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ENGINEERING

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December 18, 2025

To whom it may concern,

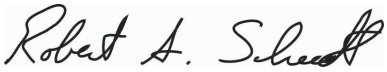
Please find attached the informed consent documents for our clinical trial.

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 Last Reviewed by IRB: 07/10/2023

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

- **informed consent form:** pages 2 through 10 of this document

Sincerely,



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

EFFECTIVE

07/10/2023

MCW IRB

Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

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

John McGuire, MD
Department of Physical Medicine and Rehabilitation
414-955-1906
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

Definitions

Vibrotactile sensation – A gentle vibration

Purpose

This project is being done to determine if a personal exercise cueing system is usable and desirable in the days and weeks after stroke.

Length

- You will be in this research project for about 3 months.

Procedures *or* Activities

List of visits:

- Baseline Visit
  - Total Number: 1 visit
  - Total Time: 60-90 min
- Inpatient Procedures
  - Total Number: 3-12 days
  - Total Time: 7-8 hrs passive monitoring/90 min active participation each day
- Follow-up Visit
  - Total Number: 1 visit
  - Total Time: 30-60 min
- In-home Procedures
  - Total Number: 2 days
  - Total Time: 24 hrs passive monitoring each day

Procedures/Activities that will occur at various visits:

Non-invasive Procedures/Activities

- Sensory motor assessment
- Motor function assessment
- Grip strength assessment
- Post-stroke function assessment
- Mild exercise cued through vibrotactile sensation
- Subjective experience surveys
- Passive monitoring by wearable device

Risks

This is a brief list of the most commonly seen risks The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Study risks:

- Muscle soreness associated with physical activity and physical assessments.
- Skin irritation or reaction to wearing the device band.
- Loss of confidentiality

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Benefits

This project may not help you, but we hope the information from this project will help us develop interventions that will aid stroke rehabilitation and therapy.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Dr. John McGuire at 414-955-1906.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you have had a stroke.

A total of about 60 people are expected to participate in this research at the Medical College of Wisconsin/Froedtert Hospital/Versiti, Inc.

The Director of the project is Dr. John McGuire in the Department of Physical Medicine and Rehabilitation (PM&R). A research team works with Dr. McGuire. You can ask who these people are.

This project is funded by the National Institutes of Health through a research grant.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to determine if a wearable device is useable and desired by patients who have had a stroke.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

Study Procedures
There are three phases to participation in this study:

Phase 1: Baseline – If you are eligible to participate in this study and provide informed consent, a member of the research team will conduct a number of assessments to determine your baselines post stroke. These assessments will be done to your arms and will include a sensory motor assessment, a motor function assessment, and a grip strength assessment. If a post-stroke function assessment was not administered at your inpatient admission, it will be conducted at this time.

Phase 2: Inpatient passive monitoring and exercise – A member of the study team will visit you each morning for 12 days while you are inpatient. This person will help you put on the wearable devices, which you will wear for 8-9 hours, and pair the devices with a smartphone. The devices will passively monitor your arm movements throughout your day. At three select time timepoints, the devices will send a gentle vibrotactile cue for you to do a set of exercises. Each set of exercises will take place over 30 minutes and will be scheduled during your idle time between therapy sessions. The member of the study team will give you instructions each morning for what exercises you should do. You may choose the exercise level that you feel you are able to complete. Exercise options include (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. At the end of the day, the study team member will return to collect the devices and smartphone. At the end of the 12th day, you will be asked to answer three short surveys about your experiences using the wearable devices during your acute inpatient recovery.

Phase 3: Follow up – A member of the study team will schedule a follow up visit with you 0-6 months after you have discharged from Inpatient Rehabilitation. Every attempt will be made to combine this with your PM&R outpatient stroke visit. If you choose not to schedule a PM&R outpatient stroke visit, the study team will schedule a research visit with you. This will occur either at the Marquette University Neuromotor Control Laboratory, or in your home. A member of the study team will repeat the sensory motor assessment and the motor function assessment. A member of the study team will help you put on the wearable devices, and you will wear them at home for 48 hrs. At the end of this period, you will be emailed or called to answer three short surveys about your experiences using the wearable devices passively at home. You will mail the devices back to the study team using pre-paid shipping materials.

Data coding
For this project, the research team will assign you a unique code, such as a series of numbers and/or letters. When collection and storing your project data, the research team will use your unique code instead of other information that could easily identify you.

The data that are recorded with your unique code rather than your name is called “key-coded data”. The study team will keep a confidential list linking your name to your code and only the research doctor and authorized research team members will have access to this list.

Some study data will identify you (such as medical records), and the ways these data may be used and shared is described later in this form.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project for about 3 months. Your data will be kept for 10 years per Medical College of Wisconsin policy.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

The research doctor may stop your participation in the project at any time for any reason without your consent. He will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems. **You need to tell the research doctor or a member of the research team immediately if you experience any problems.**

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

Skin irritation: The bands of wearable devices may feel uncomfortable against your skin. If you find you cannot tolerate the sensation, you may withdraw from the study at any time.

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

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

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. If you have questions, you can talk to the project director about whether this could apply to you.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project may or may not help you, but we hope the information from this project will help us develop a better treatment for stroke rehabilitation.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The study team can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The study team will use the Certificate to resist any demands for information that would identify you.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact Dr. McGuire.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will be paid $50 after completing the inpatient portion of the study. You will be paid another $50 after completing the follow up visit and the study team has received the three usability surveys and the wearable devices in the mail.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. McGuire at 414-955-1906.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); Versiti, Inc.; Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital; Froedtert West Bend Hospital; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information we will collect and use for this project is:

- Health information collected during this project, such as, questionnaires
- Medical records dating from when you join this project until you complete the project

E2. Who will see the health information collected for this project?

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital/Versiti, Inc. and at Marquette University, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed. Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. McGuire at *8701 Watertown Plank Rd. Milwaukee, WI 53226*. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

F1. FOR MORE INFORMATION ABOUT THE PROJECT

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can look up this project by referring to the ClinicalTrials.gov number (NCT05900999) or by asking the research team for a printed copy.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**