Title	Understanding the efficacy of the robotic rehabilitation of chronic stroke patients: pilot testing
IRB Institution	University at Buffalo
IRB Approval period	12/6/21-12/5/22

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 6, 21, 22, 24, 25, 26 and 27 do not apply.*
    - *For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.*

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 Example
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.

Response: Pilot study on the physiological response of robotic rehabilitation therapy for improving the performance of ADLs of stroke patients

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

Nikhil Tej Kantu

Dept. of Mechanical and Aerospace

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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response: version 2, 12-29-2021

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	12/29/2021	Modification	

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response: N/A

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: N/A

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: The copies of IRB correspondence or signed consent forms will be stored in a locked cabinet located in Furnas Hall Room 809. Only personnel related to the project will have access to the document.

Location: Cabinet with key access

Address: Room 809 Furnas Hall, Buffalo, NY 14260

Department: Dept of Mechanical and Aerospace Engineering

1.0 Study Summary

Study Title	Understanding the efficacy of the robotic rehabilitation of chronic stroke patients: pilot testing
Study Design	This pilot randomized controlled trial study will provide the efficacy of robotic rehabilitation for practicing activities of daily living. The study will compare the range of motion of robotic therapy and the activities of daily living.
Primary Objective	Range of motion data for activities daily living and the same tasks performed in the robotic device will be compared. Also, EMG and IMU (Inertial Measurement Unit) data will be collected during the robotic task to understand the physiological effect of the robot on adults.
Secondary Objective(s)	The efficacy of the virtual reality during robotic therapy will be studied along with the primary objective.
Research Intervention(s)/ Investigational Agent(s)	This study includes manipulation of a robotic device to perform a task that is similar to activities of daily living such as turning a pickle jar, pouring water from a pitcher, etc.
IND/IDE #	N/A
Study Population	Chronic stroke
Sample Size	40

Study Duration for individual participants	2 Years
Study Specific Abbreviations/ Definitions	sEMG: surface electromyography IMU: Inertial Measurement Unit ADL: active daily living DOF: degree of freedom SPINDLE: Spherical parallel instrument for Daily Living Emulation (Robotic device for occupational therapy)

2.0 Objectives*

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

Response:
(1) Investigate the movement and surface electromyography when performing activities of daily living using a robotic emulator
(2) Compare the range of motion of activities of daily living to the range of motion of robotic emulator
(3) Investigate the efficacy of the virtual reality in addition to the robotic therapy to promote enhancing the performance of activities during daily living

2.2 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:

(1) We hypothesized that physiological response (ex. range of motion) during activities of daily living in robotic therapy is similar to the actual activities of daily living.

(2) We hypothesized that virtual reality would improve the training effect of robotic therapy to learn the new movement of stroke patients.

3.0 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: The two primary outcome measures will be the motion and the muscle activation data of the upper body during active daily living tasks with and without the rehabilitation robot. Motion trajectory using a motion capture system will be

averaged for all subjects to understand the nominal pattern during each active daily living. Using the collected data set, the baseline of range of motion, smoothness, task duration, and the number of sub movements will be established. Surface electromyography data will be recorded and post-processed on the upper limb and trunk to identify a nominal activation pattern of the upper body with the correlation of the joint angle trajectory. The same data set will be created when individuals perform identical tasks with the robot and virtual reality system. In addition, the hand posture will be recorded from the motor encoder of the robot system.

4.0 Background*

4.1 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: About 6.6 million individuals in the United States suffer from stroke-related motor impairments[1]. Patients with stroke often lose function of their upper limbs and have difficulty performing activities of daily living (ADLs). The first three months after the onset of stroke falls within a crucial time window as most of the arm recovery happens by spontaneous neurologic recovery during this period[2]. During this acute stage, motor learning may help improve motor impairment and facilitate recovery[3]. Occupational therapy (OT) services are often utilized to remediate or restore the function of the upper limbs. However, even after the completion of standard therapy, up to 75% of individuals experience continuous challenges with ADLs. These residual impairments affecting ADLs indicate that OT may only have been moderately effective in improving ADLs outside of the hospital or clinic setting[4]. Improvement of motor function for ADLs may occur through more intensive therapy.

