| | |
|---|---|
| Title | Surveying stroke patient's current therapy and interest in robotic rehabilitation device |
| IRB Institution | University at Buffalo |
| IRB Approval period | 12/8/21-12/7/22 |
| Note | Version Date appears as 6.23.2021 because the initial approval date was 12/8/2020. There were few modifications in the study team members, age is changed from over 21 to over 18 and acute stroke is changed to stroke. |

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

# Complete Research Protocol (HRP-503)

## Table of Contents

## PROTOCOL TITLE:

*Include the full protocol title.*

Response: Surveying stroke patient's current therapy and interest in robotic rehabilitation device

## PRINCIPAL INVESTIGATOR:

*Name*
*Department*
*Telephone Number*
*Email Address*

Response:

Jiyeon Kang, PhD

Dept. of Mechanical and Aerospace

Room 1011 Furnas Hall, Buffalo, NY 14260

Phone: (716) 645 6063

Fax: (716) 645 2883

jiyeonk@buffalo.edu

## VERSION NUMBER/DATE:

*Include the version number and date of this protocol.*

v.2 June 23 2021

## REVISION HISTORY

| Revision # | Version Date | Summary of Changes | Consent Change? |
|---|---|---|---|
| 2 | June 23 2021 | Team members, age is changed from over 21 to over 18, acute stroke is changed to stroke. | Date/team changed |
| | | | |
| | | | |
| | | | |
| | | | |

## 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 and HIPPA 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** | Surveying patient's interest in robotic rehabilitation device |
| **Study Design** | This study is a survey study targeting stroke patients |
| **Primary Objective** | Investigating the interest of individuals with stroke in a novel robotic device for practicing ADL. |
| **Secondary Objective(s)** | Understanding the need and the current status of stroke rehabilitation |
| **Research Intervention(s)/ Investigational Agent(s)** | This study does not include intervention. |
| **IND/IDE #** | N/A |
| **Study Population** | Stroke patients |
| **Sample Size** | 300 |
| **Study Duration for individual participants** | 2 Years |
| **Study Specific Abbreviations/ Definitions** | ADL: activity of daily living |

## 2.0 Objectives*

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

Response: (1) To investigate the interest of individuals with stroke in a novel robotic device for enhancing the performance of ADL
(2) Understanding the need for and satisfaction of current rehabilitative therapy targeting ADL training in stroke patients.

*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 hypothesize that stroke patients will demonstrate interest in robotic technologies for practicing ADL.

(2a) We hypothesize that stroke patients will demonstrate need for rehabilitative therapy to enhance ADL post-stroke

(2b) We hypothesize that stroke patients will demonstrate decreased satisfaction with current rehabilitative therapy to enhance ADL.

(2)

## 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:

1) Report of receiving current rehabilitation therapy

2) Report of decreased satisfaction with current therapy

3) Frequency and dosage of the therapy

4) Express the need of robotic therapy

## 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:

There are approximately 6.6 million stroke survivors in the United States. Every year about 800,000 individuals experience new or recurrent strokes (Benjamin 2017). Patients with stroke often lose function of their upper limbs and have difficulty performing activities of daily living (ADLs) post-stroke. Furthermore, about 80% of stroke survivors over the age of 65 experience chronic disabilities (Barker and Mullooly 1997). After the onset of stroke, first three months are considered within the crucial time window when most of the arm recovery happens by spontaneous neurologic recovery (Kwakkel 2006). During this acute period, motor learning is a necessary condition for recovery. This learning can be promoted by rehabilitation which can reduce chronic disabilities (Duncan 2003). Occupational therapy (OT) services are often utilized to remediate or restore function of the upper limbs. OT services may include optimizing basic self-care, interaction with family, recreation, and socialization (Steultjens 2003). However, even after completion of standard therapy, up to 75% of individuals experience continuous challenges with ADLs (Sturm 2002). Importantly, four years after the incident of stroke, only 6% of patients are satisfied with the functionality of their impaired arm (Broeks 1999). There is a need to understand whether the therapy is not enough for the stroke patients to perform ADLs. Also, needs of alternative methods such as robotic therapy to address this issue should be investigated.

