**Institutional Review Board**

**Intervention/Interaction Detailed Protocol**

Principal Investigator: Dr. Paolo Bonato

Project Title: Video-based Motion Analysis and Assessment of Home Based Exercises for Upper Limb Rehabilitation of Stroke Survivors

Version Date: March 21, 2023

Version Name/Number: 01

*For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.*

1. **Background and Significance**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

* Summarize relevant literature, data, and historical background
* Describe previous pre-clinical or clinical studies leading up to and supporting the proposed research
* Describe rationale behind the proposed research and significance to patients, society, and/or science

***ENTER TEXT HERE***

1. **Specific Aims and Objectives**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

* Specify objectives and hypotheses to be tested in the research project

***ENTER TEXT HERE***

1. **General Description of Study Design**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

* Explain the basic study design, e.g., parallel group, randomized controlled trial, open-label single arm study, cross over, adaptive, etc.
* Provide study schema as applicable (a schema is required for greater than minimal risk studies, and optional for minimal risk studies

***ENTER TEXT HERE***

1. **Subject Selection**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

Describe sources of subjects and procedures for subject selection, including the following:

* Inclusion/Exclusion Criteria
* Local Recruitment Procedures:

Explain in detail the methods and procedures you will use to recruit participants. Describe in a step-by-step procedure below:

* + How individuals are identified for recruitment including description of use of recruitment materials such as flyers, brochures, advertisements, letters, etc.
  + Who is responsible (role on research team) for identifying and recruiting individuals
  + When individuals are recruited
  + Where individuals are recruited
  + How recruitment goals match the prevalence rates of the condition/disease being studied and the populations most impacted by the condition/disease being studied
  + Methods to enhance enrollment of diverse individuals and under-represented populations

***ENTER TEXT HERE***

1. **Subject Enrollment**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

* Describe any pre-screening procedures as applicable. Indicate whether subjects will be prescreened over the phone and/or will be asked to provide separate informed consent specific to screening procedures.
* Describe in a step-by-step procedure the consent process including:
  + When and where informed consent will be obtained (including description of any electronic consenting procedures)
  + A separate description for adults and children if applicable
  + The process for obtaining consent from non-English speakers if applicable
  + The process to determine capacity to consent and use surrogate decision makers if applicable
  + Procedures to minimize undue influence to enroll, particularly if recruiting the investigators’ own patients
* Describe post-consent intervention assignment and randomization method if applicable

***ENTER TEXT HERE***

1. **STUDY PROCEDURES**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

Provide detailed description of all study visits, procedures, and data collections, including:

* Description of each study visit and procedures at each visit (include a schedule/table of study procedures)
* Description of study drugs, devices, or other interventions/exposures administered, including:
  + Dose, method of administration, schedule of administration, dose modifications
  + Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications (“off-label”): How are doses, routes of administration, or participant populations different from FDA approved indicated use?
* Description of specific data variables to be collected, including data collection methods, assessments, data collection sheets, and/or schedule of assessments (A schedule/table of study assessments is preferred)
* Description of planned genetic research as applicable (e.g., specific description of whole genome sequencing, creation of immortalized cell lines or induced pluripotent stems cells, and sharing of genetic material with collaborators and central repositories as applicable, etc.)
* Description of plans for return of research results as applicable (e.g., specific description of, rationale for, and process by which research results will be returned, including to whom, by whom, and when, etc.). Include plans for managing incidental findings as applicable.
* Definition of primary and secondary outcomes/endpoints. Note that outcome measures should be quantifiable and measurable.
* Definition of study termination criteria, e.g., objective criteria for clinical worsening, lack of improvement, and/or unacceptable adverse events
* Local site restrictions or site-specific procedures as applicable, including:
  + Description of how study procedures (e.g. intervention or diagnosis) compare to standard of care, including description of alternative treatments, procedures, or methods of diagnosis
  + Description of what happens to participants receiving therapy when study ends or if a participant’s participation in the study ends prematurely.
  + For studies that are conducted entirely internationally, describe the nature of the involvement of investigators at each site in the study, i.e., indicate which personnel will be present at the international site(s) and describe the nature of their involvement, including which staff will have direct contact with subjects and/or perform any study related procedures and which staff will have access to study data and perform data analysis
* Remuneration as applicable. Indicate if payments to subjects are made upon completion of study visits/certain procedures and how remuneration is pro-rated, particularly for non-completers
* Description of plans for sending and/or receiving specimens or data with research collaborators outside Mass General Brigham or with NIH (e.g., dbGaP) or other tissue/data repositories (include details of identified versus de-identified sharing, how data or specimens are labeled/coded, secure transfer method, external IRB approval as applicable, storage for future use, secure transfer method, etc.)

***ENTER TEXT HERE***

1. **Risks and Discomforts**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

Provide detailed description of potential risks of each study-related procedure/intervention, including:

* Complications of surgical and non-surgical procedures
* Drug side effects and toxicities
* Device complications/malfunctions
* Psychosocial risks
* Privacy/confidentiality risks
* Genetic research risks
* Radiation risks
* Include description of steps taken to decrease relevant risks, including the following:
* How procedures used are consistent with sound research design and do not expose unnecessary risks
* When appropriate, researchers use procedures already being performed on subjects for diagnostic or treatment purposes

***ENTER TEXT HERE***

1. **Benefits**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

Provide detailed description of potential benefits of study participation, including:

* Either describe potential benefits to participating individuals or clearly state that there is no direct benefit to individuals
* If multiple subject populations are to be enrolled, describe any differences between groups with regard to potential benefit (e.g. potential for benefit to an affected subject population versus no potential benefit for healthy controls, etc.)
* Potential benefits to society (e.g., increased understanding of disease process, etc.)

***ENTER TEXT HERE***

1. **Statistical Analysis**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

Describe plans for statistical analysis, including:

* Statistical methods/data analysis plan
* Power analysis (e.g., sample size, evaluable subjects, etc.)

***ENTER TEXT HERE***

***ENTER TEXT HERE***

*ENTER TEXT HERE*

1. **Monitoring and Quality Assurance**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

Describe the plans that will be followed by study staff for monitoring and quality assurance, including:

* Adverse event criteria and reporting procedures
* Planned safety monitoring, e.g., data monitoring committee (DMC)/data and safety monitoring board (DSMB), independent monitor, PI-monitored, etc., including planned frequency of review. If DMC/DSMB monitored, include either charter as separate attachment or complete DMC/DSMB [APPENDIX](#APPENDIX)
* Outcomes monitoring, including planned frequency of review.
* Study stopping rules as applicable
* Internal monitoring of source data, protocol adherence, and recordkeeping, including which staff will be responsible and planned frequency of review
* Independent monitoring of source data as applicable
* Description of data management methods

***ENTER TEXT HERE***

1. **Privacy and Confidentiality**

**INSTRUCTIONS**

***Delete grey Instructions box upon completion of this section***

* Select the Privacy and Confidentiality measures that apply to this research by checking the box next to each statement (Check all that apply)
* Note that not all of the measures outlined below may apply to your study
* Do not delete statements that do not apply to your study; leave the boxes unchecked
* Describe any additional privacy and/or confidentiality measures that are not captured by the check box items in free text following the check boxes

Study procedures will be conducted in a private setting

Only data and/or specimens necessary for the conduct of the study will be collected

Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)

Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)

Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol

Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)

All electronic communication with participants will comply with Mass General Brigham secure communication policies

Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research

All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens

The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research

Additional privacy and/or confidentiality protections

***ENTER TEXT HERE***

**12. References**

***ENTER TEXT HERE***

**[APPENDIX](#APPENDIX) A**

**Data Monitoring Committee / Data and Safety Monitoring Board**

**Appendix**

* *To be completed for studies monitored by Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) if a full DMC/DSMB charter is not available at the time of initial IRB review.*
* *DMC/DSMB Charter and/or Roster can be submitted to the IRB later via Amendment, though these are not required.*

A Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) will be convened for safety monitoring of this research study. The following characteristics describe the DMC/DSMB convened for this study (Check all that apply):

The DMC/DSMB is independent from the study team and study sponsor.

A process has been implemented to ensure absence of conflicts of interest by DMC/DSMB members.

The DMC/DSMB has the authority to intervene on study progress in the event of safety concerns, e.g., to suspend or terminate a study if new safety concerns have been identified or need to be investigated.

Describe number and types of (i.e., qualifications of) members:

Click or tap here to enter text.

Describe planned frequency of meetings:

Click or tap here to enter text.

DMC/DSMB reports with no findings (i.e., “continue without modifications”) will be submitted to the IRB at the time of Continuing Review.

DMC/DSMB reports with findings/modifications required will be submitted promptly (within 5 business days/7 calendar days of becoming aware) to the IRB as an Other Event.