Robotic interventions have been developed in the past to satisfy the high-intensity and repeated training. Many robotic interventions have been successful in improving upper limb motor scores and strength[5-8], but the consensus in literature demonstrates that these improvements do not always transfer to the performance of ADLs[7]. There are three potential reasons for the limited transfer of robotic training to ADL performance. First, the current robotic therapy has focused more on the individual training of either proximal or distal arm joints. However, simultaneous training of proximal and distal joints is essential to perform daily living tasks[9][10]. Second, many robotic interventions focused on reaching tasks that are different from object manipulation. Many ADLs include manipulation tasks that require complicated three-dimensional hand posture changes. Third, robotic training sessions are often limited to patients in clinical settings because robotic systems are bulky and expensive, which makes the home-use challenging.

In our work, we designed a new training strategy using a parallel manipulator,

named Spherical Parallel Instrument for Daily Living Emulation (SPINDLE). The design is inspired by the well-known agile eye structure, which has a 3-RRR structure that enables three-dimensional rotations[11][12]. By using a 3-RRR parallel structure, this device features high stiffness, precise manipulation, and low inertia. This device will mimic activities of daily living tasks, including complicated object manipulation tasks. This device will interact with the user, and provide a compact table-top device with high torque and wide range of motion compared to off-the-shelf devices. This portable device will allow patients to train not only in the clinic but also at home or in community centers. Moreover, SPINDLE lets users explore and interact with the device like an external object similar to the daily living environment.

Using virtual reality (VR) for stroke rehabilitation is not a novel method. As early as decades ago, VR became an essential tool to enhance rehabilitation along with traditional methods. In 2001, a personal computer-based VR system was developed to recover hand function for stroke patients. This system utilized four routines which corresponded to four specific components of hand movements: range, speed, fractionation, and strength. This system proved to be an excellent addition to the traditional rehabilitation tools, as shown in the outcome of patients[13]. However, the VR routines were simple in design and might not be engaging enough for patients to follow in the long term. Around a year later, another study was conducted to observe the effect of VR on foot-based interactions. This time two VR exercises were created to be based on real-life situations and objects[14]. Nonetheless, there still could be improvements for the exercises to be more engaging. The need for change in VR rehabilitation led to a shift to VR gaming as a means to keep patients motivated. In 2008, a handheld stylus was provided for patients to play a list of VR games, such as tennis and archery, as part of the rehabilitation routine[15]. This approach, nevertheless, limited the range of motion as patients had to stand in front of a VR activity station in order to play the games. In later years, the emergence of enhanced VR devices and systems such as Wii gaming system and Xbox Kinect allowed VR rehabilitation to overcome these challenges[16][17][21]. The exercises in VR also became more similar to real-life activities such as sports, cooking, and home cleaning, which made the rehabilitation more enjoyable as well as practical[16][18][20][21][22]. In addition, there was a shift from using off-the-shelf VR games (e.g. sports games created by Wii) to using more customized games[18][20][21]. However, the activities in current VR rehabilitation routines are still limited in diversity and range of motions.

4.2 Include complete citations or references.

Response:

[1] Benjamin EJ, Blaha MJ, Chiuve SE et al. Heart disease and stroke statistics-2017 update: a report from the american heart association. Circulation 2017; 135(10): e146e603.

[2] Kwakkel G, Kollen B and Twisk J. Impact of time on improvement of outcome after stroke. Stroke 2006; 37(9): 23482353.

[3] Duncan P, Studenski S, Richards L et al. Randomized clinical trial of therapeutic exercise in subacute stroke. Stroke 2003; 34(9): 21732180.

[4] Sturm JW, Dewey HM, Donnan GA et al. Handicap after stroke: how does it relate to disability, perception of recovery, and stroke subtype? the north east melbourne stroke incidence study (NEMESIS). Stroke 2002; 33(3): 762768.

[5] Mehrholz J, Haadrich A, Platz T et al. Electromechanical and ¨ robot-assisted arm training for improving generic activities of daily living, arm function, and arm muscle strength after stroke. Cochrane database of systematic reviews 2012; 4(6).

[6] Prange G, Jannink M, Groothuis-Oudshoorn C et al. Systematic review of the effect of robot-aided therapy on recovery of the hemiparetic arm after stroke. Journal of rehabilitation research and development 2009; 43(2): 171 184.

[7] Kwakkel G, Kollen BJ and Krebs HI. Effects of robot-assisted therapy on upper limb recovery after stroke: a systematic review. Neurorehabilitation and neural repair 2008; 22(2): 111121.

[8] Lo AC, Guarino PD, Richards LG et al. Robot-assisted therapy for long-term upper-limb impairment after stroke. New England Journal of Medicine 2010; 362(19): 17721783.

[9] Oujamaa L, Relave I, Froger J et al. Rehabilitation of arm function after stroke. literature review. Annals of physical and rehabilitation medicine 2009; 52(3): 269293.

[10] Timmermans AA, Seelen HA,Willmann RD et al. Technologyassisted training of arm-hand skills in stroke: concepts on reacquisition of motor control and therapist guidelines for rehabilitation technology design. Journal of neuroengineering and rehabilitation 2009; 6(1): 1.

[11] Gosselin C, Sefrioui J and Richard MJ. On the direct kinematics of spherical three-degree-of-freedom parallel manipulators with a coplanar platform. Journal of Mechanical Design 1994; 116(2): 587593.

[12] Gosselin CM, Pierre ES and Gagne M. On the development of the agile eye. IEEE Robotics & Automation Magazine 1996; 3(4): 2937.

[13] Jack, D., Boian, R., Merians, A., Tremaine, et al. (2001). Virtual reality-enhanced stroke rehabilitation. IEEE Transactions on Neural Systems and Rehabilitation Engineering, 9(3), 308-318. doi:10.1109/7333.948460

[14] Boian, R., Deutsch, J., Lee, C. S., Burdea, G., & Lewis, J. Haptic effects for virtual reality-based post-stroke rehabilitation. 11th Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems, 2003. HAPTICS 2003. Proceedings. doi:10.1109/haptic.2003.1191289

[15] Broeren, J., Bjorkdahl, A., Claesson, L., Goude, et al.. Virtual Rehabilitation after Stroke. Organizing Committee of MIE 2008.

[16] Saposnik, G., Mamdani, M., Bayley, et al. Effectiveness of Virtual Reality Exercises in STrokeRehabilitation(EVREST): Rationale, Design, and Protocol of

a Pilot Randomized Clinical Trial Assessing the Wii Gaming System. International Journal of Stroke, 5(1), 47-51.

[17] Saposnik, G., Teasell, R., Mamdani, M., Hall, J., Mcilroy, W., Cheung, D., Bayley, M. (2010). Effectiveness of Virtual Reality Using Wii Gaming Technology in Stroke Rehabilitation. Stroke, 41(7), 1477-1484.

[18] Turolla, A., Dam, M., Ventura, L., Tonin, P., Agostini, M., Zucconi, C., Piron, L. (2013). Virtual reality for the rehabilitation of the upper limb motor function after stroke: A prospective controlled trial. Journal of NeuroEngineering and Rehabilitation, 10(1), 85.

[19] Shin, J., Ryu, H., & Jang, S. (2014). A task-specific interactive game-based virtual reality rehabilitation system for patients with stroke: A usability test and two clinical experiments. Journal of NeuroEngineering and Rehabilitation, 11(1), 32.

[20] Samuel, G., Oey, N., Choo, M., Ju, H., Chan, W., Kok, S., Ng, Y. (2017). Combining levodopa and virtual reality-based therapy for rehabilitation of the upper limb after acute stroke: Pilot study Part II. Singapore Medical Journal, 58(10), 610-617.

[21] Aşkın, A., Atar, E., Koçyiğit, H., & Tosun, A. (2018). Effects of Kinect-based virtual reality game training on upper extremity motor recovery in chronic stroke. Somatosensory & Motor Research, 35(1), 25-32.

[22] Warland, A., Paraskevopoulos, I., Tsekleves, E., Ryan, J., Nowicky, A., Griscti, J., Kilbride, C. (2018). The feasibility, acceptability and preliminary efficacy of a low-cost, virtual-reality based, upper-limb stroke rehabilitation device: A mixed methods study. Disability and Rehabilitation, 41(18), 2119-2134.