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 (Mehrholz 2012, Prange 2009) but the consensus in literature demonstrates that these improvements do not always transfer to performance of ADLs (Kwakkel 2008). 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 (Oujamaa 2009 , Timmermans 2009). 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.

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 (Gosselin 1994, Gosselin 1996). 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. In this study, we will understand if patients has high interest in adopting a new robotic therapy at home to improve their activities of daily living.

*4.2 Include complete citations or references.*

Response:

[Benjamin, 2017] Benjamin, E. J., Blaha, M. J., Chiuve, S. E., Cushman, M., Das, S. R., Deo, R., Floyd, J., Fornage, M., Gillespie, C., Isasi, C., et al. (2017). Heart disease and stroke statistics-2017 update: a report from the american heart association. Circulation, 135(10):e146–e603.

[Broeks 1999] Broeks, J., Lankhorst, G., Rumping, K., and Prevo, A. (1999). The long-term outcome of arm function after stroke: results of a follow-up study. Disability and rehabilitation, 21(8):357–364.

[Barker and Mullooly, 1997] Barker, W. H. and Mullooly, J. P. (1997). Stroke in a defined elderly population, 1967-1985: a less lethal and disabling but no less common disease. Stroke, 28(2):284–290.

[Duncan, 2003] Duncan, P., Studenski, S., Richards, L., Gollub, S., Lai, S. M., Reker, D., Perera, S., Yates, J., Koch, V., Rigler, S., et al. (2003). Randomized clinical trial of therapeutic exercise in subacute stroke. Stroke, 34(9):2173–2180.

[Gosselin 1994] Gosselin, C., Sefrioui, J., and Richard, M. J., 1994."On the direct kinematics of spherical three-degree-of-freedom parallel manipulators with a coplanar plat-form".Journal of Mechanical Design,116(2), pp. 587–593.

[Gosselin 1996] Gosselin, C. M., Pierre, E. S., and Gagne, M., 1996."On the development of the agile eye".IEEE Robotics& Automation Magazine,3(4), pp. 29–37

[Kwakkel 2006] Kwakkel, G., Kollen, B., and Twisk, J. (2006). Impact of time on improvement of outcome after stroke. Stroke, 37(9):2348–2353.

[Kwakkel, 2008] Kwakkel, G., Kollen, B. J., and Krebs, H. I. (2008). Effects of robot-assisted therapy on upper limb recovery after stroke: a systematic review. Neurorehabilitation and neural repair, 22(2):111–121.

[Mehrholz, 2012] Mehrholz, J., Hädrich, A., Platz, T., Kugler, J., and Pohl, M. (2012). Electrome chanical 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, (6).

[Oujamaa, 2009] Oujamaa, L., Relave, I., Froger, J., Mottet, D., and Pelissier, J.-Y. (2009). Rehabilitation of arm function after stroke. literature review. Annals of physical and rehabilitation medicine,52(3):269–293.

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

[Sturm 2002] Sturm, J.W., Dewey, H. M., Donnan, G. A., Macdonell, R. A., McNeil, J. J., and Thrift, A. G. (2002). Handicap after stroke: how does it relate to disability, perception of recovery, and stroke subtype? the north east melbourne stroke incidence study (nemesis). Stroke, 33(3):762–768.

[Steultjens, 2003] Steultjens, E. M., Dekker, J., Bouter, L. M., van de Nes, J. C., Cup, E. H., van den Ende, C. H., Landi, F., and Bernabei, R. (2003). Occupational therapy for stroke patients: When, where, and how? Stroke, 34(3):676–687.

[Timmermans, 2009] Timmermans, A. A., Seelen, H. A., Willmann, R. D., and Kingma, H. (2009). Technology-assisted 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, 6(1):1.

## 5.0 Study Design*

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

Response: This is a survey study.

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

Response: There will be no specific intervention in this study.

*5.2 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: N/A

*5.3 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: N/A

## 6.0 Local Number of Subjects

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

Response: 300

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

Response: 400 (Screen failure rate will be due to vision/cognitive/auditory capability to perform survey or other exclusion criteria)

*6.3 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.

## 7.0 Inclusion and Exclusion Criteria*

*7.1 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) Episode of single stroke within the past twelve weeks and 2) Individuals' age over 18 years old.

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

*NOTE: This may be done in bullet point fashion.*

Response:

Pregnant women , neurological disorders other than stroke (i.e. Parkinson's), non-ischemic stroke

Individuals with severe cognitive impairments (demonstrating difficulty to understand, read, and answer the questions in writing)

Individuals with difficulties to listen the instruction and video of the robotic device

*7.3 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

*7.4 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 as this is a pilot study. All instructions should be equally provided to the user for consistency. There will be no benefit or therapeutic effect related to this study.

## 8.0 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.*

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

Response:

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

*8.2 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.

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

Response:

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

*8.4 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").

*8.5 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.

*8.6 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

## 9.0 Eligibility Screening*

*9.1 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:

*Clinician will evaluate cognitive ability by chart review and then, answering the questionnaire of a screening sheet (see modified screening document).*

*Data will be only collected from screened participants.*

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

## 10.0 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.

*10.1 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: 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. 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.

*10.2 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 whether she or he is interested in participating in this research and want to hear more about the study details. The researcher will emphasize that participation in this survey study is voluntary and participants may stop filling the questionnaire at any time with no consequences.

*10.3 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. N/A

## 11.0 Procedures Involved*

*11.1 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 read the questions on paper and mark on the questionnaire to answer. Before starting Part B in the questionnaire, a video showing a user training with a robotic device to practice ADLs is shown to the participant. We will use an electronic frame to show the video to the participant. Participants can spend as much time as they need to finish the questionnaire. If the participant has questions, he/she can answer questions any time regarding the questionnaire.

*11.2 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: The data demonstrating satisfaction, dosage, and frequency of current therapy of stroke patients. We will also investigate the interest in robotic therapy and the potential to use it for home training.

*11.3 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: Please find the attached screening and questionnaire created by PIs.

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

Response: *electronic medical records*

*11.5 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: N/A

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

Response: The collected answers of questionnaire will not be shared with subjects or others, except disclosure via academic publication.

## 12.0 Study Timelines*

*12.1 Describe the anticipated duration needed to enroll all study subjects.*

Response: All data is anticipated to be collected in two years.

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

Response: Approximately twenty minutes.

*12.3 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 three years.

## 13.0 Setting

*13.1 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: Research procedures will be conducted in a private hospital room at Buffalo General Medical Center or UBMD Neurology Clinic.

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*13.2 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: This study will not be conducted outside of BGH at this time.

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

## 14.0 Community-Based Participatory Research

*14.1 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.

*14.2 Describe the composition and involvement of a community advisory board.*

Response:

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

## 15.0 Resources and Qualifications

*15.1 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, consent, and administration of the survey.

***Describe other resources available to conduct the research.***

*15.2 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 PI (Jiyeon Kang) and Co-PIs (Amit Kandel MD and Ghazala Saleem) will devote 10% of their time to the study. The research assistance will devote 30% of their time to the study.

*15.3 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: This research only collects answer of questionnaires. The minimal risk is to invoke frustration by reading and understanding the questionnaires. Some participants may feel boredom by answering the questionnaires.

*15.4 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: All personnel who will conduct human subject studies will be trained. Their role will be assigned, and they will be informed about the protocol, procedures, and duties. Before starting this study, all staff members will participate a dry-run test to practice their knowledge.

## 16.0 Other Approvals

*16.1 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.

## 17.0 Provisions to Protect the Privacy Interests of Subjects

*17.1 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 or stop answering the questionnaire anytime.

*17.2 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: Subjects private clinical information will be review by the attending neurologist as part of routine stroke care. The use of this information for the present study will only be done once the subject has consented to be a part of the study.

The consent and HIPAA forms will be signed by the participant before the study. Amit Kandel will have access to the clinical chart to access information needed for this study.

## 18.0 Data Management and Analysis*

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

Response: Descriptive statistics will be computed to examine the demographic of the sample. Frequency statistics will be carried out to assess percentages of responses in each category. We will use Chi-square statistics to examine the relationship between satisfaction with current therapy and the interest in robotic therapy. If a relationship exists between the two variables, we will compute logistic regression to examine if decreased satisfaction in current therapy predicts high interest in the robotic device.

*18.2 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:

*18.3 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 proceeded. Outliers will be also detected during this investigation.

## 19.0 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**.*

*19.1 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: The file linking subjects' name to ID will be in paper form and will be stored in a locked file cabinet inside PI's laboratory along with signed consent forms. The rest of the data will be stored in a password protected computer in Furnas 809 which does not have internet connection. Password will be disclosed only to individuals who are related to this project. After the mandatory 3 years of data retention, the questionnaire will be shredded. Only coded data will be reported in research papers, conference presentations and participating research lab meetings.

*19.2 A. How long will the data be stored?*

Response: The file linking subjects' name to ID will be retained until the end o f the stujdy. It will be destroyed afterwards. All data will be stored at least 3 years in a password protected folder regarding this project. After the mandatory 3 years of data retention, the data can be deleted from the password protected computer in Furnas 809 which does not have internet connection.

*19.3 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.

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

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

*19.5 A. How will the data be transported?*

Response: There is a very low chance to transport the data. 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)*

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

Response:

*19.7 B. How long will the specimens be stored?*

Response:

*19.8 B. Who will have access to the specimens?*

Response:

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

Response:

*19.10 B. How will the specimens be transported?*

Response:

## 20.0 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.***

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

Response: N/A for questionnaire study

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

Response: N/A

*20.3 Describe any safety endpoints.*

Response: N/A

*20.4 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

*20.5 Describe the frequency of safety data collection.*

Response: N/A

*20.6 Describe who will review the safety data.*

Response: N/A

*20.7 Describe the frequency or periodicity of review of cumulative safety data.*

Response: N/A

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

Response: N/A

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

Response: N/A

## 21.0 Withdrawal of Subjects*

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

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

Response: Though highly unlikely due to the short questionnaire , the participant may get tired by reading the questionnaire. He or she may be withdrawn from the study.

*21.2 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: This study does not include any drug or clinical intervention.

*21.3 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: There will be no retention from this study as this study does not include any drug or clinical intervention.

## 22.0 Risks to Subjects*

*22.1 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: We do not expect any risk in this questionnaire study.

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

Response:

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

Response: We do not expect any risk in this questionnaire study.

*22.4 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 questionnaire study.

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

Response: We do not expect any risk in this questionnaire study.

## 23.0 Potential Benefits to Subjects*

*23.1 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. The information obtained from this study will provide a better understanding of how stroke patients perceive the current therapy.

## 24.0 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.

*24.1 **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:

*24.2 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:

## 25.0 Economic Burden to Subjects

*25.1 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.

## 26.0 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.

## 27.0 Consent Process

*27.1 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)*

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

Response: Consent is obtained in a private hospital room at Buffalo General Medical Center.

*27.3 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 be also informed to be allowed to ask questions or withdraw the study when she or he felt discomfort during the study.

*27.4 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 onetime questionnaire study.

*27.5 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)*

*27.6 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:

*27.7 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)*

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

Response: Clinician will evaluate cognitive ability by chart review and then, answering the questionnaire using of a screening sheet (see modified screening document )

***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).*

*27.9 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)."

*27.10* ***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:

*27.11 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:

*27.12 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)*

*27.13 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:

*27.14**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:

*27.15 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)."*

*27.16 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:

*27.17 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:

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

Response:

## 28.0 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.

*28.1 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:

*28.2 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:

## 29.0 Process to Document Consent

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

*29.1 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).

## 30.0 Multi-Site Research (Multisite/Multicenter Only)*

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

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

Response:

*30.2 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:

*30.3 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:

*30.4 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:

*30.5 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:

## 31.0 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.

*31.1 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:

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

Response:

*31.3 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: