

December 18, 2025

To whom it may concern,

Please find attached the study protocol for our clinical trial.

Official Title of the study:

Addressing Arm Non-use by Encouraging Idle-time Activity During Early Recovery From Stroke

NCT number:

NCT05900999

Date of the Document as Reviewed by IRB: 07/03/2025

Note the locations for the following data elements in the attachment:

- **study purpose:** Section 28.1
- **relevant scientific background:** Section 28.2
- **study objectives:** Section 29.2
- **design:** Section 28.1 and Section 30.1
- **methods:** Section 30.1
- **statistical considerations:** Section 30.2

Sincerely,

Robert A. Schreiff

Robert A. Scheidt, PhD
Professor, Joint Department of Biomedical Engineering
Marquette University and Medical College of Wisconsin



1. Project Identification

1.1 * Short Title:

Wearable R21 Inpatient

1.2 * Full Title of Project:

Addressing arm non-use by encouraging idle-time activity during early recovery from stroke

1.3 * Principal Investigator (PI):

John McGuire

1.3.1 * Does the Principal Investigator, their immediate family members (spouse and dependent children) or their significant other have a "Significant Financial Interest" with the sponsors of this research or that might affect the result of this research?

Yes No

1.3.2 * Does the Principal Investigator need to access Froedtert Epic for this project? Yes

No

* Does the Principal Investigator need to access Children's Wisconsin Epic for this project? Yes No

1.3.3 * Will the Principal Investigator be involved with any of the following:

- Screening subjects for entry into a magnetic environment for MRI
- Entry into a magnetic environment for MRI
- None of the above

1.4 * Will there be other project team members in addition to the Principal Investigator?

Yes No

2. Project Team

2.1 Project Team Members Other Than PI: (Check Training Status)

For projects relying on another IRB for review: add only MCW/Froedtert Hospital/Versiti, Inc./Children's Wisconsin project team members. [i](#)

	Last Name	First Name	Primary Organization	Department	Position	Is Primary Contact	Can Edit Emails	Receives Role on Project	Consenting Subjects	MRI Involvement?	FH Epic?	CW Epic?	Human Material?	SFI
View	Bassindale	Kim	Marquette University	Non-MCW	Assistant Lab Director	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Clohesey	Kelly	Medical College of Wisconsin	Clinical and Translational Science Institute	Clinical Research Coordinator III	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Golus	Sarah	Medical College of Wisconsin	Wisconsin Institute for Neuroscience	Clinical Research Coordinator III	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Project Staff	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Morelli	Whitney	Medical College of Wisconsin	Physical Medicine and Rehabilitation	Assistant Professor	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Scheidt	Robert	Marquette University	Biomedical Engineering		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Key Personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Winkoski	Maureen	Medical College of Wisconsin	Non-MCW	Student Medical Student	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Project Category

3.1 * Which category best describes the type of project you are submitting for review?

- Case Report[†]** – Involves a description of routine medical care for three patients or less
- Quality Improvement[†]** – The entire project is initiated, overseen, and analyzed by an official Froedtert Health Entity Quality Assurance committee
- Research Project[†]** - Including clinical trials, record reviews, specimen reviews, surveys, etc.
- Research Project plus distant bank[†]** - No banking at a local project site
- Research Project plus creating a new local bank[†]** - At least one at a local project site *Note: see 3.1.1 below
- Research Project requesting reliance on another IRB[†]** - An IRB other than the MCW IRB will serve as the IRB of record for this project.
- Creating a new local bank[†]** - No research project being proposed in this submission
- Treatment Use[†]** - Use of investigational drugs, medical devices, biologics or Humanitarian Use Devices (HUDs) **solely** for clinical purposes with no elements of research or research data collection
- Emergency Use[†]** - Use of an investigational drug, medical device, biologic or Humanitarian Use Device (HUD) – after-the-fact report to the IRB
- Not Human Subjects Research[†]** – The project will not interact/intervene with living human beings

3.2 * Does the proposed project involve any of the following features?

(check all that apply)

- Deception projects
- Direct contact with subjects**
- Human Source Material (human blood, tissues, cell lines)
- Long-term Follow-up Project
- Open label extension project
- None of the above

3. Project Elements

3.3 * Does this project involve any of the following elements? i

(check all that apply)

100% of subjects are known to be deceased, e.g., work with cadavers or biospecimens of deceased persons; record reviews where all subjects are demonstrably deceased

In-vitro or laboratory diagnostic tests in the absence of FDA approval and/or CLIA certification:
 chemistry, drug monitoring, immunological/hematologic, tumor marker, genetic disorder, infectious disease, microorganism, bio-threat tests

Dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus from any source, commercial or otherwise

More than one site. Project activity will take place at other institutions or locations that are not under the supervision of the PI listed on this IRB application.

Any part of the project takes place in another country. Check here if the PI is the lead PI for a multi-site project where one or more sites are in another country or if any project related work or oversight work is being done in another country.

Application to waive informed consent requirements for certain types of planned emergency medicine research [(21 CFR 50.24 or 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research) or (FR doc. 96.24968)]

Research using the internet as a source of information or a survey tool

Project utilizes artificial intelligence (e.g. deep learning, large language models, machine learning, natural language processing, etc.) for any component of the project, including as a tool

None of the above

3.4 * Does this project involve ONLY one or more of the following minimal risk activities? i

(check all that apply)

Biospecimens collected

Blood draws with collection limited to finger, heel or ear stick, or venipuncture

Educational

Non-invasive collection of biospecimens

Non-invasive Procedures

Psychosocial Interventions

Records collected

Surveys, questionnaires, interviews, focus groups, or observation of behavior

Voice, Image or digital recording for research purposes

No, my project involves activities which are not minimal risk, or the identified activity no longer qualifies as minimal risk

3.5 Use of Identifiers - indicate the level of "subject identification" you require to BEGIN this work.

- If any element of your records, data files, or administrative records contains an identifier, you should select Identified Data.
- If you plan to de-identify data at any time other than the first day you access the information, you should select Identified Data.
- If different levels apply, choose the "most identified" one, e.g., if level A and level B apply, choose level A. i

A - IDENTIFIED DATA: Utilizes one or more identifiers, including those defined by HIPAA Privacy Rule but not using a "limited data set." See help text for complete listing.

B - CODED DATA, KEY held by project team: Data is coded; **and** key code held by any person at MCW, Froedtert Hospital, Children's Wisconsin, or Versiti, Inc. whether or not they are part of the project team.

C - CODED DATA, KEY not held by project team: Data is coded; key code not held by any local faculty member, employee, fellow, resident, or student; key code not held by any member of the project team; **and** the key code will never be accessible to any member of the project team.

D - LIMITED DATA SET: The only HIPAA identifiers utilized are dates or certain allowable geographic subdivisions; an IRB "limited data set" data use agreement has been executed by the PI; and is uploaded into this IRB application.

E - DE-IDENTIFICATION PROCESS: The IRB application describes how the project team will de-identify data in one of two approvable methods: 1) using an MCW IRB-approved "honest broker"

or 2) receiving coded data/specimens without identifiers and without a key code. For details see *"Two ways to de-identify data or biospecimens for IRB purposes."* To use these options, no code keys may be created or saved and the resulting dataset can never be re-identified. In addition, a complete list of project variables must be uploaded in Section 52.

F - ANONYMIZED: The investigator receives data in anonymized form and no other party has the potential to re-identify data (i.e. no code key exists anywhere in the world). In this case, the IRB application must include a detailed description of how the data was collected, e.g., anonymous surveys, or who provided the anonymized data or biospecimens, so the IRB can verify the source and the irreversibility of anonymization. In addition, a complete list of variables, e.g., data recording sheet, Case Report Form, anything that summarizes all the information that will be recorded, must be included in Section 52 Attached Documents.

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3C. Research using the Internet – Part I

You received this section because in Section 3. Project Elements, Question 3.3, you checked "Research using the internet."

3C.1 * How is the internet being used in this research?

(check all that apply)

- Recruiting subjects over the internet
- Observation of internet activity
- Collecting data over the internet**
- Informed Consent obtained over the internet
- None of the above

3C.2 * How will you protect the confidentiality of information collected over the internet? Include technical information such as encryption, firewalls, etc.

The surveys are distributed through the REDCap survey tool. REDCap is a secure, HIPAA compliant data storage platform.

3C. Research using the Internet – Part II

3C.3 * Will an Internet survey company be used?

Yes No

3C.4 * Describe the expertise of the investigator and/or research team with regard to conducting research on the Internet:

The PM&R research team routinely uses REDCap as a secure data platform/survey tool.

3C.5 * Have any technical consultants been involved in designing this research?

Yes No

3D. Surveys, Questionnaires, Focus Groups, Observation of Behavior

You received this section because in Section 3. Project Elements, Question 3.4, you checked "Surveys, questionnaires..."

3D.1 * Identify the activities which will be done as part of this research project:

Surveys

Questionnaires

Interviews

Focus Groups

Observation of Behavior

3D.2 Surveys:

3D.2.1 * How many surveys will be distributed?

60 x 3 surveys x 2 timepoints = 360

3D.2.2 * How many surveys do you expect to collect?

up to 360

3D.6 Observation of Behavior:

3D.6.1 * Describe subject population which will be observed:

Stroke survivors

3D.6.2 * How many subjects will be observed?

Up to 60

3D.6.3 * Will this observation be in a public or private setting?

Private setting

3D.7 * Could any disclosure of responses place subjects at risk for criminal or civil legal actions, or cause them to be at risk for damage to their financial standing, employability, or reputation?

Yes No

3D.7.1 * Please explain/justify response above:

No disclosure of any responses will place subjects at risk for criminal or civil legal actions, or

cause them to be at risk for damage to their financial standing, employability, or reputation.

These responses are to evaluate the usability of the device, provide guidance and instruction for wearing device, and user recommendations after wearing the device.

Instruction: Upload the survey, script, questionnaire, and/or coding sheet for the project in Section 52

3F. Records Research

You received this section because in Section 3. Project Elements, Question 3.4, you checked "Records collected"

3F.1 * For what purpose were the records originally created?

(check all that apply)

Clinical Care

*** Identify the Sources:**

Medical College of Wisconsin

Froedtert Hospital Campus (including all speciality clinics, the Cancer Center and the Eye Institute)

Versiti, Inc. and Blood Research Institute

Children's Wisconsin

Other

Quality assurance

School or teaching records

Billing or insurance

Program administration

Hospital or community surveillance

Different research project

Other

3F.2 * Do you plan to use/analyze records created before the date of IRB approval (retrospective records)? (i.e., NO additional cases created after that date, and NO opportunity to include follow-up information created after that date)

Yes No

3F.3 * Do you plan to access records created after the date of IRB approval (prospective records)?

Yes No

* If Yes,

3F.3.1 How will you get permission to access these records?

(check all that apply)

Using informed consent

From an IRB approved bank

Other

3F.4 * Estimate the total number of subject records that you intend to:

(The IRB expects the investigator to provide meaningful estimates and to adhere reasonably to these estimates. It is often better to make a slight over-estimate of numbers.)

Screen, whether you use the record for this project or not.

300

Use for this project.

up to 60

3F.5 * Explain how you determined the number of records to include in the project at this site.

PM&R Inpatient sees approximately 100-150 new stroke patients annually. For this two year grant, the study will screen up to 300 patients. In order to complete 30 participants, as many as 60 may be consented to begin the research study.

3F.6 * Is it practicable to conduct the project with de-identified data?

Yes No

* 3F.6.1 What kind of clinical information will you have about the records?

(check all that apply)

Patient diagnosis

Patient symptoms or signs

Patient lab values

Patient course of illness

Other

3H. Non-Invasive Procedures

You received this section because in Section 3. Project Elements, Question 3.4, you checked "Non-invasive Procedures"

3H.5 * Select the collection method or procedure which will be used:

(check all that apply)

Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject

Weighing or testing sensory acuity

Magnetic Resonance Imaging (MRI)

Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography

Ultrasound, diagnostic infrared imaging, Doppler blood flow and echocardiography

Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing

Other

3L. Voice, Image, Digital Recordings

You received this section because in Section 3. Project Elements, Question 3.4, you checked "Voice, Image, Digital Recording..."

3L.1 * Identify the recording media which will be used:

(check all that apply)

- Voice/Audio recording (digital or analog)
- Video recording
- Photographs
- Use of eye tracking software & recording
- Imaging records created for the research process only

- Other

* If Other:

3L.1.1 Specify:

Telemetry (frequency of arm movement via acceleration)

Responses Provided Prior to April 22, 2017

3H.4.1 Describe the recording media to be employed.

4. Safety and Research Review Committees

4.1 * Does this project include any of the following regulated items or resources?
Selections will determine if there are additional review requirements prior to IRB review process beginning, per MCW policy: [i](#)

(check all that apply)

- Biological Toxins
- Project with a cancer focus (including healthy subjects)
- Human Gene Transfer
- Human stem cells
- Human/Non Human Primate (NHP) Cell Lines, Tissues, or Blood Products
- Microorganisms
- Magnetic Resonance Imaging (MRI) (that is not Standard of Care)
- Radiation therapy, radioactive materials/brachytherapy, CT, X-ray, fluoroscopy
- Recombinant DNA (non-Viral vectors)
- Resources at Children's Wisconsin (such as enrolling patients, imaging, pTRU, records, samples, use of facilities/buildings/clinics/services, etc.)
- Viral Vectors

None of the above

6. Project Locations

6.1 * Under the direction/supervision of this Principal Investigator, project activities will take place at the following locations: 

(check all that apply)

Froedtert & the Medical College of Wisconsin Hospitals and Health Partners

Cardiothoracic Surgery Clinic

Drexel Town Square Health Center

Endocrinology Clinic (Oconomowoc)

Endocrinology Clinic (Waukesha)

Fitness Center (Sports Medicine)

Froedtert Bluemound Clinics (entrance on 99th Street)

Froedtert Bluemound Rehabilitation Hospital (entrance on Bluemound Road)

Froedtert Hospital (including all specialty clinics, the Cancer Center and the Eye Institute)

Froedtert Menomonee Falls Hospital

Froedtert West Bend Hospital

Germantown Health Center

Greendale Medical Clinic

Greenfield Highlands Health Center

Hartford Health Center

Jackson Health Center

Jackson Rehabilitation and Sports Medicine Center

Kewaskum Health Center

Lincoln Avenue Health Center

Menomonee Falls Behavior Health Center

Moorland Reserve Health Center

North Hills Health Center (previously Community Memorial Medical Commons – CMMC)

Orthopaedic, Sports and Spine Center

Pleasant Valley Health Center (attached to FWBH)

Sargeant Health Center

SpineCare Clinic (Oconomowoc)

Springdale Health Center

Sunnyslope Health Center

Sussex Health Center

Tosa Health Center

Town Hall Health Center

West Bend Health Center

Westbrook Health Center

Medical College of Wisconsin - Milwaukee Campus

Medical College of Wisconsin - Green Bay Campus

Medical College of Wisconsin - Central Wisconsin Campus

Center for AIDS Intervention Research (CAIR)

Adult Translational Research Unit (TRU)

Versiti, Inc.

Children's Wisconsin

Clement J. Zablocki Veteran's Affairs Medical Center†

UW-Milwaukee†

Marquette University†

Milwaukee School of Engineering†

Other

*** 6.1.1 For all locations other than MCW, Froedtert Hospital, Versiti, Inc., or Children's Wisconsin list the lead collaborator at each institution, their role at each institution, and the name of the institution.**

Robert Scheidt, PhD
Professor, Department of Biomedical Engineering
Marquette University

6.2 * Will any subject recruitment activities or research procedures under the responsibility of this Principal Investigator take place outside of Wisconsin but within the US? 

Yes No

7. Multi-Site Project

7.1 * Will the protocol be conducted exactly the same at all sites, including recruitment and study activities?

Yes No

* 7.1.1 Use the table below to detail the involvement of each site.

Site Name	Activity Details	Type	Home institution of the people carrying out these activities. Someone from:	Description
View MCW/Froedtert	Reviewing medical records/databases before informed consent to determine eligibility	- MCW - Froedtert & Medical College Hospitals and Health Partners	- MCW - Froedtert & Medical College Hospitals and Health Partners	Screening MR for eligibility
	Reviewing medical records for chart review	- MCW - Froedtert & Medical College Hospitals and Health Partners	- Froedtert & Medical College Hospitals and Health Partners	Data abstraction from MR
	Obtaining informed consent	- Froedtert & Medical College Hospitals and Health Partners	- Froedtert & Medical College Hospitals and Health Partners	Approaching eligible patients for research discussion, and consent if patient is interested in participating.
	Interacting with subjects, including interviews, surveys, focus groups	- Froedtert & Medical College Hospitals and Health Partners	- Froedtert & Medical College Hospitals and Health Partners	Study procedures while study subjects are inpatient.
	Data analysis	- MCW - Froedtert & Medical College Hospitals and Health Partners	- MCW - Froedtert & Medical College Hospitals and Health Partners	Data analysis conducted at conclusion of study.
View Marquette University	Interacting with subjects, including interviews, surveys, focus groups	- The site listed above	- The site listed above	Follow up visit for study procedures
	Data analysis	- The site listed above	- The site listed above	Data analysis conducted at conclusion of study

7.2 * Approximately how many total sites are participating in this project?

2

7.3 * Is this Principal Investigator managing the Coordinating Center of this multi-site project?

Yes No

* If Yes,

7.3.1 Describe the Coordinating Center leadership structure:

Study staff work under the direction of the PI. The PI is ultimately responsible for successful completion of the study.

7.3.2 Describe the Coordinating Center's responsibilities:

The Coordinating Center will be responsible for assuring IRB approval and compliance at both participating locations; enrollment into and successful completion of the research protocol for consented study subjects; data storage and integrity.

7.3.3 If the project is supported by any federal grants, contracts or subcontracts, list here the FWA # for each institutional site:

Medical College of Wisconsin - FWA00000820
Marquette University - FWA00005844

Instruction: When this Principal Investigator is managing the Coordinating Center, upload the following documents in Section 52:

- Local IRB approval with approved consent form or documentation of consent waiver for each performance site
- Protocol or procedure manuals to be used by any of the performance sites
- Central data collection and management plan
- Comprehensive multi-site safety monitoring plan
- If federally funded, all grants, contracts and subcontracts to non-local performance sites related to this project

8. National Cancer Institute (NCI) Cooperative Groups

8.1 * Is this project part of a NCI cooperative group? 

Yes No

10. Intervention Evaluation

10.1 * Is this research project designed to evaluate the safety or effectiveness of a research treatment/intervention? 

Yes

No

If Yes:

10.1.1 * What is the research treatment/intervention? Please identify the experimental drug, device, combination or procedure being used. 

Wearable technology fitness device that will cue for vibrotactile, visual, and auditory cuing on a stroke survivors wrist

10.2 * Does the research involve: 

(check all that apply)

Drug: FDA-approved, investigational, or other

Device: FDA-approved, 510(k), investigational, HUD, or other

Biologic: FDA-approved, investigational, or other

Botanical, medical food, or dietary supplement

None of the above

* 10.2.1 Is the purpose of the research to evaluate the safety or effectiveness of 1 or more devices? 

Yes No

10.3 * For drug, biologic or device clinical trials, please identify the phase of this clinical trial. For combined phase projects - e.g., Phase II/III - select only the smaller number. If a phase is not clearly identified, please select N/A.

(check all that apply)

Phase I

Phase II

Phase III

Phase IV

N/A

10.4 * Will this project be registered with ClinicalTrials.gov (e.g. required by Sponsor, meets Applicable Clinical Trial (ACT) criteria, or voluntarily)? 

Yes No

* 10.4.1 Provide the National Clinical Trial (NCT) number assigned by ClinicalTrials.gov:
NCT05900999

* 10.4.2 Is this Principal Investigator the responsible party for the record on ClinicalTrials.gov? 

Yes No

10. IND or IDE

10.5 * Does this project require an Investigational New Drug (IND) number?

Yes

No

N/A

10.6 * Has the FDA issued an Investigational Device Exemption (IDE) number for this project?

Yes

No

N/A

10.7 * Has the FDA issued an Humanitarian Device Exemption (HDE) number for this device?

Yes

No

N/A

10.8 * Does the FDA regulate the research treatment/intervention you intend to use?

Yes No

*** 10.8.1 What is the FDA classification of the research treatment/intervention?**
Non-Significant Risk Medical Device

10B. Devices/In Vitro Diagnostics

You received this section because of any of the following:

- in Section 03. Project Elements, Question 3.3, you checked "in-vitro or laboratory diagnostic tests..." OR
- in Section 04. Safety and Research Review Committees, you checked "Magnetic Resonance Imaging (MRI) (that is not Standard of Care) OR
- in Section 10. Intervention Evaluation, Question 10.2, you checked "Device" and answered Question 10.2.1 as "Yes"

10B.1 * Does the project sponsor and/or your clinical trial contract specify that you must follow ICH-E6 guidelines?

Yes No

10B.2 * Does any project arm use a combination of a device with drugs or biologics, being studied under an IDE?

Yes No

10B.3 * Does the project include a "sham" procedure?

Yes No

10B.4 * List all device(s) to be used as intervention(s) in this project:

Name of Device	Details
View Custom Wearable Technology Device; similar to a FitBit fitness device	<p>Responsible: Investigator: Dr. John McGuire</p> <p>Status: Meets "Not Significant Risk" criteria</p>

11. Funding Source

11.1 * Do you have funding to support any of the activities for this project:

Yes No

If Yes,

11.1.1 List all current MCW department funding for this project that is not associated with an eBridge Funding Proposal.

Title Cost Center Fund Project Number

There are no items to display

11.1.2 List all funding sources for this project (excluding department funds listed in 11.1.1): [i](#)

Type	Short Title	Funding Source	Prime Grantor	Grant Award Number	FP ID	FP Current Budget State	FP Parent State
Federal View Pass-through	Addressing learned non-use during early recovery from stroke	NIH Child Marquette Health and University Human Development		FP00020597	Active	BU00036709	

* 11.1.3 Do you have funding that is not managed through MCW, CW or Versiti, Inc.?

Yes No

12. Project Subject Types

12.0 * Does this project involve any minor subjects, or use of records or biospecimens related to minors? (Minor status is defined by the legal age of consent for the state or country where the research activity takes place; e.g., under 18 years of age in Wisconsin.)

- All minors
- Some adults and some minors
- All adults of legal age

12.1 * Enter the disease/affliction that is the focus of this project (e.g. pancreatic cancer):
Stroke

12.2 * Identify all categories of subject populations that will be included in this project:
(check all that apply)

- Cancer patients
- Inpatients
- Outpatients
- Healthy Subjects (i.e. subjects NOT selected because they have a particular medical condition or history)
- Elderly - age 70 and over
- Employees including faculty, staff, residents or fellows
- Fetuses
- Issues of cognitive or decisional impairment
- Limited or non-reader
- Neonates - nonviable/uncertain viability
- Neonates - viable
- Non-English speaking
- Nursing home residents
- Persons with alcohol or drug use disorders
- Persons with developmental disabilities - neurologic or psychiatric
- Persons with mental illness
- Poor and/or uninsured
- Pregnant women
- Prisoners - see help text
- Students - MCW
- Student population within Children's Wisconsin facilities
- Terminally ill patients
- Traumatized, sedated, or comatose patients
- Visually / hearing impaired
- Other (SPECIFY)

12.3 * Are the exclusion criteria for this project likely to exclude groups or categories of subjects based on race, socioeconomic status, or insurance coverage?

Yes No

12.4 * Are the subjects for this project limited to those who speak and read English?

Yes No

* If Yes,

12.4.1 Please provide a rationale for excluding non-English speaking subjects.
Assessments for this study are validated in English only.

Instruction: Please upload any project materials in other languages in section 52.

12B. Decreased Decisional Ability – Part I

You received this section because in Section 12 Project Subject Types, Question 12.2, you checked "traumatized, sedated or comatose patients, issues of cognitive or decisional impairment, or ... development disabilities..."

Note: "Decreased decisional ability" refers to persons who show decreased ability to understand, communicate, reason, and/or decide. The impairment may be due to disorders of a psychiatric, organic (including those suffering from delirium or degenerative brain diseases), developmental (e.g., mental retardation), substance misuse (e.g., those under the influence of or dependent on drugs or alcohol), or other nature that affects cognitive or emotional functions.

12B.1 * Describe the subjects with decreased decisional ability that you intend to include in this project:

Due to the brain injury that can occur during a stroke, patients who have survived a stroke may be left with mild, moderate or severe cognitive impairment. The Montreal Cognitive Assessment will be administered before consent to ensure a patient is decisional before signing a consent form. If the patient has completed this assessment during the current admission, study team may apply this score to the consent documents and proceed as outlined in the protocol.

12B.2 * Explain why these subjects are necessary to this project:

This project focuses on improving rehabilitation practices for people who have survived a stroke.

12B.3 * Are any of these subjects institutionalized?

Yes No

12B. Decreased Decisional Ability – Part II

12B.4 * Do the risks to subjects with decreased decisional ability fall within the federal definition of "minimal risk"?

Yes No

12B.5 * How will individual subjects' ability to provide informed consent be determined? Describe the procedures, the assessment criteria or instruments to be employed, and the qualifications of the assessors, and why they are appropriate for the subjects' conditions and the nature of the project. Before consent, a member of the study team will administer the Montreal Cognitive Assessment (MoCA). The MoCA is a common tool to test cognitive function, and study team members are trained to use this tool regularly in PM&R research studies. The MoCA is scored out of 30 pts: 30-26 indicates no impairment, 25-18 indicates mild impairment, 17-10 indicates moderate impairment, 9-0 indicates severe impairment. For the purposes of this study, study subjects with no impairment will be enrolled with no further cognitive testing. Study subjects with mild or moderate impairment can be enrolled in the study if they pass an informed consent quiz and demonstrate ability to follow 2-step directions. If the patient has completed this assessment during the current admission, study team may apply this score to the consent documents and proceed as outlined in the protocol.

12B. Decreased Decisional Ability – Part III

12B.6 * Where it has been determined that a subject lacks the decisional ability to provide informed consent, describe the provisions for obtaining consent from the subjects' legally authorized representative. [i](#)

This study will not pursue LAR consent. If a subject lacks decisional ability to provide informed consent, they will be excluded from the study.

12B.7 * If an LAR provides consent, describe how the assent of the subjects will be obtained and documented:

N/A - this study will not pursue LAR consent.

12B.8 * If subjects are likely to regain decisional ability, describe how and when their decisional ability will be assessed.

N/A - subjects will have decisional ability at time of consent

12B.9 * Is it likely that some subjects who initially give consent will lose their decisional ability during the course of the project?

Yes No

13. Determination of Number of Subjects

13.1 * How many people at this site will begin research treatment [for treatment projects] or key assessments [for other projects]? (enter your highest anticipated #)
60

13.1.1 Also provide estimates (three numbers) of how many subjects ...

- staff will screen to assess eligibility prior to informed consent
- will sign a consent form (of any type)
- are needed to complete the project in order to fulfill project objectives.

Screen 300
Consent 60
Complete 30

13.2 * Explain how you determined the number of subjects to include in the project (at this site and for the project as a whole, if multi-site). Consider the objectives of the project and the nature of the data.

- Include a power analysis if appropriate, or explain why you think the number of subjects will provide the evidence you hope to obtain.
- If screening records or subjects, show your estimate of how many must be screened to yield the number necessary for analysis.
- If the number of subjects is based on "availability" rather than "need", then explain in this context.

There are no existing pilot data from which to obtain estimates of performance variability and/or effect size needed to conduct an *a priori* power analysis of functional utility or subjective patient experience. Instead, we have selected to recruit a minimum of 30 acute stroke survivors. Based on our prior experience conducting human sensorimotor behavioral studies in stroke survivors, this number of participants is highly likely to yield success in meeting our primary and secondary study endpoints.

13.3 * What is the global enrollment goal for this project (all US and international sites combined)?
Up to 60

15. Inclusion/Exclusion Criteria

15.1 * List inclusion criteria (e.g., age, gender, ethnicity):

- First time stroke
- \geq 18 years of age
- Able to follow two-stage instructions
- Able to tolerate vibrotactile cues.

15.2 * List exclusion criteria (e.g., age, gender, ethnicity):

- Inability to give informed consent
- Length of stay at inpatient rehab no less than three days
- Concurrent illness or injury limiting the capacity to conform to study requirements
- Non-English speaking

17. Recruitment Strategies

17.1 * Will potential subjects be identified or screened by searching records of any source outside MCW/FH/CW/Versiti, Inc.? (e.g., motor vehicle records, military service records, state registries, Medicare files, other hospitals including International hospitals)

Yes No

17.2 * To recruit potential subjects, will you use any of the following:

Print advertisements (e.g. newspapers, magazines, flyers, posters, brochures)
IRB SOP: [Recruitment Methods and Compensation](#)
IRB SOP: [Advertisements](#)

Letters/emails

Radio or television advertisements

Web solicitations
Examples of web solicitations include posting on craigslist.org, use of Researchmatch.org, sponsor website, advertisements on internet search engines and social media websites.

Telephone

Recruiting company

Physician referrals (includes in-house and/or outside referrals)

Approach subjects in-person (Example: a public place or knocking door-to-door)

Briefly describe the process and specify if any patients or potential subjects will be approached in-person:

A member of the study staff will approach and recruit eligible inpatients from Froedtert Hospital Inpatient Rehabilitation Unit or those patients' pending admission to IPR from the Froedtert Hospital Neurology Unit.

EPIC Tools:

Other strategies (not already covered) to identify, screen, or recruit subjects (Other professional referral sources (PhD clinicians, nurses, other investigators) should be classified as "other".)

Specify those strategies in detail:

Eligible patients may be identified through the Stroke Survivor Recruitment Databank (PRO 26783), then approached in person.

No recruitment activities

Instruction: Upload all recruitment materials in Section 52.

18. Subject Compensation/Reimbursement

18.1 * Will you offer subjects stipends, gifts or compensation for their participation, or reimbursement for project-related expenses, e.g., transportation, baby-sitting, parking?

Yes

No

* 18.1.1 Describe the type, item or amount, the method of payment, the schedule of payment, and how this was determined to be appropriate. Any payments routed through MCW must adhere to [MCW Policy](#):

Type Amount Method Schedule How was this determined to be appropriate?

There are no items to display

Previous 18.1.1 Describe what will be offered and why this was determined to be appropriate:

Study subjects will be compensated \$50 after the clinical assessments at the end of the two-week inpatient intervention window and another \$50 when they perform the in-home arm use assessments and return the devices using the prepaid shipping materials. The proposed compensation follows MCW Corporate Policy: Honoraria and Stipends Paid to Research Subjects (BF.AP.020), as quoted in MCW Office of Research Standard Operating Procedure RECRUITMENT METHODS AND COMPENSATION - <https://www.mcw.edu/-/media/MCW/Departments/Human-Research-Protection-Program/Researchers/IRB-SOPs/IRB-SOP-Recruitment-and-Compensation-FINAL.pdf?la=en>

25. Biospecimen Collection

25.1 * In this project, will the project team (or their agents – lab technicians or cooperative surgeons) collect biospecimens from human subjects for RESEARCH purposes? 

Yes No

26. Connecting with a Bank

26.1 * Will this project contribute data, records, or biospecimens to a local bank?

Yes No

26.2 * Will this project access data, records, or biospecimens from a local bank? [i](#)

Yes No

* 26.2.1 Cite the PRO for the local bank from which you will access data (records or biospecimens) for this project: [i](#)

Bank ID	Bank Title	Principal Investigator	Bank State	Accessing Records	Accessing Biospecimens
View PRO00026783	Recruitment databank	Matt Durand		Approved <input checked="" type="checkbox"/>	<input type="checkbox"/>

28. Purpose

28.1 * Why is it significant or important to conduct this project?

Many survivors of stroke - up to 80% - have persistent impairment of upper limb function that impacts activities of daily living. Many survivors do not use their more-involved arm and hand despite retaining capacity to perform movements. This phenomenon is referred to as learned non-use. Non-use of the more-involved limb develops in the weeks and months immediately following stroke and commonly persists long into recovery (i.e., > 6 months after stroke). Learned non-use of the arm can reduce quality of life by reducing agency and engagement in meaningful activities, including social participation. We propose a *feasibility study* of a wearable idle-time exercise cueing system designed to increase patient activity through exercises that progressively increase upper extremity use during early phases of recovery from stroke.

The purpose and design of the this study focuses on the technology and experimental procedures needed to successfully motivate idle-time arm activities during acute stroke recovery. This study is necessary because without a successful demonstration of functional utility and positive user experience, a future trial of efficacy would be unwarranted and wasteful. If we are successful, the purpose and design of *future* studies will be to evaluate the efficacy of an idle-time exercise program *in situ* during inpatient acute recovery, and to optimize the features of such a program to reduce increase use of the hemiparetic arm in the months and years following stroke.

28.2 * Briefly summarize findings from previously published data or pilot projects that substantiate the soundness of protocol being proposed; or describe formulation of research questions:

There is growing evidence of enhanced neuroplasticity in the first weeks poststroke²⁵. In this time, structured progressive exercise produces gains greater than those attributable to spontaneous recovery and usual care²⁶. *Our research is predicated on the premise that motor recovery may be enhanced by increasing patient engagement in upper extremity exercise within this window.* We aim to change the early trajectory of recovery for the better by using low-cost wearable technology to motivate and monitor arm activity during idle-time outside of therapist-directed therapy sessions. By doing so, patients will increase the "intensity" of arm activity (defined here as hours/day) in the days and weeks immediately following stroke with minimal added therapist oversight. We envision this system as an early adjunct to conventional therapy. *We expect our novel exercise cueing and monitoring system will give patients more agency over their therapy and increase their objective level of participation.* A future study will test if it can ultimately increase functional independence.

25. Murphy TH, Corbett D. Plasticity during stroke recovery: from synapse to behaviour. *Nat Rev Neurosci.* 2009;10(12):861-72. Epub 2009/11/06. doi: 10.1038/nrn2735. PubMed PMID: 19888284.

26. Duncan P, Studenski S, Richards L, Gollub S, Lai SM, Reker D, Perera S, Yates J, Koch V, Rigler S, Johnson D. Randomized clinical trial of therapeutic exercise in subacute stroke. *Stroke.* 2003;34(9):2173-80. Epub 2003/08/16. doi: 10.1161/01.STR.0000083699.95351.F2. PubMed PMID: 12920254.

29. Hypotheses and Objectives

Some projects are designed around explicit scientific hypotheses. Others (chart reviews, pilot projects) may be better described in terms of Aims or Objectives. Answer the question (29.1 or 29.2) that suits your project best.

- 29.1 State the hypotheses. If this project involves community-based research, indicate so and explain the project goals:
- 29.2 Describe the Aims and Objectives of this project in such a way that the reader can determine the appropriateness of the project design:

Aim 1: To establish the functional utility of a personal exercise cueing system in an inpatient setting during the days and weeks following stroke.

Aim 2: To characterize the subjective patient experience using a personal exercise cueing system during acute recovery on the inpatient rehabilitation unit.

30. Procedures and Analysis

30.1 * Narrate project procedures listing in sequential order the steps that will be followed to conduct the protocol:

- If there are multiple cohorts/groups, describe the procedures for each cohort/group. 

Recruitment procedures:

Study participants will be recruited from the Inpatient Rehabilitation unit (IPR) at Froedtert Hospital or the Neurology Unit at Froedtert Hospital (for those accepted patients into IPR and awaiting transport) by a member of the study team. Potential participants will be identified by screening medical records for inclusion/exclusion criteria, or through the Stroke Survivor Recruitment Database (SSRD - PRO 26783). Individuals meeting inclusion/exclusion criteria will be approached by a member of the study team, who will describe the study to them. At this time, the individual can demo the wearable device to get a sense of the vibrotactile cues. Should the individual be interested, the MoCA will be administered to assure decisionality (if MoCA was completed during current inpatient admission, study staff may apply this score) an ICF quiz administered as appropriate, and informed consent will be obtained by a member of the study team. If the patient is identified through the SSRD, the MoCA will not be repeated as this assessment is conducted in order to be eligible to enroll in the database.

Baseline procedures:

After consent, a member of the study team will conduct baseline assessments:

Sensory Motor Assessment - Fugl-Meyer assessment of upper extremity sensorimotor impairment. The participant is coached through a series of arm movements to assess movement, strength, reflex and sensation. Please see scoring sheet in 52.0 for specific movements.

Motor Function Assessment - Action Research Arm Test of motor function. The participant is coached through a series of arm movements to assess motor function. If this test proves to be too time intensive, then the Box and Blocks assessment of motor function will be substituted. A scoring sheet for both tests is provided in 52.0

Grip Strength - Grip strength will be assessed using a dynamometer. A set of 3 squeezes on the dynamometer will be performed. Subjects will have at least 30 seconds of rest between each squeeze to allow for optimal recovery. Subjects will be asked to grab the dynamometer with a neutral grip, and then squeeze the dynamometer as hard as possible while exhaling. The highest value reached for each trial will be recorded. Three trials will be performed for each hand and the highest score will be the final score. A scoring sheet is provided in 52.0

Post-stroke Function Assessment - Traditionally the NIH Stroke scale is administered at IPR admission, every Friday during the patients stay and at discharge. This information will be recorded into the REDCap database. If the scale is not available in chart review, it will be completed at time of enrollment. The scale measures stroke impairments through a series of questions and movements. If this assessment does not provide enough data about post-stroke function, the Chedoke-McMaster Stroke Assessment will be substituted. Scoring sheets are provided in 52.0

Electronic Medical Record data will be obtained and uploaded into REDCap (See Supporting Docs-52- for print out of information that will be entered into REDCap)

Inpatient Study procedures:

After baseline procedures are complete, the study protocol will begin. For 12 days over approximately two weeks, a member of the study team will visit the study subject each morning in their IPR room to help them don the wearable devices. The devices will be worn for approximately 9 hours each day. The study team member will pair the devices using Bluetooth connectivity to a password protected smartphone. The devices will be enabled with three 30-minute exercise sessions that will be scheduled during the patient's idle time. The patient and study staff will agree on the exercises to be performed each day from a preset list of choices: (1) using the less affected hand to tap the wrist of the more affected side; (2) using the less affected hand to help guide the more affected elbow through flexion/extension movements; (3) moving the more affected elbow through flexion/extension movements without assistance. The devices will passively monitor arm movements in between exercise times. At the end of the day, the study team member will return to collect the devices and smartphone. Data will be offloaded and devices and phone will be recharged. And the end of the 12th day, the study team will administer three usability surveys: the System Usability Scale, Intrinsic Motivation Inventory and the Quebec User Evaluation of Satisfaction with assistive Technology. The surveys are provided in 52.0

Follow up visit:

A follow up visit will occur 0-6 months post discharge from IPR. Every effort will be made for this to coincide with the patient's stroke follow up appt in the PM&R Stroke Clinic. At this visit, the Sensory Motor Assessment and the Motor Function Assessment will be repeated. The patient will be given a set of devices to wear at home for 48 hours. The devices will passively gather arm movement. At the conclusion of the 48-hr period, the participant will complete 3 usability surveys (as they did at the end of their inpatient portion of the study) via REDCap and mail the devices back to the study team using pre-paid mailing supplies. Subjects will provide their email to study staff during the time of their IPR stay. Staff will record email into the REDCap demographic form and surveys will be sent out to patient electronically (via a REDcap link) during the follow up period. Participants will be instructed to check their email inbox for this link.

If the patient does not schedule a follow up stroke visit, then the research team will schedule a research visit either at the Marquette University Neuromotor Control Laboratory, or in the patient's home. The Marquette study team has established protocols for in-home visits with patients, which include the buddy system, and safety check-ins.

Note: If desired, upload an activity table into Section 52 listing tests that will be conducted (e.g., lab draws, EKG, chest x-ray, genetics, proteomics, H&P, survey) as well as the frequency of these tests.

30.1.1 Explain the details of all research treatments.

- Where will the research treatments take place (inpatient, outpatient, residential or home setting)?
- Identify any research treatments being performed by a home health care agency (include the name of the agency)
- Describe the availability of emergency medical care or equipment
- What degree, professional license, or training do those administering the research treatment possess? 

30.2 * Explain how you intend to analyze the data:

- Data analysis - Primary Outcomes

This project has two Specific Aims, which will be addressed through separate analyses focused on primary measures of objective system utility (Aim 1) and subjective user experience (Aim 2).

Aim 1: To establish the functional utility of a personal exercise cueing system in an inpatient setting during the days and weeks following stroke.

To assess the system's functional utility, we seek to answer (Q1): "Is use of the more-involved arm greater during cued exercise intervals than control intervals wherein no activity is scheduled?" Given our broad inclusion criteria, we expect considerable diversity of patient motor capacity and performance on the more involved side and thus, standard parametric analyses of functional utility are not warranted. Instead, we will compute for each testing day, in each subject, the ratio of average activity duration in ITAA periods to the average activity duration in silent-monitoring periods for the more involved arm. *System utility will be operationally supported if, for the majority of patients, the daily ratio exceeds a value of 1.0 for at least three out of the four days in at least one of the three stages of the testing protocol.*

Aim 2: To characterize the subjective patient experience using a personal exercise cueing system during acute recovery on the inpatient rehabilitation unit.

We seek to characterize the subjective patient experience using our exercise cueing system during early stroke recovery. We operationally define a positive user experience as one where patients find the system to be usable, motivating, AND satisfying. Just prior to discharge from the inpatient rehab unit, we will administer 3 surveys: the SUS, the IMI, and QUEST. We chose these three instruments to answer 3 specific questions:

(Q2): "Do participants find the system to be usable?" SUS scores greater than 68 (out of 100) indicate above average system usability³⁴. We will use a planned one-sided, one-sample t-test to test whether SUS values significantly exceed a nominal value of 68. System usability will be supported if SUS values exceed 68.

(Q3): "Do participants find the system motivating?" IMI interest / enjoyment subscale values greater than 4 (out of 7) would indicate that participants found the system motivating to use. Planned, one-sided, one-sample t-test will test whether IMI interest / enjoyment subscale values equal or exceed a nominal value of 4. System motivation will be supported if IMI interest / enjoyment values equal or exceed 4.

(Q4): "Are participants satisfied in their experience using the system?" We will use the average QUEST score as a measure of user satisfaction, with values of 3 or greater (out of 5) indicating general satisfaction. We will use a planned one-sided, one-sample t-test to test whether average QUEST scores exceed a nominal value of 3. User satisfaction will be supported if average QUEST scores significantly exceed 3.

In order to conclude that the system provides a positive user experience, we require that the three analyses addressing questions Q2-Q4 must all yield significantly positive results.

Expected results: We expect the proposed system will have utility in motivating more-involved arm use during cued exercise intervals (Aim 1). We expect patients will have a positive experience using the system on the inpatient rehabilitation unit of Froedtert Hospital (Aim 2). Deviations from expectation will be studied by analyzing arm-use and questionnaire results at finer (subscale or item) resolution to guide system redesign in anticipation of follow-on studies evaluating the impact of idle-time exercise during early recovery from stroke.

• Data analysis - secondary outcome

We will estimate participant attrition rate through 2-month follow-up testing, in which we will assess more-affected arm motor capacity (via ARAT) and performance (via 48 hr arm-use accelerometry). We will use the attrition rate estimate to guide design of a larger follow-on clinical trial of intervention efficacy. We will use the capacity and performance data for additional exploratory analyses, as described below.

Expected results: Regardless of attrition rate through 2-month follow-up testing, we will have sufficient data at the study's end to know whether a follow-on study is warranted, and how to power that study if it is.

• Additional exploratory data analyses

Our study will yield a rich dataset that will permit a wide range of additional exploratory analyses we can use to refine the design of a future, randomized clinical trial testing the efficacy of an idle-time exercise intervention. • For example, we will explore the extent to which factors such as age, lesion side, impairment severity, motor capacity in the arm and hand, strength, cognition status, and pre-stroke hand dominance may moderate primary measures of objective system utility and subjective

user experience, as well as secondary measures of arm motor capacity and performance assessed at 0-6-month follow-up testing. • In addition to the ratio of activity durations to be analyzed to address research question Q1 (Aim 1), we will also explore other potential performance measures such as the overall amount of arm activity (defined by "activity counts,") and the frequency of high-intensity activity in each arm both in the inpatient rehabilitation unit and in the patient's home. These analyses may help refine the design of a future randomized clinical trial testing the efficacy of an idle-time exercise intervention. • We have no reason to suspect that men and women will differ with regards to the objective utility or subjective user experience with the proposed exercise cueing and monitoring system. Because our sample size is relatively small (about 30 patients total), we consider evaluation of any sex-related effects in our primary outcome variables as exploratory.

31. Procedures and Expenses for Subjects

31.1 * Explain which procedures are research-related:
All procedures are research related.

31.2 * Explain what expenses are NOT covered in the project, i.e., the expenses the subject is expected to pay:
The subject is not expected to pay for any part of this research study.

31.3 * Explain what expenses ARE covered in the project, i.e., the expenses the subject is not expected to pay:
All research procedures are covered by the study.

32. Risks and Safeguarding Against Risks

32.1 * List all reasonably foreseeable risks or discomforts. Consider physical, psychosocial, confidentiality, and privacy risks. List in order of frequency (likelihood), but be sure to include uncommon risks that might influence a person's decision to participate. 

Vibrotactile sensation: The wearable devices use a gentle vibrotactile sensation to cue the participant to begin exercises. Some people may find the sensation unpleasant. If the participant finds that they cannot tolerate the sensation, they may withdraw from the study at any time.

Skin irritation: The bands of wearable devices may feel uncomfortable against the skin. If the participant finds that they cannot tolerate the sensation, they may withdraw from the study at any time.

Mild exercise: The participant could experience slight muscle soreness from these activities.

Physical assessments: Some of the physical assessments require the participant to make exercise-like motions. The participant could experience slight muscle soreness from these activities.

Another risk may be loss of confidentiality. Every effort will be made to keep the participant's research records confidential. The participant will be assigned a unique code to further protect confidentiality.

32.2 * Identify features of the project, e.g., recruitment practices, project design, procedural plans, intended to minimize safety risks to subjects:

Cognitive impairment: This study seeks to enroll patients who may have cognitive deficits. The study team will administer the MoCA prior to consent to determine if a patient has the cognitive ability to sign for themselves. If the patient has completed this assessment during the current admission, study team may apply this score to the consent documents and proceed as outlined in the protocol. Patients who score in the mild to moderate cognitive impairment range, but otherwise meet study inclusion/exclusion criteria, may enroll if they pass an ICF quiz.

Vibrotactile sensation: The devices are self-contained, commercial, off-the-shelf devices that are advertised as ideal for research and clinical studies involving patient activity monitoring and gait analysis, among other suggested applications. The vibrations provided by the devices derive from miniature vibration motors that do not inject significant energy into the patient.

Skin irritation: A member of the study team will observe the wrist for any redness, itching, or burning or any discomfort of the area in which the device is placed. The device will be removed immediately should any of these side effects occur. Study personnel will check for skin irritation at the beginning of each day, and will halt the participant's participation in the study if significant skin irritation is observed.

Confidentiality: Consent forms and data collection forms will be stored in a locked cabinet in the PM&R offices. Electronic study files will be housed on the PM&R network drive, or in secure HIPAA-compliant platform such as Box or SharePoint. Wrist band data will be stored at Marquette University on their secure HIPAA-compliant network drive. Data sharing between the study teams will occur through and online platform such as Box or SharePoint. Research data will be coded.

34. Privacy and Data Confidentiality

34.1 * Explain provisions to protect privacy interests of subjects. This refers to how investigators will contact subjects and/or access private information from or about subjects during and after their involvement in the research (e.g. time, place, etc. of research procedures) and the subjects' expectations of privacy in the situation. 

Patient will be approached about this research study in their private IPR room. Enrollment, baseline procedures and study procedures will all occur in the privacy of this room.

Follow up study visit will occur in a private clinic room before/after the patient's stroke follow up visit in PM&R Stroke Clinic. If the patient does not schedule for a stroke follow up visit, then the study follow up visit will occur in a private room in the Marquette University Neuromotor Control Laboratory, or in the privacy of their home.

34.2 * Will the data collected in the course of the project be considered sensitive data, e.g. mental health, HIV status, Social Security Number, etc.?

Yes No

34.3 * Have you or will you develop a Data Management and Sharing Plan as required by National Institute of Health (NIH) policy? Reference: [MCW Research and Data Management Sharing Support](#)

Yes
 No
 N/A

34.4 * Describe security measures to be used to protect collected data and biospecimens. Organize your response to address the security measures associated with each of three stages of the project:

- While data are being collected
- After all data have been collected, but are still being analyzed
- After all analyses are completed, and data have been archived 

Participants will be assigned a unique study code. Data will be coded while the study is in progress. Consent forms and paper data collection forms will be stored in a locked cabinet in the PM&R office. Electronic data will be stored on secure HIPAA-compliant network drives at both Medical College of Wisconsin and Marquette University, and on REDCap. Data will be shared between institutions through secure HIPAA compliant sharing platforms, such as Box or SharePoint.

Coded data will be stored for 10 years, per MCW policy.

34.5 * Will the project team store research data containing identified subject information on a portable electronic data storage device (e.g., laptop, flash drive, external hard drive, etc. – i.e., any electronic storage other than an MCW/FH/CW Workstation)? 

Yes No

35. Benefits

35.1 * Identify any potential benefits to subjects:

There are no direct benefits to participating in this study.

35.2 * Identify any potential benefits to science and society:

Data from this study will hopefully show that using wearable devices to cue exercise during idle time is usable and desirable from a patient perspective. Data from this study will serve as pilot data to apply for a follow-on efficacy trial.

38. Informed Consent

38.1 * Indicate your approach to the informed consent process requirement for this project:

(check all that apply)

Informed consent process and document will be used

Informed consent process and document will be used but a waiver of documentation of consent is being requested

Alteration of the informed consent process and/or document is being requested (an informational letter, phone script, etc.)

Waiver of the informed consent process and document is being requested

None of the above

* 38.1.1 Please identify which pathways are applicable to this project.

(check all that apply)

Project will not have direct contact with subjects, and an informed consent process or document is not required per MCW policy

Project will have direct contact with subjects, and an informational letter or equivalent will be provided

Project qualifies for Approval without the Requirements of Informed Consent under the 2006 FDA guidance regarding In-vitro diagnostic evaluation using de-identified, discard clinical specimens

Informed consent has already been addressed (i.e. previously IRB approved bank, incoming data from another institution, etc.)

39. Informed Consent Process – Part I

39.1 * **Describe how the required information is being presented to subjects, in addition to providing a consent form (orally, video presentation, etc.).**
Information will be presented orally to the subject.

39.2 * **Describe the circumstances under which consent will be obtained, including where the process will take place.** 

Prior to consent, a member of the study team will administer the MoCA to determine if the patient has cognitive deficits. If the patient has completed this assessment during the current admission, study team may apply this score to the consent documents and proceed as outlined in the protocol. At this time the individual can demo the wearable device to get a sense of the vibrotactile cues.

If deemed eligible after MoCA and possible ICF quiz, consent will be obtained in the patient's IPR or IPN room. The minimum time for the consent process is approximately 10 minutes. After the consent form is signed the baseline procedures for the study may begin.

39. Informed Consent Process – Part II

39.4 * The persons who will provide informed consent for this project are: [i](#)

The subjects (i.e. only eligible adults with decisional ability)

Legally Authorized Representatives, as defined by MCW IRB policy (i.e. none of the subjects will be capable of informed consent)

Either the subject or Legally Authorized Representative, depending on the decisional status of each subject

39.5 * How will you make sure that the subjects or the subjects' authorized representatives comprehend the information presented?

A member of the study team will administer the MoCA to determine a patient's ability to sign consent for themselves. If the patient has completed this assessment during the current admission, study team may apply this score to the consent documents and proceed as outlined in the protocol. Patients who score 'normal' are able to sign right away. Patients who score 'mild' or 'moderate' impairment must additionally pass an ICF quiz and demonstrate the ability to follow 2-step directions before signing a consent form. At this time, the individual can demo the wearable device to get a sense of the vibrotactile cues.

39.6 * What steps will be taken to minimize the possibility of coercion or undue influence upon subjects during the consent process?

Participants will be informed that choosing not to participate or to leave during the study will not adversely affect their care or prevent them from participating in future research studies.

42. HIPAA: Protected Health Information

42.1 * Will potential subjects be identified or screened by searching any kind of pre-existing MEDICAL records before consent is obtained? (e.g., medical records, hospital census or procedure logs, emergency room visit rosters)

Yes No

* 42.1.1 Does this research team request permission to screen existing medical records for potentially eligible subjects before consent is obtained? Do not check "Yes" unless you intend to obtain informed consent for subjects who decide to enroll in the project

Yes No

If No, only the physician or nurses caring directly for the patient are allowed to review the patient's records.

* 42.1.2 Does this research team request permission to retain screening logs as part of the investigator files?

Yes No

* If Yes:

Justify retaining Protected Health Information without consent:

Retaining PHI in screening logs is necessary to avoid rescreening ineligible patients and avoid reapproach to patients that have declined participation.

42.2 * Indicate the HIPAA authorization pathway applicable to this project. Generally, the Health Insurance Portability and Accountability Act (HIPAA) prohibits collecting, accessing, using or disclosing a person's protected health information (PHI) for research without valid authorization. Under some circumstances, a waiver of authorization may be granted by the IRB:

(check all that apply)

No Protected Health Information (PHI) will be Accessed or Used For This Project

An IRB-Approved Consent Process and Document will be Used that incorporates the required HIPAA authorization

Waiver of HIPAA Authorization Is Requested. Generally, this request should accompany the "Waiver of the Informed Consent Process" at 38.1.

Research using only information on deceased persons

Limited Data Set, as defined by HIPAA regulations (download "Data Use Agreement" form located on InfoScope HIPAA website, complete it or an equivalent, and upload in Section 52)

De-identification of data subject to the IRB's definition and verification of de-identification

None of the above

44. Use and Access of Protected Health Information

44.1 * Explain why the use of personal identifiers is necessary for this project: [i](#)
Medical records must be accessed for recruitment and data collection purposes for this study.

44.2 * If you will collect identified or coded data, explain whether you intend to destroy all personal identifiers at any one of the following three stages and how long the data will be stored at MCW:

- When you have collected all the necessary data for each subject, one at a time
- After you have collected all the necessary data for all subjects, and before you begin data analysis
- After you have completed all data analysis, and are ready to archive the dataset [i](#)

Subject data will be coded while the study is on-going and during data analysis.

Data will be deidentified at time of archive. This data will be retained for 10 years per MCW policy.

44.3 * If there is health or research justification for retaining identifiers or such retention is required by law (e.g. you must retain identifiers for FDA-regulated projects for the required period of data retention), explain that here.

N/A

52. Supporting Documents

52.1 * Select all items that will be included for IRB review: i

(select all that apply and upload documents in Section 52.1.2, using the prefix in the title of the document. For example, ICF-PRO1234 (document name), IB-PRO1234(document name))

PRO - Sponsor's protocol, protocol summary or narrative

IB - Investigator Brochure

ADV - Advertisement

ICF - Informed Consent form

SMP - Safety Monitoring Plan

DM - Device Manual

TRANSL(LNG) - Translated document(s) (LNG-Insert Specific Language of Translated Document)

SUR - Surveys / Questionnaires

DCF - Data Collection forms/tools

INF - Informational material for subjects

TBL – Activity table, schedule of assessments

BNK – Bank documents and forms

SAF – Ancillary Safety Committee or Human Stem Cell Committee approvals, Adult Treatment Research Unit (TRU) approvals, Children's Wisconsin Imaging Form

LET - IND/IDE/HDE or 510(k) documentation, communication from/with the sponsor, IRB approvals or administrative letters from other institutions

DA - Data agreements or contracts

CWNR - Children's Wisconsin Nursing Research Review Process Milestone Checklist

Other(s) (SPECIFY)

*** 52.1.1 Give a brief description of "Other" items:**

ICF Quiz

MoCA

Subjective Feedback Questions

Software User Guide

52.1.2 Upload each item specified from 52.1 and 52.1.1 in the section below: i

Name	Last Modified Date	Version
 ICF PRO 42316 Wearable R21 06.12.23 (0.06).docx(0.06)	6/12/2023 10:34 AM	0.06
 SUR-IMI Silent Monitoring (0.01)	5/15/2023 12:24 PM	0.01
 PRO - Wearable protocol 01.11.23 (0.03).docx(0.03)	1/11/2023 3:10 PM	0.03
 DCF-REDCap Data(0.01)	12/19/2022 10:34 AM	0.01
 Software User Guide_5_24.docx(0.01)	12/14/2021 1:34 PM	0.01
 DM - MetaMotionR-PS3.pdf(0.01)	12/14/2021 1:34 PM	0.01
 Other - PRO 42316 Subjective Feedback Questions.docx(0.01)	11/12/2021 12:43 PM	0.01
 SUR - SUS.pdf(0.01)	11/12/2021 12:38 PM	0.01

Name	Last Modified Date	Version
 SUR - QUEST.pdf(0.01)	11/12/2021 12:38 PM	0.01
 SUR - IMI.pdf(0.01)	11/12/2021 12:37 PM	0.01
 DCF - CMSA Score Form.pdf(0.01)	11/12/2021 12:37 PM	0.01
 DCF - NIH_Stroke_Scale_508C.pdf(0.01)	11/12/2021 12:37 PM	0.01
 DCF Grip Strength.docx(0.01)	11/12/2021 12:36 PM	0.01
 DCF - Box and Blocks Test.pdf(0.01)	11/12/2021 12:31 PM	0.01
 DCF - ARAT_scoring.pdf(0.01)	11/12/2021 12:31 PM	0.01
 DCF - Fugl Meyer Upper Extremity Score Sheet.pdf(0.01)	11/12/2021 12:31 PM	0.01
 Other - MoCA Test.pdf(0.01)	11/12/2021 10:38 AM	0.01
 Other - ICF Quiz PRO 42316.pdf(0.01)	11/12/2021 10:33 AM	0.01
 PRO - Wearable R21 grant narrative.pdf(0.01)	11/12/2021 10:17 AM	0.01

Final Check

(a) Submission Instructions:

- The Principal Investigator must click the "Submit Application" activity in the workspace to submit this Project for Departmental, Ancillary and/or Safety Committee(s) review. **Once these reviews have been completed, the submission will automatically get routed to the IRB for review.**
 - Clicking "Go to Workspace" does NOT submit this Project for review.
 - Clicking "Go to Workspace" saves your work and exits the SmartForm, taking you back to the Workspace.

(b) **Spelling and Grammar:**

IRB will not accept any application that has not been checked by the submitter for spelling and grammatical errors. Spell checking capability is not available within the eBridge system at this time.

(c) **Attached Documents:**

Make sure all documents have been uploaded before submission.