[23] Wu P, Zeng F, Li YX, et al. Changes of resting cerebral activities in subacute ischemic stroke patients. Neural Regen Res. 2015;10(5):760-765. doi:10.4103/1673-5374.156977

[24] P. He, B. Xu and J. Kang, "Spherical Parallel Instrument for Daily Living Emulation (SPINDLE) to Restore Motor Function of Stroke Survivors," 2020 8th IEEE RAS/EMBS International Conference for Biomedical Robotics and Biomechatronics (BioRob), 2020, pp. 364-369, doi: 10.1109/BioRob49111.2020.9224451.

5.0 Study Design*

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

Response:

The experiment will consist of four different sets of patient groups. All the patients will perform the natural ADLs before the experiment and after the experiments. The patients will be randomly assigned to the below four groups such that the total number of each group A-D will be identical:

1) Group A: Active assistive robotic therapy experiment
   Ten chronic stroke patients will conduct tasks similar to representative ADL tasks with the robotic device, and assistive force will be provided by the electrical motors to guide their hand to complete daily living tasks.
2) Group B: Active resistive robotic therapy experiment
   Ten chronic stroke patients will conduct tasks similar to representative ADL tasks with the robotic device, and resistive force will be provided by the electrical motors to guide their hand to complete daily living tasks.
3) Group C: Active assistive virtual robotic therapy experiment
   Ten chronic stroke patients will conduct representative ADL tasks with the assistive force will be provided by the robotic device and virtual reality goggle. Head-mounted goggle will be used to visualize the starting and goal point of the task.
4) Group D: Active resistive virtual robotic therapy experiment
   Ten chronic stroke patients will conduct representative ADL tasks with the resistive force will be provided by the robotic device and virtual reality goggle. Head-mounted goggle will be used to visualize the starting and goal point of the task.

Four studies will be designed using the above four groups.

1) Compare Group A and B: the physiological measures (movement and sEMG signals) of ADLs in the robotic device with resistive versus assistive forces will be compared by performing same ADL tasks.
2) Compare Group A and C: the physiological measures (movement and sEMG signals) of ADLs during the robotic device with assistance force, with and without virtual reality will be compared by performing same ADL tasks.
3) Compare Group B and D: the physiological measures (movement and sEMG signals) of ADLs during the robotic device with resistance force, with and without virtual reality will be compared by performing same ADL tasks.
4) Compare Group C and D: the physiological measures (movement and sEMG signals) of ADLs in the robotic device with resistive versus assistive forces, with virtual reality will be compared by performing same ADL tasks.

6.0 Study Intervention/Investigational Agent

1.1 Description: *Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

Response:

Spherical Parallel Instrument for Daily Living Emulation (SPINDLE) is a robotic rehabilitation device for stroke patients who needs more intense manipulation practice. The device was developed by Dr. Jiyeon Kang and students who are involved in this study from University at Buffalo. It is a compact table-top device that enables stroke patients to train diverse activities of daily living training and increase the time of occupational therapy at home. With SPINDLE, you can

simulate daily living activities such as opening a jar, pouring water, turning the key, or flipping a book page by manipulating the handle of the device. The structure of SPINDLE consists of 3D printed links and three motors. Each motor has an encoder that can track the device handle. Three motors of SPINDLE give the proper resistant force based on different activities. The user can feel up to 39 N when holding in the middle of the handle, which covers most of the daily living activities we can experience in daily life. Using the robotic device, subjects can practice up to 180-degree rotations in three rotational axes. SPINDLE will provide users a tremendous convenience and an efficient home-based recovery method, helping users improve the quality of life and reduce the risk of exposure to COVID-19. In addition to SPINDLE, we will use an off-the-shelf virtual reality device Vive Pro (HTC, Taiwan). The user needs to wear the wireless goggles and can have three dimensional visual experience. For some groups, this virtual reality goggle will be used to promote the training effect which is demonstrated by other stroke related studies.

6.1 Drug/Device Handling: If the research involves drugs or device, 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.

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Response: SPINDLE will be stored in Furnas 809 or at UBMD where the study will be conducted. Only researchers in this study have access to the device. The device will be handled only by the researchers who are included in this study who have enough knowledge to operate the device. Dr. Jiyeon Kang will make sure that researchers are properly trained before the device is used by the subjects.

6.2 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:

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research 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: This is a Non-significant Risk device according to 21 CFR 812.2(b).

- The risk of the device is minimal: repeated training with/without the robot can be fatiguing subjects. There is a higher chance for the resistive force group subjects. Some subjects who are assigned to the virtual reality group may feel dizzy. If this is the case, the participant is withdrawn from the study immediately.
- The device is NON-INVASIVE: the subject will only hold the handle of the device during tasks similar to activities of daily living.
- This is NOT a drug study.
- Biologic samples are NOT collected.

7.0 Local Number of Subjects

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

Response: 40 (Chronic stroke)

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

Response: 100 (Screen failure rate will be due to vision/cognitive/auditory capability to perform survey or other exclusion criteria. Patients with hemorrhage stroke and Aphasia will also fall in the exclusion criteria for this study. These above capabilities and conditions are assessed by the professional clinicians)

7.3 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:

We typically see between 200-300 patients with stroke in a 4 weeks period at Buffalo General Medical Center (BGMC) and UBMD Neurology clinic. Assuming a conservative 10% of those patients are interested or eligible for the

study, the expected number of patients recruited over a 2 years period is around 500.

This study also includes chronic stroke participants. As this study will be conducted in a college, recruiting 40 subjects will be feasible considering two years of study duration.

8.0 Inclusion and Exclusion Criteria*

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

NOTE: This may be done in bullet point fashion.

Response:

1) Stroke participants (40): Episode of single ischemic stroke past six months (chronic stroke) [23] and over 18 years old. Medically and neurologically stable as assessed by medical history.

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

NOTE: This may be done in bullet point fashion.

Response:

Stroke patients who are in serious uncontrolled medical conditions; excessive pain in any joint of the more affected extremity that could influence participation in the tasks; impossibility to perform at least two tasks with the shortest trajectories in the pre-test of SPINDLE; 45º of shoulder flexion and 45º of elbow flexion to be able to use SPINDLE; dizziness and discomfort by using a virtual reality system. Patients with hemorrhage stroke are excluded as we are targeting homogenous patientgroup as we are only targeting ischemic stroke patients (who are affected blood clot in their brain arteries). We also exclude Aphasia patients as they will be having difficulty in understanding the training process. Once the screening process is completed, participants will undergo practice trials with SPINDLE to ensure their comfort to manipulate the device.

8.3 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

8.4 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: We will exclude non-English speaking individuals. All instructions should be equally provided to the user for consistency. There will be no benefit or therapeutic effect related to this study.

9.0 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.

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

Response:

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

9.2 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.

*9.3 For research that involves **prisoners**, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

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

*9.4 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").

*9.5 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.

*9.6 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:

☒ **N/A:** This research does not involve students, employees of a specific firm or economically or disadvantaged persons.

10.0 Eligibility Screening*

*10.1 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:

For stroke participants, Clinician will evaluate cognitive ability by chart review and then, answering the questionnaire of a screening sheet (see stroke criteria.docx). Hearing issues will be evaluated by asking questions and

answering. Visual issues will be evaluated by asking them to read the first part of the questionnaire. Prior to the participation of the training, participants will try to manipulate SPINDLE to check the required range of motion to perform task.

Data will be only collected from screened participants.

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

11.0 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.

11.1 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:

For stroke patients, potential subjects will be recruited at Buffalo General Medical Center at 100 High Street, Buffalo, NY, 14203, UBMD Neurology clinic at 5851 Main Street, Williamsville, NY, 14221, and UBMD Neurology clinic at conventus, 1001 Main Street, 4th floor. Buffalo, NY, 14203. All patients with stroke get an evaluation by the stroke service. Potential participants will be recruited/informed about the research opportunity during a routine clinical encounter by clinician who will be the part of the research team. Should the subject be interested, a detailed description of the study from the consent document will be provided verbally and in writing and consent will be obtain.

11.2 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: Before explaining the experiment to the potential participants, the examiner will ask the question of whether she or he is interested in participating in this research and want to hear more about the details of the study. The researcher will emphasize that participation in this study is voluntary, and subjects may withdraw at any time with no consequences. Also, the researcher will explain

that there will be a video recording upon the participant's consent. The researcher will explain that the participant does not have to agree to record videos, if they wish to participate in the study only. The recruitment process will be conducted by clinician during the routine check-up. The recruitment process will be performed in a private room of BGMC or UBMD Neurology clinic.

11.3 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:

Participants will be recruited by stroke team at BGMC or UBMD Neurology clinic.

12.0 Procedures Involved*

*12.1 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.

Response:

Participants will be asked to wear comfortable clothing that won't restrict their natural movement. Prior to the data collection, participants will be asked whether they consent or dissent to the video recording. Participant will be randomly assigned to a specific group using Matlab function, but the researcher will assign them to a different group manually if one group has too many participants compared to the other one. Participants are required to wear reflective markers on the whole body to record the motion by a Vicon motion capture system. Markers will be attached on the skin or clothes until they are visible to Vicon system. Similarly, Delsys surface electromyography sensors with embedded IMU are attached to the skin of the participant to record the muscle activation during the active daily living. These sensors are frequently used in clinical trials where study requires human gait analysis and muscle activation analysis. Participants who only provided written consent to the video recording will be recorded during full trials. Study team members will show tutorial video recordings of each activity and will also perform live demonstration to help the participant to understand the task. Later, participant

will practice task trials for about 5 minutes until they feel comfortable to conduct the experiment with the robotic device or the virtual reality goggle. Representative active daily living tasks will be chosen and ask the participant to repeat each task for 10 times. There will be 5 minutes of break provided between tasks. After finishing six representative active living tasks, the study will be completed and the participant can leave the study. Examples of the representative active daily tasks are as follows (Engdahl 2019):

1. Screwing a lightbulb: Participants will have a lightbulb on the table in front of them that is parallel to the table's surface and 75% of arm's length away from the torso. The subject will perform 3 twists counterclockwise, unscrewing the lightbulb from the socket, and will then, performing 3 clockwise twists, screw the lightbulb back into the socket.

2. Screwing a screw: Participants will use a screwdriver to screw a screw into a board flat on the table. The subject will first unscrew the screw with 3 counterclockwise twists and then screw the screw back in with 3 clockwise twists.

3. Drinking water: Participants will first have to reach forward and grasp the cup that is 75% of the arm length from the torso. The subject will then bring the cup to their mouth to mimic drinking water from the cup.

4. Hammer a nail: Participants will first pick up the hammer that lies next to the striking area. The subject will then hammer the area marked as the striking area 3 times.

5. Throwing out the trash: Participants will first grasp a piece of paper crumpled into a ball that is next to them on the table. They will then throw the piece of paper with an overhand throw into a garbage can that is 6 feet away.

6. Combing Hair: Participants will hold a comb when they start the test. They will then comb their hair from back to front 3 times. The subject will then restart the task, but will comb their hair from front to back 3 times.

Except for the control group, the participant will hold the handle and conduct representative daily livings tasks similar to the above examples. The starting and the ending posture of each task will be visually described on a computer monitor. Depending on the group, participants will receive different types of forces. The passive group only receives only a small force to overcome the friction of the device. The active resistance group will receive a small resistance to provide small challenges to perform the task. The active assistance group will receive assistive force from the robotic device similar to the following publication:
J. Kang, S. Logan, J. C. Galloway, and S. K. Agrawal, "A chase-game to teach children on a robot to follow moving objects," in IEEE International Conference on Robotics and Automation (ICRA), 2014, pp. 234–239.

The virtual reality group will wear a HTC Vive Pro Head mount device instead of using a computer monitor for indicating the starting and ending posture. The head strap will be adjusted to fit the head-mounted device to the user. Before the experiment, ten minutes of adjusting time will be provided to the user to ensure they do not feel dizzy by wearing the virtual reality device.

12.2 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: This experiment is a single session study. Reflective, sEMG, and IMU (Inertial Measurement Unit) data will be collected. In addition, the device movement from embedded encoders of the robotic device. All data will be collected during the same day. The video of trials will be recorded for only participants who agreed to take the recording.

12.3 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: Vicon motion capture system, Delsys Trigno sEMG system, and HTC Vive Pro virtual reality system will be used in this study. A robotic device, named SPINDLE, will be used by stroke participants as a potential intervention for stroke patients. (please see the attached document for robotic rehabilitation device - SPINDLE)

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

Response: N/A

*12.5 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: The experimental result will not be shared with the subjects.

*12.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: Anonymous, aggregated results may be shared as posters, presentations, or publications.

13.0 Study Timelines*

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

Response: All data will be collected in two years of a time window.

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

Response: Maximum of four hours will be used to collect the data

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

Response: We expect to collect and analyze the data within two years.

14.0 Setting

14.1 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: A laboratory setting (Furnas Hall Room 809) in the Department of Mechanical and Aerospace Engineering equipped with a Vicon motion capture system, Delsys sEMG system, and HTC Vive virtual reality system. A computer station can control Vicon, Delsys, and virtual reality system all together simultaneously. Research procedures will be also conducted in a private hospital room at Buffalo General Medical Center or UBMD Neurology Clinic.

14.2 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.

15.0 Community-Based Participatory Research

15.1 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.

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

Response:

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

16.0 Resources and Qualifications

*16.1 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:

Jiyeon Kang (PI) has background on rehabilitation robotics and collected biomechanical data of healthy individuals, Parkinson disease, cerebral palsy, and cerebellar ataxia patients. Amit Kandel MD. has practice on various stroke patients and works in Buffalo General Medical Center. Ghazala Saleem has background on occupational therapy and worked with stroke, traumatic injury, and pediatric disorder patients. Student researchers will be get involved this study. Student researchers who are working in this project finished CITI program training to establish a basic knowledge of human subjects research. Amit Kandel MD. will be involved in recruitment and consent.

Describe other resources available to conduct the research.

16.2 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: We estimate that the student PI (Nikhil Kantu) will devote 30% of time to the study and Co-PIs (Jiyeon Kang, Amit Kandel MD and Ghazala Saleem) will devote 10% of their time to the study. The research assistants will devote 30% of their time to the study.

16.3 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: NA. This research only collects the motion and muscle activation data during active daily living tasks or perform similar movement in the robotic device. There should be no negative medical or psychological consequences related to this present study.

16.4 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: Dr. Kang will train all personnel who will conduct human subject studies. Their role will be assigned and informed about the protocol, procedures, and duties. Before starting this study, all staff members will run a dry-run test to practice their knowledge.

17.0 Other Approvals

17.1 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:

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

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 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 be assigned an unidentifiable code when analyzing the data. During the study, the participant can ask questions anytime.

18.2 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: This study does not require any source of information about the subjects except the basic anthropomorphic data such as age, height, and weight.

19.0 Data Management and Analysis*

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

Response: The collected motion capture data will be labeled and filtered with a 4^{th} order Butterworth filter. All sEMG data will be post-processed by bandwidth filter, enveloped, smoothed, and scaled. To define the beginning and the end of each repetition, the speed of the markers is used as a threshold. The data will be time scaled and averaged over different trials.

A comparison between the tasks in the physical world and robotic device will be performed. A two-way ANOVA will be performed to investigate the significant change. Prior to the main analysis, normality assumption will be checked with Kolmogorov-Smirnov test. Two-way ANOVA will be performed for different tasks and experiment conditions. It will be followed by post-hoc analysis to determine whether there is an effect from different tasks that are designed in different experimental conditions. The statistical significance will be defined as $p < 0.05$. Programming software, including Matlab, SPSS, and Labview will be used for the analysis.

19.2 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: This is an investigational pilot study. No power analysis has been performed.

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

Response: The post-processed data will be visually investigated whether all the procedures were properly applied. Outliers will also be detected during this investigation.

20.0 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**.*

*20.1 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: All sensors data and videotape will be stored in a lab computer for at least 3 years in a password protected folder regarding this project. After the data is used in the study, all data will be deleted from the main computer. Only coded data will be reported in research papers, conference presentations and participating research lab meetings.

Recorded videos or pictures will be stored and saved by a coded patient identifier as well. If the portions of the videotapes and pictures are shown to scientific and educational audiences for research and instructional proposes, facial features or specific individual identifiers will be not exposed in the tape/picture provided in such sessions. Videos or pictures will be saved for three years, and then destroyed from the main storage computer.

20.2 A. How long will the data be stored?

Response: All sensors' data and video recording will be stored at least 3 years in a password protected folder regarding this project. After the use of the data/recording, it will be deleted from the main computer.

20.3 A. Who will have access to the data?

Response: Only researchers directly involved in the study will have access to this data. Access will only be available to those working on the project through password protection.

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

Response: Only Dr. Jiyeon Kang will be responsible or the receipt or transmission of the data.

20.5 A. How will the data be transported?

Response: There is a low probability that data will be transported. But if there is a certain need, a password-protected hard drive will be used.

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)*

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

Response:

20.7 B. How long will the specimens be stored?

Response:

20.8 B. Who will have access to the specimens?

Response:

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

Response:

20.10 B. How will the specimens be transported?

Response:

21.0 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.

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

Response: This is a single session study which only records the motion and muscle activation of participants while participants are performing simple daily active tasks with or without the robot. The participants will move the robot by holding the handle to perform tasks similar to activities of daily living, in addition to the virtual reality goggle. The robot has an emergency switch that will be operated in case of any kind of emergency.

After every session study team will review the data to evaluate for no harm caused to the participants. There will be regular weekly meeting with the faculty to discuss any new adverse effects.

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

Response: N/A

21.3 Describe any safety endpoints.

Response: N/A

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

Response: N/A

21.5 Describe the frequency of safety data collection.

Response: N/A

21.6 Describe who will review the safety data.

Response: N/A

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

Response: N/A

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

Response: N/A

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

Response: N/A

22.0 Withdrawal of Subjects*

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

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

Response: The active daily living tasks are quite simple and easy to perform for individuals. Though highly unlikely, if the participant cannot follow the active daily living tasks he or she may be withdrawn from the study. Also, if the participant feels dizzy from the virtual reality system, then she/he will be withdrawn from the study.

22.2 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: An exit interview will be performed if a patient withdrew.

22.3 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: Subjects can leave the research at any time; it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

23.0 Risks to Subjects*

23.1 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: This research involves minimal risk to participants. Though highly unlikely, there can be fatigue by repeating active daily living tasks multiple times or manipulating the robot.
If this is the case, the participant can request a break as much as he/she needs. Also, attaching electrodes on the skin can cause mild skin irritation.

The virtual headset may cause some discomfort such as motion sickness, nausea, or other discomforts, while viewing virtual reality content. Once the participant expresses discomfort, we will stop the experiment and remove the virtual reality headset. These adverse effects are temporary and won't last for long time.

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

Response: Researchers who will perform this study will be trained to ask the participant if the participant feels fatigued every 15-20 minutes.

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

Response: We do not expect any risk in this experimental procedure.

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

Response: We do not expect any risk in this experimental procedure.

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

Response: We do not expect any risk in this experimental procedure.

24.0 Potential Benefits to Subjects*

24.1 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: No direct benefits are expected for subjects in this study.

25.0 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.

*25.1 **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:

25.2 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:

26.0 Economic Burden to Subjects

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

NOTE: Some examples include transportation or parking.

Response: There will be no cost that subjects will be responsible for because of 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.

27.0 Compensation for Participation

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

Response:

☐ **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.

28.0 Consent Process

28.1 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)*

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

Response: The consent form is obtained by PI or researchers in the laboratory located in Furnas Hall Room 809.

28.3 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: The participant will be informed before the consent that he or she can use as much as time as he/she needs. Participants will also be informed to be allowed to ask questions or withdraw the study when she or he felt discomfort during the study.

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

Response: This is a single session study.

28.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. 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)*

28.6 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:

28.7 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, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. 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)*

28.8 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).*

28.9 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)."

28.10 ***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:

28.11 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:

*28.12 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)*

*28.13 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:

*28.14**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:

28.15 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)."

*28.16 Describe 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:

*28.17 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:

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

Response:

29.0 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.

29.1 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:

29.2 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:

30.0 Process to Document Consent

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

30.1 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).

31.0 Multi-Site Research (Multisite/Multicenter Only)*

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

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

Response:

*31.2 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following. See "WORKSHEET: Communication and Responsibilities (HRP-830).":*

- *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 in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

31.3 Describe the method for communicating to engaged participating sites (see "WORKSHEET: Communication and Responsibilities (HRP-830)"):

- *Problems (inclusive of reportable events)*
- *Interim results*
- *Study closure*

Response:

31.4 If this is a multicenter study ***where you are a participating site/investigator****, describe the local procedures for maintenance of confidentiality. (See "WORKSHEET: Communication and Responsibilities (HRP-830).")*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Response:

31.5 If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewheres in the protocol.

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

- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Response:

32.0 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.

*32.1 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:

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

Response:

32.3 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: