PROTOCOLS

#2508 - Comparing different rehabilitation exercise strategies for improving arm recovery after stroke

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Expedited	**Approved**	**Mar 10, 2025**	**--**

Expiration Date	Initial Approval Date	Initial Review Type
Mar 09, 2026	**Apr 28, 2023**	**Full Board**

Feedback

Approval Comment

The IRB Approval Letter and any approved documentation (e.g., stamped consent forms) can be downloaded in the Attachments section of the protocol.

Protocol Renewal Form

Renewal Information

Protocol Type

Are you submitting a renewal for an IRB, sIRB, or hSCRO protocol?

IRB (UCI is the IRB of Record)

IRB Renewal Instructions

Timing of Submission

Exempt and Expedited IRB protocols must submit a short version of the renewal every three (3) years unless determined otherwise by the IRB. Investigators should plan ahead and submit 60 days prior to the study's expiration date.

Full Committee IRB protocols must submit a renewal at least annually (not more than 365 days). Investigators should plan ahead to meet required continuing review dates. For full committee review protocols, please submit 90 days prior to the expiration date to guard against a lapse in IRB approval.

Amendments at the Time of Renewal

Please refrain from making major changes during the renewal as this could result in a lapse of IRB approval.

Protocol Closure

To close out an approved protocol at the time of renewal, the transaction must be submitted as Request Close. If this option was not initially selected and closure is required, please Abandon the draft and start again. For more information, visit Post-Review Responsibilities and select the Protocol Renewal Tab.

Renewal Screener

Does any of the following apply to the currently approved protocol:

- **research involves Greater than Minimal Risk (Full Committee)**
- **research is subject to Food and Drug Administration (FDA) regulations**
  - **Involves a drug**
  - **A clinical investigation of a medical device**
- **research is funded/supported by the Department of Justice (DOJ)**
- **current approval period is 1 year or less**

Yes (Continuing Renewal Required)

Protocol Expiration

Protocol Expiration

Has approval for this protocol expired or will it expire within 3 weeks?

No

Confirmation of Protocol

Study Team

Review the Study Team Section and consider whether anyone should be removed at this time via an Amendment.

RP Heat Map

Are RP tracked outside the approved protocol, in accordance with the RP Heat Map?

Yes, RP are tracked on a Study Team Log or other comparable log

Financial Interests

Review the Study Team section and specify below if there have been any changes in the study team's related financial disclosable interests.

See Conflict of Interest Oversight Committee (COIOC) for more details.

No, there have been no changes to the study's teams related disclosable financial interests

Relying Non-UCI Entity (as applicable)

When UCI is the IRB of Record for a non-UCI entity (i.e., site or independent investigator), review the sIRB section and remove any non-UCI entities (site or independent investigator) that are no longer *engaged* in research via an Amendment.

Clinicaltrials.gov Status

ClinicalTrials.gov Registration

Does this research meet the definition of a clinical trial that requires adherence to Clinicaltrials.gov (CT.gov)?

Yes

Confirm the accuracy of ClinicalTrials.gov section in the IRB protocol (select one):

Please review the ClinicalTrials.gov section in the IRB protocol to verify that the information is still accurate.

If any revisions are required, please submit an amendment to request a 'Change in Clinicaltrials.gov' and update the the protocol accordingly.

As lead researcher, I confirm that the CT.gov information is accurate as indicated in the protocol

Specify who is responsible for registering, maintaining, and updating the CT.gov record:

UCI Investigator

Confirm the accuracy of the information on the ClinicalTrials.gov Protocol Registration and Results System (PRS):

IMPORTANT! Per federal requirements (42 CFR 11.64(a)(1)(ii)), clinical trial registration information on PRS must be updated not less than once every 12 months.

Please review the information on PRS to verify that the following fields are accurate and up to date:

- **Study Status:**
  - **Record Verification Date: Not less than every 12 months, enter the date on which the responsible party last verified the clinical study information on PRS, even if no additional or updated information was submitted.**
  - **Overall Recruitment Status: 30 calendar days after a change in overall recruitment status, enter the status for the clinical study as a whole, based upon the status of the individual sites. If at least one facility in a multi-site clinical study has a status of "Recruiting," then the overall status for the study must be "Recruiting."**
  - **Primary Completion Date: 30 calendar days after the clinical trial reaches its actual primary completion date, enter the date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes. IMPORTANT! This date cannot be in the past, please revise the date as necessary.**
  - **Study Completion Date: 30 calendar days after the clinical trial reaches its actual study completion date, enter the date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant's last visit), whether the clinical study concluded according to the pre-specified protocol or was terminated. IMPORTANT! This date cannot be in the past, please revise the date as necessary.**
- **Oversight:**
  - **Human Subjects Review Board Status: 30 calendar days after a change in status, ensure the status of IRB approval information is accurate.**
- **Contacts, Locations, and Investigator Information: 30 calendar days after a change, ensure the information is accurate.**

As leader researcher, I confirm that the clinical trial information (listed above) on PRS is accurate and up to date.

Enrollment Status

Accruals

Please mark the option that represents the current status of subject enrollments:

Enrollment and research procedures complete - only access to identifiable data / data analysis ongoing

Subject Enrollments

Please confirm the total number of subjects (i.e. individuals, specimens, records) approved by the UCI IRB in the Subject Populations section.

Indicate the number of new subjects enrolled since last IRB review:

2

Indicate the total number of subjects (including the number in the previous question) enrolled since initial UCI IRB approval:

2

Did the total number of subjects enrolled to date exceeds the total number approved by the IRB?

No

Indicate the total number of subjects enrolled per group since initial IRB approval:

Man (total):
22

Woman (total):
15

Nonbinary (total):
0

Not Collected (total):
0

Adults (total):
37

Minor (total):
0

Multi-Center Studies: If known, indicate the total number of subjects enrolled at ALL sites to date:

For Rancho Los Amigo Rehab Center: 10 Males and 2 Females - total of 12 participants. For Casa Colinas Rehab Center: 10- males, 13 females - total of 23 participants

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Subject Withdrawals

Early Termination(s)

Did the Lead Researcher or a Co-Researcher remove any subject(s) from the study?

No

Voluntary Withdrawal(s)

Did any subject(s) voluntarily withdraw from the study?

No

Reportable Events

Reportable Events

Have there been any problems that required prompt reporting to the UCI IRB?

No problems that require reporting

Complaints

Have there been any complaints from UCI participants or others that required reporting to the UCI IRB?

No

Progress Report

UCI Progress

Please provide a detailed description of the progress of the study, including a brief summary of any interim findings or trends, and plans for the next approval period:

We have completed our recruitment and enrollment for our study. All study procedures and follow up assessments have been completed. We are in the process of performing data analysis and manuscript preparation.

Relying Entity Progress (as applicable)

If UCI is the IRB of Record for a non-UCI entity, provide a progress report for each relying entity (e.g., number of participants enrolled at the sub-site; data analysis performed, if any, etc):

0

Sponsor Multi-Center Progress (as applicable):

Is a multicenter progress report / newsletter is available from the Sponsor?

No

Provide any available information related to multi-center progress from the Sponsor:

We are in the process of data analysis and will generate a final report and manuscript from the study.

Internal and External Audits

Internal Audit(s)

Have any internal (UCI/UCI Health) audits occurred since last IRB review?

No

External Audit(s)

Have any external (FDA/OHRP/Sponsor) audits occurred since last IRB review?

No

Risk and Safety Assessments

Relevant Recent Literature

During the past year has there been anything in relevant literature that the IRB should consider when reviewing this application for continuing approval?

No

Current Risk/Benefit Assessment

Has there been a change in risk/benefit?

Take into account the information gathered during the past year such as interim results, reportable events/problems, changes in scientific knowledge, and/or relevant regulatory actions regarding study-wide safety and/or efficacy (e.g., product recall). This assessment should be sufficiently detailed to assist the IRB in determining whether continuation of IRB approval is appropriate.

No

Data Safety Monitoring Board (DSMB)

Has there been any new DSMB findings relating to subject safety?

Not applicable

Investigator's Brochure (IB)

For FDA regulated drug studies, enter the current version number and date of the Investigator's Brochure in the Supplemental Documents section.

End of renewal form!

IMPORTANT! Go to the next section to complete the amendment form.

Protocol Amendment Form

Amendment Instructions

Specify the type of submission:

RENEWAL: This is a renewal that does not require changes to the approved protocol

End of amendment form!

Project Details

Project Title (100 words max):

Comparing different rehabilitation exercise strategies for improving arm recovery after stroke

Lead Researcher/Investigator:

An Hong Do

Lead Unit (i.e., Department, Organized Lead Unit, Center or Institute):

IR-7455 - NEUROLOGY (Lead Unit)

Kuali Research (KR) follows the KFS Organizational Unit Hierarchy.

ATTENTION! For new submissions, Department Chair (DC) or Organized Lead Unit Director (OLUD) sign-off in KRP is required before final committee approval will be granted. For more information, visit the listserv.

Submission Screener

Submission Type:

IMPORTANT! Be sure to select the correct 'Submission Type'. When 'Submission Type' is changed, the contents of the form will be cleared and replaced with a set of new questions specific to the submission type.

Institutional Review Board (IRB) Review

Lead Researcher's primary school/department/program is:

Biomedical (Health Sciences)

Select the level of review for this protocol:

Greater than Minimal Risk (Full Committee)

Is this expanded access, humanitarian use device, or right to try?

Not applicable

Specify who initiated/authored the project:

Investigator

Is this study an extension of a UCI IRB approved study (e.g., resubmission of ongoing exempt research; open label extension) or is it otherwise related to a UCI IRB approved study?

No

Supplemental Documents

Does this study include a Sponsor's Master Protocol (MP) or detailed project proposal?

No

Project Funding

Select the funding source(s) (check all that apply):

Grant/Contract

Select the sponsor type(s) (check all that apply):

National Institutes of Health (NIH)

Clinical Trials

Is the research a *clinical investigation*?

A *clinical investigation* is any experiment that involves a *test article* and one or more *human subjects*, and that meets any one of the following:

- **Any administration of approved drugs for research purposes that is not according to their approved indications, route of administration, population, or dose**
- **Any activity that evaluates the safety or effectiveness of a medical device**
- **Any activity the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit**

An individual becomes a *human subject* for FDA purposes if their data or specimens are used as the recipient of the test article or control. For example, when retrospective data are used as the control, the individuals become human subjects. Likewise, when an individual's blood sample is used to test an assay, the individual becomes a human subject.

Yes

Clinicaltrials.gov

Registration on ClinicalTrials.gov may be required if one (or more) of the following is true:

- **Study meets the definition of an Applicable Clinical Trial (ACT) (ACT Checklist)**
- **Study is NIH funded and meets the NIH definition of a clinical trial**
- **Study is DoD funded and registration is required by your specific program**
- **Study meets the International Committee of Medical Journal Editors (ICMJE) definition of a clinical trial**
- **Study includes reimbursement of Medicare claims**

Does this research meet the definition of a clinical trial that requires adherence to Clinicaltrials.gov (CT.gov)?

Yes

Specify the rationale for CT.gov registration (check all that apply):

NIH funded clinical Trial

Provide the CT.gov registration NCT # (Enter 8-digit sequence of numbers only):

NCT05880940

ATTENTION! All clinical trials initiated at the School of Medicine (SOM) must be performed under the auspices of an Organized Lead Unit (OLU).
Go to Project Details and choose the appropriate OLU for the trial.

Scientific/Scholarly Review

Investigator-authored research involving greater than minimal risk to subjects (full board review) requires scientific/scholarly merit prior to IRB review - with few exceptions.

The following options identify the scientific merit process for the proposed research and the order of IRB review. Researchers should work with their Departments and the applicable committee (e.g., PRMC) to coordinate the review of their projects, as necessary.

The proposed research qualifies as greater than minimal risk, investigator-initiated biodmedical research.

REQUIRED! Review from the Biostatistics, Epidemiology and Research Design (BERD) unit of the Institute for Clinical and Translational Science (ICTS) is required. The UCI IRB staff will coordinate the review in conjunction with the expertise of the BERD.

Please click on the following link to arrange a consultation with one of the ICTS BERD Statisticians: ICTS BERD Statisticians - Consultations.

Is the research cancer-related?

No

Other UCI Committee Reviews

Research involving human subjects sometimes requires the approval or authorization of Other Reviews Required by UCI (e.g., School of Medicine Review Committees).

Additional Review by the following Committees *may* be required prior to IRB review:

- **Human Stem Cell Oversight (hSRCO) Committee**
- **Institutional Biosafety Committee (IBC)**
- **Radiation Safety Committee (RSC)**

For a list of all ancillary committees, their requirements and how they relate to the IRB review process, refer to the Other UCI Required Reviews Chart.

Potentially Hazardous Materials

Specify if any of the following hazardous materials are used for research-related purposes (i.e., not for standard of care) (check all the apply):

Not Applicable

Study Team

- **Lead Researcher (LR): The LR must meet LR Eligibility requirements or have a Faculty Sponsor (FS) listed who is eligible.**
- **Co-Researcher (CR): CRs are key personnel for conducting the research study. These individuals work closely with the LR to design, conduct, and/or report on the research.**
- **Research Personnel (RP): Review the RP Heat Map to determine whether they should be listed below.**
- **Administrative Contact (AC): Add ACs in the Permissions tab. Do NOT list below.**
- **Non-UCI researchers: Address non-UCI researchers in the Single IRB Reliance (sIRB) section. Do NOT list below.**

All study team members must complete the following Collaborative Institutional Training Initiative (CITI) trainings:

- **Human Subjects Research Protections and**
- **Good Clinical Practice, as applicable**

Incomplete or expired CITI training will delay IRB approval. For more information, visit HRP Training and Education.

Researcher:

An Hong Do

Email:

and@uci.edu

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Training

GCP for Clinical Investigations of Devices - Refresher Course 03/23/17 - 03/22/20 Expired	GCP for Clinical Investigations of Devices - Basic Course 11/10/22 - (no expiration)
GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA focus) - Basic Course 10/26/21 - 10/25/24 Expired	GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA focus) - Refresher Course 03/23/17 - 03/22/20 Expired
Biomedical Investigators - Refresher Course	11/10/22 - (no expiration)

Degree:

MD

Degree Other:

Position/Title:

Associate Professor

IR-7455 - NEUROLOGY (Lead Unit)

Affiliation:
UCI Faculty

Specify other UCI affiliation:

Researcher Role:
Lead Researcher

Permissions:
Full Access

Duties:
Oversight of Research
Screen/Recruit Subjects
Finalize Informed Consent
Access/Analyze Identifiable Information

Specify which research procedures:

Specify relevant training and experience for the referenced duties/responsibilities:
Will oversee all aspects of the project. Dr Do graduated with MD from UCLA/UCR, and underwent neurology residency at UCI, and Spinal Cord Injury/Neurorehab fellowship at UCI, LBVA, and Rancho Los Amigos National Rehabilitation Center. Will have access to subject identifiable data and will consent subjects

Researcher:
David J Reinkensmeyer

Email:
dreinken@uci.edu

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

“Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"
Yes

Training

GCP for Clinical Investigations of Devices - Refresher Course 12/16/20 - 12/16/23 Expired	GCP for Clinical Investigations of Devices - Basic Course 12/15/23 - (no expiration)
Biomedical Investigators - Basic Course	03/23/22 - 03/22/27

Degree:
PhD

Degree Other:

Position/Title:
Professor

IR-7338 - MECHANICAL AND AEROSPACE ENGINEERING (Lead Unit)

Affiliation:
UCI Faculty

Specify other UCI affiliation:

Researcher Role:
Co-Researcher

Permissions:
Full Access

Duties:
Screen/Recruit Subjects
Finalize Informed Consent
Access/Analyze Identifiable Information
Access/Analyze Identifiable Biospecimens

Specify which research procedures:

Specify relevant training and experience for the referenced duties/responsibilities:

Dr. Reinkensmeyer has experience in human subjects' research in the areas of biomechanics, neural control of movement, and rehabilitation. His Ph.D. work in Electrical Engineering at U.C. Berkeley involved research into human hand and wrist movement, and rehabilitation devices for stroke patients. Before joining UCI as an Assistant Professor in Mechanical and Aerospace Engineering in 1998, he was a Research Assistant Professor in the Department of Physical Medicine and Rehabilitation at Northwestern University Medical School, and a Senior Research Scientist at the Rehabilitation Institute of Chicago. The RIC has been recognized for over ten years by U.S. News and World Report as the nation's top rehabilitation hospital, and has an internationally recognized program in research to aid individuals with a disability. At the RIC, he received training in pathophysiology and biomechanics of neurologic impairment, and performed experiments with individuals with stroke, cerebral palsy, and traumatic brain injury, using several novel mechatronic devices he designed. Dr. Reinkensmeyer has continued this line of research at UCI, developing several robotic systems for retraining movement after stroke and spinal cord injury. Will have access to subject identifiable data

Researcher:

WaiKi Vicky Chan

Email:

vchan2@uci.edu

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

“Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Training

GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA focus) - Basic Course 11/17/23 - (no expiration)	GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA focus) - Refresher Course 12/18/20 - 12/18/23 Expired
Biomedical Investigators - Basic Course 09/30/24 - (no expiration)	Biomedical Investigators - Refresher Course 10/14/19 - 10/12/24 Expired

Degree:

Other

Degree Other:

PT, DPT

Position/Title:

Physical Therapist

Physical Therapy - IP

Affiliation:
UCI Staff

Specify other UCI affiliation:

Researcher Role:
Co-Researcher

Permissions:
Full Access

Duties:
Screen/Recruit Subjects
Finalize Informed Consent
Access/Analyze Identifiable Information
Access/Analyze Identifiable Biospecimens
Research Procedures (specify below)

Specify which research procedures:
Will assist in recruiting stroke subjects, will assist in all testing with stroke subjects, and will assist in data collection and analysis. Will have access to subject identifiable data and will consent subjects.

Specify relevant training and experience for the referenced duties/responsibilities:
Ms. Chan graduated from Texas Woman's University with a BS in Human Biology/ Magna Cum Laude and MS in Physical Therapy. She has completed her Doctor of Physical Therapy from the University of Montana. She worked as the primary physical therapist at the acute rehabilitation unit at UCI. She has worked as study coordinator for the Bio-robotics Laboratory for ten years overseeing over five clinical trials. Will assist in recruiting stroke subjects, will assist in all testing with stroke subjects, and will assist in data collection and analysis. Will have access to subject identifiable data and will consent subjects

Are RP tracked outside the approved protocol, in accordance with the RP Heat Map?

Yes, RP are tracked on a Study Team Log or other comparable log

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sIRB Screener

Is a non-UCI investigator and/or their site engaged in human subjects research activities (e.g., interact with subjects; have access to identifiable information)?

No

Non-Technical Summary

Provide a non-technical summary of the project that can be understood by non-scientists (250 words max):

Stroke is a leading cause of chronic disability with 6.8 million survivors currently living in the United States, and an annual cost over $50 billion. An estimated 40% of people with a stroke live with moderate to severe impairment of their upper extremity [1-3]. One likely reason the percentage of people who end up with nonfunctional arms is so disappointingly high is that the number of arm movement repetitions provided as part of standard of care rehabilitation therapy is very small, especially early after stroke during their heightened period of brain plasticity. This is in part because practicing rehabilitative movements with a very weak upper extremity is difficult. There is a shortage of technologies that successfully address this problem of too low a dose of arm movement, especially among the large population of stroke survivors with more severe deficits. The goal of this study is to test a new lever drive movable wheelchair arm rest device that facilitates a person performing high amounts of practice with the severely impaired upper extremity (UE) during early stroke recovery. We will randomize a total of 58 individuals with a subacute stroke to exercise using a movable wheelchair arm rest device or receive additional conventional therapy during their inpatient stay, in addition to their normal rehabilitation. We hypothesize that the individuals who use the movable wheelchair arm rest device to exercise the arm will improve a measure of their upper extremity movement ability more than the control group as assessed at a follow-up evaluation.

Background & Purpose of Research

Describe the purpose, specific aims or objectives and specify the hypotheses or research questions to be studied:

For this study, we hypothesize that use of movable wheelchair arm rest device during inpatient therapy will lead to significantly greater improvements in UE motor recovery than conventional treatment. (For a demonstration video of the movable wheelchair arm rest device, please visit: https://youtu.be/RfbaOGhJfug). Our Aim is to perform a randomized controlled trial of the movable wheelchair arm rest device with inpatients with subacute stroke in three different inpatient rehabilitation facilities (N=58; Months 6-24). UCI will be one of the study sites. Rancho Los Amigos Rehabilitation center and Casa Colina Hospital and Centers for Healthcare will potentially be the other two study sites. We are in the process of negotiating the contracts between sites. Participants will be >3 days and <3 weeks post-stroke, with initial FM scores <4239. Participants will be randomized to receive the movable wheelchair arm rest device or an electronic exercise program and instructed to practice moving their arm between therapy sessions. The primary outcome measure will be change in FM score from baseline to three-months post-stroke. We hypothesize that participants who receive movable wheelchair arm rest device will have significantly greater improvements in FM score than control ($p<0.05$, RM-ANCOVA) without an increase in pain or spasticity, if they exceed the putative threshold of UE motor drive needed for recovery16. Success Criteria**:** A significantly greater increase in FM of >4.25 points (the FM MCID40) between movable wheelchair arm rest device and control at three months.

At project end, we will have validated the clinical feasibility and efficacy of the movable wheelchair arm rest device and optimized it for production and mass distribution. If our plan is successful, we will have demonstrated that wheelchair-based “rocking therapy” can help patients routinely achieve the threshold level of sensory motor drive needed to provoke true UE recovery.

Provide the scientific or scholarly rationale for the research and describe the relevant background information and the specific gaps in current knowledge that this study intends to address:

One in six people will have a stroke; over half will incur chronic upper extremity (UE) impairment [1–3]. While intensive rehabilitation reduces impairment4–9, most individuals do not perform enough movement practice [4,5] in the critical window early after stroke when plasticity is heightened. A key reason is that inpatient rehabilitation is focused on achieving the functions needed to return-to-home: transferring, toileting, dressing, and other forms of self-care. This is what health care payors demand: discharge as quickly as possible, preferably to the home. And yet, ironically, in teaching patients compensatory strategies for achieving daily function, true UE recovery is likely bottlenecked. Our working hypothesis is that there is a threshold level of UE motor drive needed to provoke true UE recovery[6], yet individuals with stroke do not routinely exceed this threshold during current inpatient rehabilitation practice.

To remove this bottleneck, Flint Rehab and UC Irvine propose to develop and test a novel device for enabling individuals with severe arm impairment to substantially increase UE motor drive early after stroke “in situ”. We will leverage a ubiquitous piece of technology – the manual wheelchair – based on two key observations. The first is a pivotal study by Feys et al. [7,8] that had patients with subacute stroke (N=100) rock themselves in rocking chairs by repetitively reaching forward to press against a rail, with patients performing about 500-1000 reaches per day[7]; these patients had a significantly greater increase in UE Fugl-Meyer (FM) score of 17 points at a five-year follow up compared to a control group who were passively rocked[8]. This is a remarkable effect, five times the effect of most robotic arm therapy studies, and yet this “rocking therapy” remains unimplemented in routine clinical practice. A critical question then, is, how do we routinely implement such rocking therapy? This leads to the second observation: approximately 70% of stroke inpatients (and nearly 100% of those with severe impairments) spend several hours each day sitting passively in manual wheelchairs, often with their paretic arm statically strapped into an arm trough. Further, when they ambulate in their chair, they are pushed, or taught to ambulate with their “good” arm and leg (note again: function is prioritized over true recovery). What if patients could use “wheelchair time” to practice “rocking therapy”, without needing to transfer to a rocking chair and without requiring direct therapist supervision? That is, what if we gave patients and therapists a novel tool that allowed them to collaborate in generating plasticity-inducing levels of UE motor drive outside of formal treatment time?

We have already demonstrated the feasibility and preliminary clinical efficacy of this wheelchair-based approach: a moveable wheelchair arm rest device that promotes repetitive forward reaching practice. In our design sequence, experimenting with several prototypes, we solicited critical feedback from clinicians, culminating in the device we propose to test here. This movable wheelchair arm rest device is a novel wheelchair armrest that quickly clicks into a manual wheelchair frame just like a conventional armrest. However, unlike a conventional armrest, the device allows users to activate arm muscles in a way that is appropriate for the early stages of stroke recovery and consistent with the Feys et al. rocking chair approach: with biomechanical support of the shoulder, without high cognitive demand, and focusing on the “out-of-synergy” movement pattern that requires elbow extension. To achieve this, the movable wheelchair arm rest device incorporates an innovative linear mechanism that enables arm activation in two modes: 1) with the chair remaining stationary (“Stationary Mode”), or, 2) with the user contributing to propelling their wheelchair with their impaired arm (“Overground Mode”). Overground Mode transforms the "good arm + good leg" compensatory wheelchair propulsion technique into “good arm + good leg +

impaired arm" propulsion. Thus, the movable wheelchair arm rest device is a pragmatic tool for enabling individuals to activate the arm motor system during "wheelchair time".

Provide relevant preliminary data (animal and/or human):

From our previous work, we developed a novel lever-drive wheelchair, Lever Actuated Resonance Assistance (LARA), [10] that was designed to be used as a user's primary wheelchair, thus enabling UE rehabilitation without sacrificing mobility, requiring a transfer, or requiring a separate device to be attached to the wheelchair before use. Specifically, Lever Actuated Resonance Assistance (LARA) allowed people to perform stationary UE rehabilitation in their wheelchair by moving attached levers back and forth with their impaired arm, or, after switching a manual switch, to propel their wheelchair bimanually with the levers. Using motion capture and EMG, we confirmed that persons with stroke achieved wheelchair propulsion by moving their impaired arm with normative biomechanics while activating elbow extension muscles. We tested LARA in a pilot, two-site randomized controlled trial with individuals with subacute stroke. We found that both stationary and overground exercise with LARA led to a significantly greater reduction in arm impairment than conventional treatment at a one month follow-up.

Describe the primary outcome variable(s), secondary outcome variables, and predictors and/or comparison groups as appropriate for the stated study objectives/specific aims:

Primary outcome measure
The primary outcome measure will be the change in Fugl-Meyer Arm Motor Assessment Score (FMAMA) from baseline to three-month post-stroke to assess increases in motor recovery of the upper extremity.

Secondary outcome measures
Secondary outcome measures will include the change in:

1. Box and Block Test
2. Modified Ashworth Spasticity Scale for shoulder elbow and wrist joints
3. Shoulder subluxation distance in centimeters
4. Visual Analogue Pain scale to assess shoulder, elbow, wrist, and hand pain.
5. Motor Activity Log (MAL) – Post therapy and Follow-up assessments only
6. Functional Ambulation Category (FAC)
7. Number of exercise repetitions performed with device or exercise program.

List up to ten relevant references/articles to support the rationale for the research:

1. Ma VY, Chan L, Carruthers KJ. Incidence, Prevalence, Costs, and Impact on Disability of Common Conditions Requiring Rehabilitation in the United States: Stroke, Spinal Cord Injury, Traumatic Brain Injury, Multiple Sclerosis, Osteoarthritis, Rheumatoid Arthritis, Limb Loss, and Back Pa. *Arch Phys Med Rehabil*. 2014;95(5):986-995.e1. doi:10.1016/j.apmr.2013.10.032
2. Heller A, Wade DT, Wood VA, Sunderland A, Hewer RL, Ward E. Arm function after stroke: measurement and recovery over the first three months. *J Neurol Neurosurg Psychiatry*. 1987;50(6):714-719.
3. Dobkin BH. *Neurologic Rehabilitation*. Philadelphia: F.A. Davis Company; 1996.
4. Lohse KR, Lang CE, Boyd LA. Is more better? Using metadata to explore dose-response relationships in stroke rehabilitation. *Stroke*. 2014;45(7):2053-2058. doi:10.1161/STROKEAHA.114.004695
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Subject Population(s)

Targeted subject populations/data sources (check that apply):

Adults Competent to Provide Informed Consent
Subjects who are unable to communicate in English
UCI Inpatients or Outpatients (Receiving Diagnosis/Treatment/Surgery)

Sample Size

Specify the maximum and expected numbers of individual-level information and/or biospecimens to be accessed/analyzed within each category/group.

Category/Group
Adults with Stroke

18-84

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected
30

Number Expected to Complete the Study or Needed to Address the Research Question
10

Will this study take place only at UCI (i.e., does NOT involve other non-UCI sites)?
No

Overall Study Sample Size: Specify total number of subjects across all sites.
58

Sample Size Determination:

1. **Explain how the overall target sample size was determined (e.g., power analysis; precision estimation). Power analysis should (at least) match the primary outcome/endpoint.**
2. **Provide justification of the effect size for the primary outcome based on preliminary data, current knowledge/literature and/or cost consideration.**
3. **If appropriate, provide sample size justification for secondary outcomes.**

Based on a power analysis using data from our previous LARA RCT with individuals with subacute stroke (n=19)36, enrolling 29 participants in each group, brings a total of 58 from 2 groups, will provide an 80% chance to demonstrate a significant difference in FM between the device and control at the three-month follow up (α = 0.05), assuming a dropout rate of 10%.

Eligibility Criteria

IMPORTANT! If utilizing UCI Health Enterprise Data & Analytics services, include specific timeframes for each eligibility factor, as applicable.

Example:

1. **Birth sex: female**
2. **Age: >= 18 years old as of 2020-01-01**
3. **The result of the most recent SARS-CoV-2 test (of any type), performed between 2020-01-01 and 2020-12-31, was positive**
4. **With any sub-classification of type 2 diabetes (E11*) diagnosed at any date prior to 2020-01-01**
5. **Did NOT have an ED visit between 2020-01-01 and 2020-12-31**

Inclusion/Exclusion Criteria: Identify the factors for limited eligibility and provide a scientific rationale.

Category/Group Eligibility

Adults with stroke

Inclusion Criteria

• 18 to 84 years of age • Experienced a single stroke or multiple strokes >3 days and < 3 weeks prior to study enrollment. For participants with bilateral involvement, PI will define an index side (i.e.: the side that is affected by the most current stroke). If the participant's current stroke is bilateral in nature, then PI would identify the index side as the one with the lower FM score. Ultimately, the training therapists will determine which UE should be trained with Boost and that UE should remain th3 same throughout the study. • Currently admitted or accepted into Acute Rehabilitation program for stroke • UE FM <42/66 • Absence of moderate to severe shoulder pain while using the movable wheelchair arm rest device (<6 on the 10-point visual analog pain scale) • Absence of severe tone at the affected UE (score <4 on the Modified Ashworth Spasticity Scale) • Deem to be an appropriate candidate for manual wheelchair by ARU clinicians.

Exclusion Criteria

• Subarachnoid hemorrhage • Presence of other neurological or psychological disorders affecting motor functions • Moderate to severe pain in the stroke-affected upper extremity (score > 6 on 10-point visual analog pain scale), while using the movable wheelchair arm rest device • Severe tone at the affected upper extremity (score > 4 on the Modified Ashworth Spasticity scale) • Severe aphasia (score of 2 or higher on the NIH stroke scale – question 9). PI may dismiss this criterion if the participant is deemed able to follow all study instructions • Deficits in vision, language, attention, neglect or other cognitive functions severe enough to interfere with safe operation of wheelchair or the movable wheelchair arm rest device • Currently pregnant • Difficulty in understanding or complying with instructions given by the experimenter • Inability to perform the experimental task that will be studied

Is eligibility based on age, gender, pregnancy/childbearing potential, social/ethnic group, or language spoken (e.g., English Speakers only)?

No, Subject Eligibility is not based on these factors

Pre-Screening for Recruitment

Will identifiable information be accessed/obtained for the purpose of screening, recruiting, or determining eligibility of prospective subjects?

Yes

Pre-Screening Activities (check all that apply):

Study team will screen medical records

Medical Records

IMPORTANT! Partial waiver of HIPAA authorization is required for screening/recruitment purposes only. Signed authorization obtained prior to further access to PHI.

Specify Medical Record Source (check all that apply):

Study team will access their own UCI patients' records and abstract data directly from those records

---

Data Points

Provide a complete list of ALL data points, variables, and/or information that will be collected/recorded (i.e. data abstraction form) for pre-screening/recruitment purposes:

We will use existing information about the date, type (ischemic or hemorrhagic), and location of stroke, as well as whether it has caused weakness, and the age of the patient.

If the list of variables will be attached as a separate document [i.e. case report form (CRF; eCRF)], enter "See Attached" above and check the confirmation box below.

The list of variables is attached as a separate document

IMPORTANT! Under a partial waiver of HIPAA authorization, only the minimum necessary information should be accessed for pre-screening/recruitment activities, this includes:

- **determining eligibility (i.e., shows an inclusion or exclusion criteria) and**
- **contacting the subject.**

The information should not be further accessed, used, or disclosed above and beyond pre-screening/recruitment activities until a signed consent form (and signed HIPAA authorization, as applicable) is obtained.

Explain why pre-screening/recruitment activities could not be done without access to the information listed above:

Research recruitment could not practicably be conducted unless given access to protected health information. This is due to the screening processes to assess the eligibility of the individuals, confirming that they suffered a single or multiple ischemic or hemorrhagic strokes resulting in upper extremity weakness.

Recruitment Methods

IMPORTANT! Recruitment materials must adhere to UCI Recruitment Guidelines. Various templates are available here: IRB Forms → Recruitment Templates.

Indicate all methods that will be used to recruit subjects for this study:

Recruitment Method:
Flyers/Brochures

Specify 'Other' recruitment methods:

Specify Where Posted:
UC Irvine Health Clinical Trial web page, clinicaltrials.gov web page

Type of Space:
Private (i.e., site/media that allows control of access to content)

REQUIRED! Applicable consent documents must include reference to the use of SONA.

REQUIRED! The ClinicalTrials.gov statement must be in all applicable consent documents.

REQUIRED! The study listed on the Center for Clinical Research (CCR) Find a Trial web page must be registered on ClinicalTrials.gov

Specify how contact information will be obtained:

Examples:

- **Individuals who are economically, educationally or cognitively disadvantaged**
- **Physician's own inpatients and/or outpatients**
- **Students (undergraduate, graduate, and medical students)**
- **Employees of UCI (administrative, clerical, nursing, lab technicians, post-doctoral fellows and house staff, etc.)**

REQUIRED!

1. **Subjects must be approached with an emphasis that participation is voluntary; and**
2. **Subjects must be informed in a caring manner that no matter their decision, it will NOT affect:**
    a. **Their relationship with UCI**
    b. **How their doctor cares for them as a patient or their care at UC Health in general and/or**
    c. **How their instructor grades their participation in the course; and**
3. **The information above in item 2 must be included in applicable recruitment and/or consent documents.**

Specify the precautions taken to avoid compromised objectivity:

IMPORTANT!

- **Colleagues may provide a copy of the consent and other UCI IRB approved materials, but do NOT obtain subjects' consent for the research or act as representatives of the investigators.**
- **A partial waiver of HIPAA authorization is required to allow a treating physician to obtain verbal permission from a patient to disclose their name and contact information to the study team.**

IMPORTANT! Colleagues must NOT obtain subjects' consent for the research or act as representatives of the investigators.

REQUIRED!

- **Upload the recruitment letter to be signed by the treating physician in the Attachments section.**
- **For Exempt Self-Determinations, maintain on file the recruitment letter to be signed by the treating physician.**

Recruitment Method:

Clinicaltrials.gov

Specify 'Other' recruitment methods:

Specify Where Posted:

Type of Space:

REQUIRED! Applicable consent documents must include reference to the use of SONA.

REQUIRED! The ClinicalTrials.gov statement must be in all applicable consent documents.

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Examples:

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REQUIRED!

1. Subjects must be approached with an emphasis that participation is voluntary; and
2. Subjects must be informed in a caring manner that no matter their decision, it will NOT affect:
    a. Their relationship with UCI
    b. How their doctor cares for them as a patient or their care at UC Health in general and/or
    c. How their instructor grades their participation in the course; and
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IMPORTANT! **Colleagues must NOT obtain subjects' consent for the research or act as representatives of the investigators.**

REQUIRED!

- **Upload the recruitment letter to be signed by the treating physician in the Attachments section.**
- **For Exempt Self-Determinations, maintain on file the recruitment letter to be signed by the treating physician.**

HIPAA Authorization

Does this study involve the creation, use, or disclosure of Protected Health Information (PHI) (i.e. access to medical records)?

List of 18 PHI Identifiers from medical records/clinical encounters:

1. **Names**
2. **Social Security Numbers**
3. **Dates (including birth date, admission date, discharge**
4. **date, date of death and exact age if over 89)**
5. **Medical record numbers**
6. **Address**
7. **Health plan numbers**
8. **Phone numbers**
9. **Fax numbers**
10. **Email address**
11. **Account numbers**
12. **License/Certificate numbers**
13. **Vehicle ID numbers**
14. **Device identifiers/Serial numbers**
15. **Web URLs**
16. **IP address numbers**
17. **Biometric identifiers**
18. **Facial Photos/Images**
19. **Any other unique identifier**

Yes

Identify the Health Insurance Portability and Accountability Act (HIPAA) Authorization process (check all that apply):

Partial waiver of HIPAA authorization requested for screening/recruitment purposes only. Signed authorization obtained prior to further access to PHI.
Signed HIPAA authorization obtained

Waiver of HIPAA Authorization

The Health Insurance Portability and Accountability Act (HIPAA) and the California Confidentiality of Medical Information Act (CMIA) address medical confidentiality and access to medical information for research studies that use, create, or disclose health care related data and records, termed "personal health information."

- **HIPAA Authorization Waivers: The HIPAA Privacy Standard [45 CFR 164.512(h)(i)(2)(ii)] requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Personal (Protected) Health Information.**

For more information, visit: Protected Health Information.

Partial Waiver of HIPAA

A Partial Waiver of HIPAA Authorization is Requested.

Does the use or disclosure of personal health information involve more than minimal risk?

No

Would the granting of the waiver adversely affect privacy rights and welfare of the individuals whose records will be used or disclosed?

No

Explain (justify) the answer:

Information will be protected to avoid any breach of confidentiality and will be used by the research team to find patients with ischemic or hemorrhagic strokes with arm weakness

Could the research practicably* be conducted without a waiver of HIPAA authorization?

No

Explain why research could not be done if authorization was required:

It is not practicable to ask a considerable number of patients to sign the HIPAA Authorization to review their medical records to confirm eligibility and identify 30 eligible subjects.

Could the research practicably* be conducted without access to, use or disclosure of the personal identifiers listed in the PHI question?

No

Explain why research could not be done without access to, use or disclosure of PHI:

Research recruitment could not practicably be conducted unless given access to protected health information. This is due to the screening processes to assess the eligibility of the individuals, confirming that they suffered a single or multiple ischemic or hemorrhagic strokes resulting in upper extremity weakness.

Are the privacy risks reasonable relative to the anticipated benefits of the research?

Yes

Describe the risk/benefit analysis performed to explain the answer above:

: Researchers from the study will store all study records and other information in secure location and only study personnel will have access to it.

Describe the plan to destroy the personal identifiers at the earliest opportunity, or provide a health or research justification for retaining the identifiers:

Potential subjects are identified through chart review according to our inclusion and exclusion criteria. A screening log will be created to keep an accounting of prospective patients and their interest in study participation. The screening log will be retained for the duration of the study. The screening log will be stored with a coded identifier on password protected computers and paper forms will be filed securely in a HIPAA approved storage in the Acute Rehab Unit (ARU) or Gross Hall at UCI main campus no longer than 6 years after the completion of the study. The number of patients we screen, number of patients enroll in the study, and the number of patients who do not qualify for the study will be retained (with no patient identifiers) for the NIH reports and manuscripts.

Describe the plan to protect the personal identifiers from improper use and disclosure (i.e., describe data security methods):

The screening log for non-participants will be kept in a HIPAA approved storage in ARU or Gross Hall at UCI main campus until the completion of study, when they will be destroyed. All other paper forms will be kept in this secure locked cabinet for no longer than 6 years, at which time, the documents will be physically destroyed by shredder

Provide assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

As the Lead Researcher, I assure all of the above

Informed Consent Process

Identify the methods of Informed Consent or assent process as applicable for each participant population (check all that apply):

Paper-based signed informed consent/assent

Paper-based Signed Informed Consent

Indicate the paper-based signed informed consent/assent (check all that apply):

Signed Informed Consent

REQUIRED! Submit the Adult Consent Form, Child Assent Form and/or Parental Permission Form in the Attachments section.

Circumstances of Consent

Indicate the location where the consent process will take place (check all that apply):

Private room

Specify how the research team will assure that subjects, their parents, or their legally authorized representative (LAR) have sufficient time to consider whether to participate in the research:
Subjects or their LAR will be allowed 'X amount of time' to consider whether to consent

Specify hours, days or weeks for subjects, parents or their LAR will be allowed to consider whether to consent:
24 hours

Non-English Speakers

What type of consent process will be used for Non-English Speaking Participants?
The English version of the consent materials will be translated for non-English speaking participants or their LAR once IRB approval is granted. An interpreter will be involved in the consenting process.

Indicate how non-English speaking subjects or their LAR will be consented in their language and who will be responsible for interpreting and facilitating the informed consent discussion for the non-English speaking subjects:
The study team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this study

Project Locations

Check all sites where UCI investigator(s) will conduct research activities (e.g., recruitment, informed consent, and research procedures including accessing identifiable, private information about participants):

UCI Campus Facilities or Sites (e.g. school, lab, etc.)

UCI Health Facilities or Sites (e.g. hospital, clinics, etc.)

Study Design & Statistics

Include an explanation of the study design (e.g., randomized placebo-controlled, cross-over, cross-sectional, longitudinal, etc.) and, if appropriate, describe stratification/ randomization/blinding scheme:

This is a randomized controlled phase II clinical trial designed to test if use of movable wheelchair arm rest device reduces arm impairment compared to conventional training, in addition to standard rehabilitation therapy.

We will recruit individuals with an acute or subacute stroke from the Acute Rehabilitation Unit at UCI Medical Center to participate in this study. Participants will have arm impairment, which we will confirm with the Upper Extremity Fugl-Meyer Motor Assessment. After baseline evaluation, study participants will be equally randomized into two groups: device group versus control group. Randomization will proceed by block allocation based on time of enrollment.

Movable wheelchair arm rest device group: participants in this group will be provided with a wheelchair equipped with movable wheelchair arm rest device and will be trained by training therapists on how to use the device to perform stationery reaching practice and to help them move around using the overground mode. Training therapists can customize the range of motion needed for device's integrated electronics to count a "repetition" based on participant's ability. Once training therapists determine participants are competent to operate the device, they will be instructed to perform stationary reaching practice and to use the device to move around the inpatient facility with supervision from study personnel. A target dose of 1000 device "repetition" per day is encouraged. We estimated this will take about 30 minutes per day of device use at around 1 repetition every 2 second. Once participants are discharged from the unit, they will be allowed to keep the movable wheelchair arm rest devices until their 3-month post stroke follow up visit, the last visit of the study. Participants' utilization of the device will be supervised by therapists who have been trained in the device operation. Tenovi Gateway device will be used to collect the amount of use data. This data will be automatically uploaded to secure web portal through a Tenovi Gateway device, which plugs into the wall at subjects' rooms at the Acute Rehab Unit and subjects' homes. The Teniovi Gateway device will automatically communicates with the exercise repetition counts from the movable wheelchair arm rest through bluetooth, then uploads the data to the web portal through a low-speed cellular data connection.

Control group: participants in this group will be given an electronic exercise program designed by training therapists. These exercises will be assigned to the participants electronically using a commercial home exercise program platform commonly used by hospital systems (i.e.: Medbridge). They will be encouraged to exercise for 30 min/day in addition to the regular rehabilitation therapy at ARU. These exercises will be monitored and supervised by therapists who have been trained in the study protocol. Once participants are discharged from the unit, they will be allowed to keep the electronic exercise program until their 3-month post stroke follow up visit, the last visit of the study.

All study participants will receive 3 evaluations from a blinded evaluator: baseline at admission to the ARU, at discharge from ARU, and a 3-month post-stroke follow up visit.

Please see attachment for the schedule of study activities.

Is this a study for which a statistical analysis plan is appropriate (e.g. quantitative study design)?

Yes

Describe the statistical methods for the stated specific aims and hypotheses. The analysis plans should match the stated study specific aims and hypotheses:

All reported data from this study will be disaggregated by sex to test for any potential bias due to this biological variable. Data will be analyzed using modified intention-to-treat analysis. That is, all participants will be included in the analysis if the follow-up assessment is available, regardless of any deviations from the protocol. The effect of treatment on the primary outcome measure will be assessed using a repeated measures analysis of covariance (RM-ANCOVA) to account for any baseline differences between groups or variability in treatment intensity, with follow-up comparisons performed using Bonferroni-corrected t-tests or Wilcoxon rank sum tests if the data violates the assumption of normality. We hypothesize the participants in the movable wheelchair arm rest device group will have significantly greater and clinically meaningful (i.e. >4.25 FM points) reductions in motor impairment than participants in the control group due to the increased dose of UE motor system activation. Using data from the sensors on movable wheelchair arm rest device, we will test if this effect depends nonlinearly on the number of repetitions performed with the device, consistent with recent meta-analyses of forelimb recovery in a rodent model of stroke. That is, we hypothesize that the movable wheelchair arm rest device will provide a benefit only if the dose exceeds a threshold. A key goal is to also identify that threshold (by making a graph for humans like the one for rats), which will enable us to move forward with effective clinical prescription and goal setting with the movable wheelchair arm rest device. Visual analog pain, spasticity, and FAC scores will also be analyzed using RM-ANCOVA to test for significant changes related to use of the device. All analyses will be reviewed by a statistical consultant in the Institute for Clinical and Translational Science at UC Irvine.

Provide precise definitions of the study endpoints and criteria for evaluation; if the primary outcomes are derived from several measurements (i.e., composite variables) or if endpoints are based composite variables, then describe precisely how the composite variables are derived:

The endpoint of the study is 3-month post-stroke follow up visit. The primary outcome measure is the Fugl-Meyer Upper Extremity Motor Assessment Score at the 3-month post-stroke follow-up.

Describe the statistical method(s) that will be used to analyze the primary outcome(s) or endpoints:

t-tests with Bonferroni corrections, or Wilcoxon rank sum tests if the distributions fail the Lilliefors test for normality.

If appropriate describe secondary or post hoc analyses of primary outcome(s) or other exploratory analysis and if necessary, provide a breakdown of the methods used per outcome or endpoint:

The effect of treatment on each outcome measure will be assessed using a repeated-measures ANOVA

Safety Monitoring Plan

UCI IRB requires that all clinical investigations involving greater than minimal risk to subjects develop a data and safety monitoring plan to assure the safety and welfare of the research subject/patient.

This is aligned with with NIH requirements and with federal regulations that require that IRBs assure that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects/patients.

For clinical protocols involving a test article, it is common to have an independent Data Safety Monitoring Board (DSMB).

Please read the applicable HRP webpage for further guidance.

Does this protocol require a Safety Monitoring Plan?

Yes

- **Feel free to cut and paste into this section from the following sources, as applicable:**
  - **For NIH-sponsored clinical trials, the Data Safety Monitoring Plan (DSMP) should be part of the grant application.**
  - **For industry sponsor-initiated clinical trials, a FDA-approved DSMP should be part of the Master Protocol or the Data Safety Monitoring Committee/Board Charter.**
  - **For protocols conducted at the Institute for Clinical and Translational Science (ICTS) or Cancer Center (PRMC), the DSMP information approved by one of these committees should be inserted into this section**

- **REQUIRED! Submit the following documents, as applicable in the Attachments section:**
  - **Signed DSMB recommendation forms from independent DSMB.**
  - **The finalized DSMB charter must be submitted before enrollment begins.**

Provide details of those individuals who will be responsible for the safety oversight of your protocol, including the relevant experience/expertise of each individual (for UCI investigator initiated studies conducted only at UCI, provide the names and titles as well):

The Data Safety Monitoring Board for the current study will be the research team that comprises individuals with various academic backgrounds:

- An Do, M.D., has experience in human subjects' research in stroke rehabilitation
- David Reinkensmeyer, PhD, has experience in human subjects' research in the areas of biomechanics, neural control of movement, and rehabilitation.
- Vicky Chan PT,DPT, is a licensed Physical Therapist with over 20 years' experience in stroke rehabilitation treatment and research.
- Alison McKenzie, PT, DPT, PhD, is a professor at the Department of Physical Therapy at Chapman University. She has over 25 years' experience in stroke rehabilitation treatment and research.

Indicate how frequently accumulated protocol data will be reviewed and evaluated for participant safety, protocol conduct and progress, and, when appropriate, efficacy:

The DSMB reviews study data monthly to evaluate the course of data collection with healthy and stroke subjects and to evaluate safety concerns. Efficacy is evaluated when enrollment ceases for each phase.

Describe the events that would trigger an unscheduled review. Also include stopping guidelines and un-blinding rules if applicable:

Unanticipated problems related to the use of the equipment could trigger an unscheduled review. Regarding any device in the study, any malfunctioning of the device resulting in altered risk assessment would need to be promptly assessed by the DSMB team and subsequent modifications applied.

List who will be *locally* monitoring and collecting information on adverse events and/or unanticipated problems (e.g., UCI Lead Researcher, Research Coordinator, etc.).

Include the name, title and experience of the individual(s) and further describe each individual's role in the oversight of subject/patient participating in the protocol.

Vicky Chan, PT, DPT, is a licensed Physical Therapist with over 20 years' experience in stroke rehabilitation treatment and research.

Describe the plan for annual reporting of the participants' safety, and the protocol's conduct, progress, and efficacy, when appropriate:

Annual reporting will take place in the annual progress report as part of the electronic renewal application each year.

Project Procedures

Research Procedures (check all that apply):

Audio, Video, Digital or Image Recording and/or Photography for Collection of Research Data
Behavioral Experiments (e.g., Cognition, Perception, Motivation, Communication, Social Behavior)
Clinical Investigation involving an Investigational Device
Secondary use of Identifiable Private Information (i.e., Medical/Student Records)
Surveys/Questionnaires/Interviews/Focus Group

Provide a detailed chronological description of the procedures:

Participants will be invited for an initial assessment within three days of admission to an IRF to confirm they meet the inclusion criteria and to establish a baseline measure. Those who qualify will be randomly assigned to either the movable wheelchair arm rest device group or the control group. To ensure matched levels of impairment between groups, subjects will be stratified by their FM score into two levels (0-21, 22-42) and then randomized by alternating block allocation based on the time of enrollment. Individuals in the device group will be provided with a wheelchair equipped with movable wheelchair arm rest device and trained how to use it to perform stationary reaching practice and to help them ambulate. Once participants are competent, they will be instructed to perform stationary reaching practice and to use the movable wheelchair arm rest device to ambulate around the inpatient facility, with a target dose of 1000 device “reps” per day, which we estimate will take about 30 minutes of device use at around 1 rep every 2 seconds. The supervising therapist will customize the range of motion needed for device’s integrated electronics to count a “rep” based on each patient’s abilities. Participants in the control group will be given an electronic home exercise program (HEP) of proximal arm exercises developed by study therapists. They will be encouraged to exercise for 30 minutes a day with the electronic HEP (i.e. to match the duration with device). A supervising therapist will check in with all participants once per week to check on engagement with their exercise program and to troubleshoot any issues with device or the electronic exercise program. To measure compliance and quantify dose, the device will report the date, time, and number of repetitions completed for each movement type (stationary/overground) throughout the study using integrated electronics. Using technology, we previously developed for another study, the electronic exercise program provided to control participants will record how long the book is opened each day with a hidden magnetic sensor and data logger. Participants in both groups will continue therapy for the duration of their inpatient stays (average length of stay for individuals with moderate to severe impairment is 14 to 22 days, respectively, based on 104, n = 4142). The actual length of stay for each participant will be quantified and included as a covariate in the data analysis. Once participants are discharged, they will receive a post-therapy assessment and they may be allowed to keep the device and the exercise program based on the therapists' recommendations for the duration of the study. Participants will return three months following stroke onset for a final assessment. We would like to utilize the Tenovi Gateway device to collect the amount of use data. This data will be automatically uploaded to secure web portal through a Tenovi Gateway device, which plugs into the wall at subjects' rooms at the Acute Rehab Unit and or subjects' homes , automatically communicates with the exercise repetition counts through bluetooth, then uploads the data to the web portal through a low-speed cellular data connection. A study team member may visit participants' homes to set up the devices.

Boost is a novel arm rest that clips on a standard wheelchair with standard wheelchair features where anti-tipping bars in the back will prevent the wheelchair from tipping over. We have different sizes of the wheelchairs, 16", 18" and 20", to fit various patients according to their size and weight. We also have adjustable leg rests where we can fit patients with leg lengths or heights. We will have routine maintenance to make sure the wheelchairs operate well and are safe. For all study visits, we will have study personnel or nursing staff at the acute rehab unit present for the patients if patients need any help.

Specify the total duration of a subject's participation in the study and clearly outline the duration of participation for each study visit and sub-study, as applicable:

The duration of the subject's participation in the study will be approximately 3 months after the onset of stroke.

List all data collection tools (e.g., measures, questionnaires, observational tool) below; include citations for standardized/validated measure(s):

- Upper Extremity Fugl-Meyer Motor Score
- Box and Block Test
- Shoulder subluxation distance in centimeters
- Motor Activity Log (Post therapy and follow up assessments)
- Visual analog pain score for the shoulder and hand
- Modified Ashworth Spasticity Scale for elbow and wrist flexors and extensors
- Functional Ambulation Category (FAC)
- NIH Stroke Scale
- Number of exercise repetitions performed with device or exercise program
- Days of inpatient hospitalization stay
- Vital signs (heart rate, blood pressure)

Are all data collection tools standardized or validated?

Yes

List all procedures involving the use and/or collection of photographs, or audio/video recording:

Collection of photographs or video recording will only take place during treatment sessions.

UCI Health Clinical Services

Will this study require clinical items/ services from UC Irvine Health?
No

Use of Identifiable Information

Source of Information

Indicate the types/sources of identifiable private information (check all that apply):
UCI Health Medical Records

Medical Records

This study will use medical records, indicate the source:
Study team will access their own UCI patients' records and abstract data directly from those records

Data Points

Specify the date-range of the data used for the project (e.g. January 2002 to January 2020):
March 2023 to August 2024

Provide a complete list of ALL data points, variables, and/or information that will be collected (i.e. data abstraction form):

We will collect the date of stroke, type of stroke, sex, age of the participants and medical record numbers.

If the list of variables will be attached as a separate document [i.e. case report form (CRF; eCRF)], enter "See Attached" above and check the confirmation box below.

The list of variables is attached

Medical Devices

Please read the HRPP webpage for information about the use of devices in clinical investigations.

Name of Device or Product:

Movable wheelchair arm rest device

Device Manufacturer:

Flint Rehabilitation

Description of the device:

The movable wheelchair arm rest device is a novel wheelchair armrest that quickly clicks into a manual wheelchair frame just like a conventional armrest. However, unlike a conventional armrest, the movable wheelchair arm rest device allows users to activate arm muscles in a way that is appropriate for the early stages of stroke recovery and consistent with the Feys et al. rocking chair approach: with biomechanical support of the shoulder, without high cognitive demand, and focusing on the “out-of-synergy” movement pattern that requires elbow extension.

Specify the proposed use of the device for this study:

Half of the study participants will exercise using the device in two different modes: stationary mode and overground mode, to promote arm motor recovery while they are sitting in the wheelchair.

Does this device have an Instructions for Use/User Manual/Product Brochure?

Yes

REQUIRED! Submit the Instructions for Use, User Manual or Product Brochure in the Attachments section.

Include information to describe how it works and the foreseeable risks associated with its use:

Is the device a medical device?

Yes, this device is a medical device

If “no”, for minimal risk studies and the device is intended to be used in a clinical setting, provide justification for selecting “no”, citing any regulatory guidance as applicable:

Are you testing the safety and/or efficacy of this device?

Yes, we are assessing the safety and/or efficacy of this medical device; this is a clinical investigation

If “no”, for minimal risk research and if the device is the object of the investigation, provide justification for selecting “no”, citing any regulatory guidance as applicable:

Is the device approved for marketing in the United States?
No

How is the device approved in the United States?

Select one of the following:

Is the device authorized for use under an FDA Emergency Use Authorization (EUA)?
No, this is not covered under an EUA

Is the device being used in this study according to its approved indication?

Is the Device Exempt from the Investigational Device Regulations (21 CFR 812)?
No

Select the device exemption that meets one of the following categories:

Clarify how the device meets the category selected:

Is this device a Significant Risk (SR) device?
No, this device is not a significant risk device. This device is also not exempt; it is not a HUD/HDE

Has the investigator or sponsor of this research obtained an Investigational Device Exemption (IDE) from the FDA for the use of this device for this research?

REQUIRED! **Submit the IDE Authorization Letter in the Attachments section.**

IDE Number:

Holder of the IDE (check all that apply):

Specify Lead Researcher:

Specify 'Other' IDE Holder:

Does the IDE allow billing of subjects?

Does the IDE cover a combination use (e.g., combination of an investigational drug and device)?

Specify the combination use:

Specify why an IDE has not been obtained yet:

Specify 'Other' reason:

Based on the criteria for a significant risk device listed in the link below, explain why the device as it is used in this study, qualifies as Non-Significant Risk (NSR) device:

The device is a non-significant risk device because none of the risks associated with using the device could be life-threatening, could result in permanent impairment of a body function, or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure. The risks associated with the device are fatigue and soreness from exercise, and there is a small possibility of pinching the fingers in the Boost mechanism but this risk is minimized by a cover and by training the user how to use the device."

Has the FDA or another IRB determined the device to be non-significant risk as it is used in this study?
No

Indicate who will be responsible for the management of the device during the study:
Engineers from Flint Rehabilitation Services will be responsible for the management of the device during the study.

Explain the plan to ensure that the investigational device is used only in accordance with the UCI IRB approved protocol:
All engineers from Flint Rehab services and study personnel will undergo protocol and device training prior to the start of the study.

Indicate who will have access to the device and how access will be controlled to secure the device (or device stock):
Only engineers from Flint Rehab services and study personnel will have access to the devices. All device usage will be kept in a device log which will be secured in a log cabinet and locked office at the unit. Also, Flint representatives who come to UCI for services and maintenance will be registered as vendor per UCI medical center policy.

Specify how records for control of the device (or device stock) will be recorded:
The Device Log provided by the Sponsor will be used

REQUIRED! **Submit the Sponsor Device Log in the Attachments section.**

Specify why no log will be used:

Indicate whether the investigational device is manufactured in a UCI facility:
No

Identify the lab and location:

The medical device form is completed. Click the 'Done' button.

If you need to add more devices, click on the + Add Line button above the table to enter additional devices.

Name of Device or Product:
Tenovi Gateway Device

Device Manufacturer:
Tenovi

Description of the device:
It is a device that can capture amount use data, or exercise repetitions, and upload to a secured website via low-speed cellular signal.

Specify the proposed use of the device for this study:
To collect amount use data from the moveable wheelchair arm rest device.

Does this device have an Instructions for Use/User Manual/Product Brochure?
Yes

REQUIRED! Submit the Instructions for Use, User Manual or Product Brochure in the Attachments section.

Include information to describe how it works and the foreseeable risks associated with its use:

Is the device a medical device?
No, this is not a medical device

If “no”, for minimal risk studies and the device is intended to be used in a clinical setting, provide justification for selecting “no”, citing any regulatory guidance as applicable:

This is a device NOT to make any diagnosis nor treatment. The Tenovi platform is a device to capture the number of movement counts when participants exercise using the movable arm rest.

Are you testing the safety and/or efficacy of this device?

If “no”, for minimal risk research and if the device is the object of the investigation, provide justification for selecting “no”, citing any regulatory guidance as applicable:

Is the device approved for marketing in the United States?

How is the device approved in the United States?

Select one of the following:

Is the device authorized for use under an FDA Emergency Use Authorization (EUA)?

Is the device being used in this study according to its approved indication?

Is the Device Exempt from the Investigational Device Regulations (21 CFR 812)?

Select the device exemption that meets one of the following categories:

Clarify how the device meets the category selected:

Is this device a Significant Risk (SR) device?

Has the investigator or sponsor of this research obtained an Investigational Device Exemption (IDE) from the FDA for the use of this device for this research?

REQUIRED! **Submit the IDE Authorization Letter in the Attachments section.**

IDE Number:

Holder of the IDE (check all that apply):

Specify Lead Researcher:

Specify 'Other' IDE Holder:

Does the IDE allow billing of subjects?

Does the IDE cover a combination use (e.g., combination of an investigational drug and device)?

Specify the combination use:

Specify why an IDE has not been obtained yet:

Specify 'Other' reason:

Based on the criteria for a significant risk device listed in the link below, explain why the device as it is used in this study, qualifies as Non-Significant Risk (NSR) device:

Has the FDA or another IRB determined the device to be non-significant risk as it is used in this study?

Indicate who will be responsible for the management of the device during the study:

Explain the plan to ensure that the investigational device is used only in accordance with the UCI IRB approved protocol:

Indicate who will have access to the device and how access will be controlled to secure the device (or device stock):

Specify how records for control of the device (or device stock) will be recorded:

REQUIRED! **Submit the Sponsor Device Log in the Attachments section.**

Specify why no log will be used:

Indicate whether the investigational device is manufactured in a UCI facility:

Identify the lab and location:

The medical device form is completed. Click the 'Done' button.

If you need to add more devices, click on the + Add Line button above the table to enter additional devices.

Return of Results

Will Individual results be shared with subjects?

No

Will overall study results will be shared with subjects?

The overall study results will be listed on Clinicaltrials.gov

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Risk Assessment

Risks and Discomforts

1. Describe and assess any reasonably foreseeable risks and discomforts associated with each procedure for each subject population — physical, psychological, social, legal or other.

2. If this study will involve the collection of identifiable private information, even temporarily, for which the disclosure of the data outside of the research could reasonably place the subjects at risk, include the risk of a potential breach of confidentiality.

A bullet point list is recommended.

The possible risks and/or discomforts associated with the procedures described in this study include the Following:

- Repetitive movement exercise may cause muscular fatigue (make the subject's muscles feel tired), muscle soreness, joint soreness, or arm pain. The subject will be instructed to cease exercise and consult the supervising therapist and physician if any pain arises from the exercise.
- There is a small risk of having the subject's fingers or hand or arm pinched or bruised by the device. The subject will be trained on how to use the device appropriately to avoid this risk.
- There is a risk of a breach of privacy if someone unrelated to the study obtains the videotapes of the subject, but the study investigators will protect against this risk by storing the tapes in a locked cabinet with a coded identifier. The subject will be asked for consent if the investigators wish to use any of the videotapes for publication or presentation of the study.
- Unknown risks: There may be risks related to the research that we don't know about yet. However, the subject will be informed of any additional risks to which he or she may be exposed, and any changes that are made to the study, as a result of any newly-identified risks.

EXPEDITED/FULL COMMITTEE ONLY: Include an assessment of their expected frequency (e.g., common – 65%, less common – 40%, unlikely – 5%, rare - <1%) and the seriousness (mild, moderate, severe).

Discuss what steps have been taken and/or will be taken to prevent and minimize any risks/potential discomforts to subjects:

Prior to exercising with the movable wheelchair arm rest device, subjects will be trained on how to avoid all potential problems described above. The subject will be trained on how to use the movable wheelchair arm rest device appropriately to avoid this getting his or her fingers pinched. The subject will be instructed to cease exercise and consult the supervising therapist and physician if any pain arises from the exercise. The risk of a breach of privacy will be minimized by all study staff members are trained under HIPAA regulations.

Certificate of Confidentiality

Is the research partially or wholly funded by National Institutes of Health (NIH), including NIH Institutes and Centers?

Yes

A CoC is automatically issued for this research by NIH.

REQUIRED! Ensure that the requisite CoC language is in consent document; see the consent form template: IRB Forms.

Indicate in what situations identifiable private information protected by a CoC will be disclosed (check all that apply):

As required by Federal, State, or local laws, excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others

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Potential Benefits

Is there the prospect of a direct benefit anticipated for subjects?

Yes

Describe the potential benefits subjects may expect to receive from participation in this study:

It is possible that exercising with the device may improve upper extremity functions. It is also possible that receiving extra exercise assignment in the control group may improve upper extremity functions. The movable wheelchair arm rest device group may also be allowed to keep the device provided to them upon discharge.

Specify the expected potential societal/scientific benefit(s) of this study:

It is possible that exercising with the device may improve upper extremity functions. It is also possible that receiving extra exercise assignment in the control group may improve upper extremity functions. The movable wheelchair arm rest device group may also be allowed to keep the device provided to them upon discharge.

Alternatives to Participation

Describe the alternatives to participation in the study available to prospective subjects. Include routine (standard of care) options as well as other experimental options, as applicable (check all that apply):

No alternatives exist. The only alternative to study participation is not to participate in the study

Participant Compensation

Compensation is when participants are paid for their time & efforts in research.

- **Compensation should be offered on a prorated basis when the research involves multiple sessions.**
- **For additional information about researcher's/department's responsibilities and current Accounting procedures, see UCI Policy Sec. 701-03.**

For more information see: Compensation Info.

Are participants compensated?

Yes

Compensation method:

Cash

Specify amount:

50

Compensation schedule:

Other

Specify 'Other' schedule:

After each clinical evaluation visit. A maximum of $150 cash compensation each participant will receive upon completion of the study.

Will the cash compensation method include all subjects?

Yes

Specify compensation cohort:

Is the total monies participants receive greater than or equal to $600?
No

Participant Costs

Will subjects or their insurers be charged for study procedures?
No

Reimbursement

Will subjects be reimbursed for out-of-pocket expenses?
No

Confidentiality of Research Data

Participant Identifiers

Will subject/patient identifiers be collected or retained?
Yes

Will any subject/patient identifiers be collected or retained for data analysis, recruitment, consenting and/or compensation (check all that apply)?

All elements of dates that are directly related to an individual: birth date, admission date, discharge date, death date, and all ages over 89
Email addresses
Medical record numbers
Names
Telephone numbers

Coding Identifiers

Will a code be used to link subject/patient identifiers with the information and/or biospecimens?

A code will be used. Subject/Patient identifiers will be kept separately from the information and/or biospecimens. The code key will be destroyed at the earliest opportunity, consistent with the conduct of this research

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Photos/Audio/Video

Will any identifiable photos or audio/video recordings be collected or used (check all that apply)?

Photographs / Digital Images
Video Recordings

Photographs/Digital Images

Will the identifiable photographs/digital images be de-identified?

Yes

Specify timeframe for the photographs/digital images de-identification and how will the photographs/digital images be de-identified:

We will blur out or black out participants' facial images only used in publication which will be within 5 years from the end of the study.

Video Recordings

How will the video recordings be transcribed?

Identifiable video recordings will not be transcribed

Provide rationale on why identifiable video recordings will not be transcribed:

The video recordings for this study will mainly for movement analysis, therefore, there is no need to transcribe them.

Will the identifiable video recordings be de-identified?

Yes

Specify timeframe for the video recordings de-identification and how will the recordings be de-identified:

We will blur out or black out participants' facial images only used in publication which will be within 5 years from the end of the study.

Presentation/Publication

Specify whether subject/patient identifiers be disclosed in presentations and/or publications:
Subject/Patient identifiers will not be disclosed

Identifier Retention

Specify how long all subject/patient identifiers will be retained. This includes identifiers stored in paper format, stored electronically as well as video recordings, audio recordings, photographs, etc.:
Destroyed after publication/presentation or end of protocol

Info/Biospecimen Storage

Indicate how information and/or biospecimens (including signed consent forms) will be stored (check all that apply):
Information will be maintained electronically. Information will be password protected and maintained in an encrypted format
Information will be maintained in hard copy. Information will be stored in a locked area that is not accessible to non-study team members

Encrypted Format

Specify where the information will be maintained electronically:

Data will be stored with a coded identifier in paper format in the double locked cabinet at the Acute Rehabilitation Unit at UCI Medical Center. Study Data will later be entered and stored on a REDCap database, an electronic data capture system provided by UCI OIT. All other materials such as video files will also be stored with a coded identifier, without names or identification, and will be stored in an encrypted and password protected data server in Gross Hall.

Hard Copy

Specify where the information will be maintained in hard copy:

Data will be stored with a coded identifier in paper format in the double locked cabinet at the Acute Rehabilitation Unit at UCI Medical Center. Study Data will later be entered and stored on a REDCap database, an electronic data capture system provided by UCI OIT. All other materials such as video files will also be stored with a coded identifier, without names or identification, and will be stored in an encrypted and password protected data server in Gross Hall.

Info/Biospecimen Transport

Will research data/biospecimens be transported or maintained on portable devices (e.g., laptop, smartphone, external hard drive, etc.)?

No

Info/Biospecimen Retention

Indicate how long research information/biospecimens will be retained:

In accordance with UCOP policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement

Info/Biospecimen Sharing

The research team, authorized UCI personnel, the study sponsor (as applicable) and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to participants' study records to protect their safety and welfare.

Sharing Within Scope of Project

Will research materials (information/ biospecimens) be shared with collaborators (i.e., researchers not covered under the UCI project), for purposes within the scope of the current project?

No

Sharing Outside Scope of Project

Will information and/or biospecimens be shared, used again, or stored for undefined future research purposes beyond the scope of the current protocol?

No

Attachments

For UCI IRB templates, visit IRB Forms.

ATTENTION! If requisite documentation is not attached, the submission will be returned as incomplete.

Maximum file size is 30MB

Device Brochure.docx

Attachment Type
Medical Device Instructions (User Manual/Product Brochure)

File Comments
Device Brochure

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)
Add

Study Timeline.docx

Attachment Type
Other

File Comments
Schedule of study activities

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

2508 Consent Form 01-17-24.docx

Attachment Type
Consent Form

File Comments
Consent Form Closed to Enrollment; Deactivated

File Name

Status (HRP Use Only)
Approved - Editable Version

Agenda (HRP Use Only)
Add

2508 Recruitment Flyer 04-28-2023.docx

Attachment Type
Recruitment Material

File Comments
Recruitment Flyer Closed to Enrollment; Deactivated

File Name

Status (HRP Use Only)
Approved - Editable Version

Agenda (HRP Use Only)

2508 HIPAA authorization form 04-28-2023.docx

Attachment Type
HIPAA Research Authorization Form

File Comments
word version - HIPAA Authorization Form Closed to Enrollment; Deactivated

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

Pre Screeniing Form_2_5_2023.docx

Attachment Type
Case Report Form (CRF, eCRF)

File Comments
Pre-Screening Form

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

Study Device Log_2_12_2023.xlsx

Attachment Type
Sponsor Device Log

File Comments

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)
Add

Dave_COI_2023.pdf

Attachment Type
Other

File Comments
COI For Dr. Reinkensmeyer reviewed and approved by COIOC and added to Consent.

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)
Add

Tenovi user's guide.pdf

Attachment Type
Other

File Comments
Tenovi Gateway Device

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

Surevey_Boost RCT_Form_v2_1_16_2024.docx

Attachment Type
Data Collection Tool/Instrument

File Comments
Post therapy survey

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

KAIST_certificate_SJK.pdf

Attachment Type
Other

File Comments
Korean credentials

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)
Add

H.S. Diploma - Luis Garcia Fernandez.pdf

Attachment Type
Other

File Comments
Spanish credentials

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)
Add

2508 Renew & Amend Approval Letter 3-10-25.pdf

Attachment Type
UCI IRB Approval Letter

File Comments

File Name

Status (HRP Use Only)
Approved

Agenda (HRP Use Only)

2508 Spanish Consent Form 03-22-24.docx

Attachment Type
Translated Consent Form

File Comments
Closed to Enrollment; Deactivated

File Name

Status (HRP Use Only)
Approved - Editable Version

Agenda (HRP Use Only)

2508 Korean Consent Form 03-22-24.docx

Attachment Type
Translated Consent Form

File Comments
Closed to Enrollment; Deactivated

File Name

Status (HRP Use Only)
Approved - Editable Version

Agenda (HRP Use Only)

2508 Korean HIPAA 03-22-24.pdf

Attachment Type
HIPAA Research Authorization Form

File Comments
Closed to Enrollment; Deactivated

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

2508 Spanish HIPAA Form 03-22-24.pdf

Attachment Type
HIPAA Research Authorization Form

File Comments
Closed to Enrollment; Deactivated

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

Rancho Los Amigos Rehabilitation Center IRB Approval Letter.pdf

Attachment Type
Non-UCI IRB Approval Documentation

File Comments
Rancho

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

Casa Colina Hospital IRB Approval Letter.pdf

Attachment Type
Non-UCI IRB Approval Documentation

File Comments
Casa

File Name

Status (HRP Use Only)

Agenda (HRP Use Only)

Lead Researcher Certification

Investigator's Assurance

As Lead Researcher, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to all Institutional Review Board (IRB) requirements, federal regulations, and state statutes for research involving human subjects.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. The information provided in this application has been discussed and shared with my Department Chair. Any requests for changes based on this discussion are included in this application upon submission or will be initiated by the research team either during the IRB review process or via an amendment.
3. All named individuals on this project have read and understand the procedures outlined in the protocol and their role on the study.
4. All named individuals on this project have completed the required Educational research tutorials and have been made aware of the "Common Rule" (45 CFR Part 46), applicable Food and Drug Administration (FDA) regulations (21 CFR Parts 50, 56, 312 and 812), have read the Belmont Report, and UCI's Federalwide Assurance (FWA) that are available on the Human Research Protections Program (HRP) website.
5. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.
6. Any responses submitted on my behalf by named individuals on this project I have prospectively agreed to.
7. I understand that, if the study described in this IRB application is supported by a federal award or used as a basis for a proposal for funding, it is my responsibility to ensure that the description of human subjects activities in the proposal/award is identical in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary to assure the proposal/award and application are identical in principle.

I and all co-investigators and research personnel agree to comply with all applicable requirements for the protection of human subjects in research including, but not limited to, the following:

1. Obtaining the legally effective informed consent of all human subjects or their legally authorized representatives (unless waived) and using only the currently approved, stamped consent form (if applicable).
2. Per federal regulations, once a human research study has received IRB approval, any subsequent changes to the study must be reviewed and approved by the IRB prior to implementation except when necessary to avoid an immediate, apparent hazard to a subject. See Reporting of Unanticipated Problems.
3. Reporting any unanticipated problems involving risk to subjects or others, including protocol violations per UCI IRB policy. In addition, HIPAA privacy violations must be PROMPTLY disclosed to the UCI Privacy Officer. There are time requirements for reporting these breaches of confidentiality, which, if not met, may result in monetary damages to the researcher and the institution.

4. Responding appropriately to subjects' complaints or requests for information about the study; and reporting to the IRB any subject complaints that are not resolvable by the study team.
5. Promptly providing the IRB with any information requested relative to the project.
6. Assuring the appropriate administration and control of investigational test articles (i.e., investigational drugs, biologics or devices) by a qualified investigator or other appropriate individual or entity (e.g., UCI Health pharmacy), and assuring use and maintenance of an Investigational Drug/Biologic Accountability Log or Device Accountability Log.
7. Registering applicable clinical trials with clinicaltrials.gov. For more information about this topic, visit the ClinicalTrials.gov web page or the HRP webpage. The consequences of not meeting the registration and reporting requirements include monetary damages to the researcher and the institution.
8. Obtaining continuing review prior to study expiration (I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all human research activities must cease until IRB approval is obtained).
9. Promptly and completely complying with an IRB decision to suspend or terminate its approval for some or all research activities.
10. Submitting to a routine review of human subject research records. The Compliance & Privacy Office at UCI Health performs ongoing routine reviews of open biomedical research protocols, in an effort to ensure in part that human subject research activities are conducted in accordance with regulations, laws and institutional policies regarding the protection of human subjects. In addition, the HRP unit of the Office of Research has developed the Education Quality and Improvement Program (EQUIP). Through EQUIP, HRP staff conduct periodic quality improvement monitoring and educational outreach.
11. For clinical trials initially approved by the IRB on or after January 21, 2019, posting one (1) IRB-approved clinical trial consent form at a publicly available federal website. The consent form must be posted after recruitment closes, and no later than 60 days after the last study visit. For additional guidance, refer to the OHRP FAQs on Informed Consent.
12. Filing a final report with UCI HRP at the conclusion of this project.

As the Lead Researcher, I assure all of the above

Investigators' Disclosure of Financial Interest

In order to inform research subjects of circumstances that may affect their decision to participate in this study, all researchers are required to disclose their financial interests with outside institutions.

The Lead Researcher of the protocol must ask the following question of all study team members:

"Do you, your spouse/registered domestic partner, and dependent children together have any disclosable financial interests (i) that would reasonably appear to be affected by the research; or (ii) in entities whose financial interests would reasonably appear to be affected by the research?"

A member of the study team who answers in the affirmative will be contacted by the Conflict of Interest Oversight Committee (COIOC) to obtain additional information regarding their specific financial interest(s).

IMPORTANT! If there has been a change in the financial disclosures of the LR or the study team, please also request a 'Change in Financial Interests'.

As Lead Researcher, I certify that the disclosures for all study team members are accurate

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Need Help?

09/27/2022 UPDATE: There is a slight time delay (30+ seconds) when "submitting" a transaction. Please do not refresh or close the page. The transaction will eventually go through.

Kuali is currently working to resolve the performance issues our customers are experiencing. Thank you for your patience and your partnership.

Contact the Office of Research

For KRP technical questions or issues:

- **Visit the KRP User Guide**
- **Contact Electronic Research Administration (ERA)**

For IRB questions and regulatory or institutional guidance:

- **Visit Human Research Protections (HRP)**
- **Contact the HRP staff**

Administrative Details Form

Project Status

Committee:
IRB A

Project Status:
Approved

Date of Action/Determination:
03-10-2025

Amendment Status:
Approved

Date of Amendment Action/Determination:
03/22/2024

ERA Transcription Date:

Not applicable for new studies submitted after September 07, 2021

Pre-2018 Common Rule:

Not applicable for studies initially approved after January 21, 2019
No

Date of Transition:

Not applicable for studies initially approved after January 21, 2019