well as leave-one-person-out evaluation. Particularly, we will compute sensitivity, specificity, and F-measure values. Then we will generate a learning curve that plots classification accuracy as a function of training set size and will add data collection time until the curve plateaus. Our previous research work has shown that it is critical to collect enough sensor training data in building robust models. Similarly, we will consider recruiting new participants until the curve plateaus.

Aim 2: Sample size estimation was based on the repeated measures ANOVA test of within subjects change in standardized assessment scores from baseline to follow-up. With $\alpha = 0.05$, power = 0.8, 4 measurements, and a desired effect size (f) = 0.25 to detect, a sample size of 15 participants is needed. This effect size is consistent with studies on functional activity performance and recovery following stroke.68 A total of 20 participants will be recruiting to account for a 25% attrition rate.

16.3 Describe any procedures that will be used for quality control of collected data.

Validation of the system in aim 1 acts as a quality control.

17.0 Confidentiality

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*17.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response: Data collected from participants will be coded with a participant number. Subject identifiers (e.g., name, address, birth date) will be kept separate from other data in a locking cabinet in the PI's South Campus office (Kimball Tower 522). Thus the signed consent forms and master list of participants will be in a secure location accessible to the PI and co-researchers. Data will be retained for a minimum of three years. Digital data such as video tape will be kept on a password protected server. If manuscripts related to this work continue to be generated at the end of three years the data will be maintained until all manuscripts have been published.

17.2 A. How long will the data be stored?

Response:

Data will be stored a minimum of three years

17.3 A. Who will have access to the data?

Response:

Research personnel

17.4 A. Who is responsible for receipt or transmission of the data?

Response:

Research personnel

17.5 A. How will the data be transported?

Response:

Data will be coded and entered into computerized spreadsheets accessible on a secure drive.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 19.0)*

17.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

17.7 B. How long will the specimens be stored?

Response:

17.8 B. Who will have access to the specimens?

Response:

17.9 B. Who is responsible for receipt or transmission of the specimens?

Response:

17.10 B. How will the specimens be transported?

Response:

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

18.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response:

Data will be reviewed by the PI on a quarterly basis. If concerns or comments from participants arise they will be noted and discussed by

research members. We want to ensure the participant's well-being in the study and promote a positive experience without compromising the integrity of the research. Serious events and problems will be reported by the primary investigator to the SBSIRB in a within 24 hours.

18.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response:

Performance on assessments of movement, and strength will be reviewed. In addition, performance on the Upper Limb Training will be reviewed.

18.3 Describe any safety endpoints.

Response:

Participants will safely complete the technology guided upper limb Training.

18.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: Participants will be monitored during data collection in aim 1. In aim 2, participants will start the technology guided upper limb Training in the lab with direct mentoring and then progress to completing it independently at home. At the start of the in-home program, members from the research team will either go to the participant's home to confirm that the system is working correctly or will use a platform such as skype to converse with the participant and see the set up. Research members will work with participants if they experience technical difficulties by going to their house, skype or a phone conversation. They will be provided with contact information for the PI and other research personnel in case they have concerns or difficulties at home. Participants will also be asked about their in home upper limb training experience at their post-intervention testing.

18.5 Describe the frequency of safety data collection.

Response:

Quarterly or within 24 hours of a participant raising a concern.

18.6 Describe who will review the safety data.

Response:

The PI

18.7 Describe the frequency or periodicity of review of cumulative safety data.

Response:

Quarterly

18.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response:

Participants will be debriefed following training, if they report concerns about the in-home training these will be recorded and evaluated by the research personnel. If participants call in to report concerns, these will be recorded and considered by research personnel.

18.9 Describe any conditions that trigger an immediate suspension of the research.

Response: If participants report concerns that the research team deems could cause difficulties for all participants, research will be suspended.

19.0 Withdrawal of Subjects

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*19.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: If participants fail to complete the testing sessions in Aim 1 in a timely manner, they may be withdrawn from the study.

Participants will be assessed with the Berg Balance Scale. If they do not score above a 42, they will only perform exercises in a seated position in Aim2. If participants report pain with activities in the program and the program cannot be modified to eliminate pain, the participant will be taken out of the study.

19.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: Exit interview with research personnel. If balance concerns have prompted termination in the training portion of the study, the PI will consult with the participant. The participant will need to return the rehabilitation device and fill out the paper work for payment of the pre-intervention testing session.

19.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response:

Data collected prior to participant's departure from the study may be used in portions of the data analyses.

20.0 Risks to Subjects

20.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response Risks to the Subjects

It is possible for the participant to experience:

- fatigue
- loss of balance, possibly resulting in a fall
- a muscle strain or orthopedic injury
- breach of confidentiality with your personnel information

20.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Risks to participants are minimized by:

- screening participants using the inclusion/exclusion criteria
- providing the participants with rests as they wish between assessments
- tailoring the Upper Limb Training program to the abilities of each participant
- reminding participants that they can terminate their participation at any time, without penalty.
- Coding data used in analyses

*20.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response:

The Upper Limb Training is a new approach to rehabilitation at home. It is possible that participants may have difficulties with this home exercise program. To reduce risks, participants who score at or below 42 on the Berg Balance Scale must complete all home exercises in a seated position. The Training program will also be tailored to each participant's abilities.

20.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response:

The procedures should not cause increased risk to the embryo or fetus.

20.5 If applicable, describe risks to others who are not subjects.

Response:

The procedures should not cause risk to others who are not subjects.

21.0 Potential Benefits to Subjects

21.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: It is unlikely that participants in Aim 1 will experience a direct physical benefit for their participation in the study. It is possible that participants that complete aim 2 may experience some level of benefit in their ability to move their arm/hand. The results of the study may influence rehabilitation approaches in the future. All participants may derive satisfaction from the potential to help others. The risk to benefit ratio is excellent.

22.0 Compensation for Research-Related Injury

☐ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*22.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

Safety precautions will be taken to limit the risks to participants in the study to "minimal risk". The Upper Limb Training may involve activities in standing, making it possible that the participant may fall. By assessing individuals for fall risk, using a clinical assessment, prior to enrollment into aim 2 of the study, we will lower the risk to the participant.

If a participant feels like they have been injured because of taking part in this study. They should inform the PI and they will be encourage to consult with their physician. Treatment options will be explained by your physician. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

22.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

NA

23.0 Economic Burden to Subjects

23.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response: No costs are associated with participation in the research

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

24.0 Compensation for Participation

25.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response:

If you agree to take part in the first part of this research study, we will pay you _$30 for your time and effort. The paperwork for the check will be completed at the testing session. Processing payment may take 4-6 weeks.

If you have had a stroke and agree to take part in the second part of this research study, we will pay you _$25 each for the pre and post intervention testing sessions and $200 for completing the 11 week in home Upper Limb Training program (5 weeks baseline and 6 weeks training). This will be a total of $300. The paperwork for the check will be completed at the last testing session. If participants do not complete the training program, they will be asked to bring the equipment back to Kimball Tower and will complete the paperwork for payment of the pre-test sessions. Processing payment may take 4-6 weeks.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

25.0 Consent Process

25.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 27.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 27.0)*

25.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response:

When potential participants come to South campus for an in lab session, they will again be given a description of the study. Any questions potential participants may have will be answered to their satisfaction by study personnel. Once all questions have been answered, potential participants will be asked if they wish to continue in the study. Their written consent is necessary for enrollment into the study.

25.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response: Participants will be encouraged to ask questions and will be given the time they desire to determine if they would like to participate. If participants feel comfortable signing the informed consent, we will then start the assessments.

25.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response:

At the beginning of each testing session, the participant will be given a summary of the activities to be completed that day. Participants will be asked if they want to continue.

25.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects. *(Skip to Section 26.8)*

25.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 6.4 of this protocol.

Response:

25.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults. *(Skip to Section 26.9)*

25.8 Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent. (*Skip to Section 26.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 26.11 and 26.12).*

25.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

25.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

25.11 Describe the process for ***assent of the adults****:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.*

Response:

- *If assent will not be obtained from some or all subjects, provide an explanation of why not.*

Response:

25.12 Describe whether ***assent of the adult*** *subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 27.0)*

*25.13 Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response:

*25.14**For research conducted outside of New York State**, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

25.15 Describe whether parental permission will be obtained from:

Response:

☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

25.16Describe whether permission will be obtained from individuals ***other than parents****, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

25.17 Indicate whether assent will be obtained from all, some, or none of the ***children****. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

25.18 When assent of children is obtained, describe how it will be documented.

Response:

26.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

26.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

26.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

27.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 29.0)

27.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response:

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

28.0 Multi-Site Research (Multisite/Multicenter Only)

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

*28.1 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as:*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

28.2 Describe the method for communicating to engaged participating sites:

- *Problems*
- *Interim results*
- *Study closure*

Response:

28.3 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

28.4 If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

Response:

29.0 Banking Data or Specimens for Future Use

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*29.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response:

29.2 List the data to be stored or associated with each specimen.

Response:

29.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response:

30.0 Drugs or Devices

☐ **N/A:** This study does not involve drugs or devices. This section does not apply.

30.1 If the research involves drugs or devices, list and describe all drugs and devices used in the research, the purpose of their use, and their regulatory approval status.

Response:

Participants will be using a common smartphone purchased commercially and 3D printed objects. These items do not pose undue risk to the participant.

30.2 Describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

Response:

The participant will be provided with a smartphone during the study. When smartphones are not in use by participants, they will be stored securely in the lab by research personnel.

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

30.3 Identify the holder of the IND/IDE/Abbreviated IDE.

Response:

NA

30.4 Explain procedures followed to comply with FDA sponsor requirements for the following:

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response: N/A

31.0 Humanitarian Use Devices

☒ **N/A:** This study does not involve humanitarian use devices. This does not apply.

31.1 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Response:

31.2 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

Response: