Study Title: Robotically Augmented Mental Practice for Neuromotor Facilitation

Document Title: Consent Form

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Key Information for Robotically Augmented Mental Practice for Neuromotor Facilitation:

What Am I Being Asked To Do?

You are being asked to be a volunteer in a research study. This page will give you key information to help you decide if you would like to participate. Your participation of voluntary. As you read, please feel free to ask any questions you may have about the research.

What Is This Study About and What Procedures Will You be Asked to Follow?

The purpose of this study is to understand how mental practice with or without robot control influences brain activity and motor performance. We will attach sensors to your trunk and arm muscles. You will be asked to control a remote robot by contracting your muscles or think about the motion of your hand. We will apply brain stimulation during these tasks. Your participation in this study is expected to be 3 hours per day for 2 days.

Are There Any Risks or Discomforts you Might Experience by Being in this Study?

You will receive brain stimulation of much shorter duration and lower intensity than the individuals who had seizures. The probability of your having a seizure is very rare (< 1% chance). To minimize any possible risk of seizure, you must certify that you have never suffered an epileptic seizure. The tape used to attach sensors may irritate the skin in a small percentage of people. You may experience an elevated heart rate, temporary general fatigue, temporary muscle fatigue, and muscle strains.

What Are the Reasons You Might Want to Volunteer For This Study?

You are not likely to benefit in any way from joining this study. However, your participation in this study may assist researchers in understanding how interactions with a robot affect brain activity and motor performance. As compensation for your time, we offer $90 after your full participation. You will be given the prorated amount even if you decide to leave the study early.

Do You Have to Take Part in the This Study?

It is fully your decision if you wish to be in this study or not. If you choose not to participate, or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

Project Title: Robotically Augmented Mental Practice for Neuromotor Facilitation

Principal Investigator: Minoru Shinohara, PhD (Georgia Institute of Technology)

You are being asked to be a volunteer in a research study. The Georgia Tech (GT) School of Biological Sciences is conducting a research study, led by Associate Professor Minoru Shinohara and the Human Neuromuscular Physiology Lab. You are being asked to be a volunteer in a research study.

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.

Purpose
Mental practice for hand motions can increase brain excitability for hand muscles. The purpose of this study is to understand how mental practice with or without robot control influences brain activity and motor performance. We will look at the effect of this additional task by magnetically stimulating the brain and recording muscle activity. We expect to enroll 19 abled-bodied adults and 6 post-stroke adults in this study.

Exclusion/Inclusion Criteria
Participants must be a healthy able-bodied adult (age: 18-39 years old) or a post-stroke adult (age: 21-75 years old). The study involves magnetic stimulation of the brain (TMS brain stimulation) from the skin surface. Brain stimulations of various intensities will be applied to your brain. According to our questionnaire, you are eligible for the study and do not have risk factors that prevent brain stimulation.

Procedures
We will conduct the study in the Human Neuromuscular Physiology Lab. The Lab is located in the Biological Sciences/Applied Physiology Building of the Georgia Tech Campus, 555 14th St. NW, Atlanta, GA 30318. This study consists of experiments to be performed on two non-consecutive days. Your participation in a whole procedure will last about 3 hours per day, including preparation. If you agree to take part in this study, we will ask you to read and sign this consent form. We will then ask you to go through the following procedures on both days. The total hours of participation will be approximately 6 hours. Remember, you may stop at any time.

Preparation
First, you will complete a questionnaire (called Edinburgh handedness inventory) to determine your preference for hand use.

You will then comfortably sit in a chair. Your hands will be placed in a comfortable resting position. We will place small monitors (electrodes) on your hand, arm, and torso (chest and back around the shoulder) with medical tape. These monitors will record the movement of your muscles. We will clean your skin before attaching these monitors. If there are hairs that cover the spot for sensor attachment, we will shave them. We will ask you to remove any metal objects from your body or clothing above your shoulder (watch, jewelry, hairpins, eyeglasses, body piercings, earrings, wallet, keys, etc.). Your hands will be placed in a natural resting position. You will have a robotic hand near the hand. The preparation will take about 1 hour.

After the preparation, you will relax your muscles or perform mental or motor tasks. The mental task is imagining a hand motion. The motor tasks are brief contractions of torso muscles. A robotic hand may or may not move during these tasks. The whole tasks below will take about 2 hours.

Brain stimulation
You will receive magnetic stimulation to your head at rest or during the tasks below. We will place a light coil on your head for brain stimulation. We will tell you when the stimulation is about to begin. You will feel as if you were tapped with a finger in your head, and it is not painful. We will first find your brain areas that control the hand muscles. Then we will give you a series of stimulations (called magnetic pulses). This way, we will find the spot that controls your hand muscles. Next, we will find the lowest stimulation to activate the muscles. At this point, we will be ready for testing muscle contractions with brain stimulation in various tasks. The interval of brain stimulations will be 4-5 seconds.

Mental task
You will be asked to relax your muscles and imagine that you are moving your hand. We will ask you to do it several times. You will have resting intervals of 1 minute or longer. You will complete a questionnaire that asks about your assessment of performance.

Motor task
You will be asked to activate the trunk muscles about your shoulder. The muscle activity will control a robotic hand motion or be displayed on a monitor. We will ask you to contract muscles several times. You will have resting intervals of 1 minute or longer.

Reaction task
You will move the index finger as soon as you hear a sound. We will ask you to do it several times.

Risks or Discomforts
The amount of brain stimulation you will receive will be in a range that is considered low risk. Seven people out of several tens of thousands without epilepsy have been known to suffer a seizure after *repetitive* magnetic brain stimulation. You will not receive

repetitive but single-pulse or duble-pulse stimulation that is known not to induce seizures. Also, to minimize any possible risk of seizure, you must certify that you have never suffered an epileptic seizure. There is a rare or < 1% chance of you having a seizure. Should a seizure occur, we will assist you carefully to sit or lay down on the floor, lay a blanket over you (and a soft pillow underneath your head if you lay down), and call 911 immediately.

Aside from potential risks associated with TMS, the risks in other procedures are no greater than those in everyday physical activity (and physical or occupational therapy clinics for post-stroke adults). You may experience an elevated heart rate with muscle contraction, temporary general fatigue, temporary muscle fatigue, and muscle strains. Mild to moderate fatigue is a normal response to the repetition of muscle contraction. Fatigue will be monitored across the session, while we will provide enough rest periods between trials.

Other risks/discomforts may be possible in rare cases: The tape used to attach electrodes (medical grade surgical tape) may irritate the skin in a small percentage of people who are allergic to adhesives. This effect will last no longer than a day or so.

Benefits
There are no direct benefits to participating in the study. However, this study has the potential to benefit society. We (doctors, researchers, and scientists) may learn new things that will help better the lives of individuals suffering from impaired motor function (e.g. elderly, stroke victims). You will learn information on how nerves work for controlling movement.

Compensation to You
You will receive $90 after full participation. If you choose to withdraw your participation before full completion, you will receive prorated compensation for $15 per hour or portion thereof.

U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Storing and Sharing your Information
Your participation in this study is gratefully acknowledged. Your information/data may be enormously valuable for other research purposes. By signing below, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Any future research must be approved by an ethics committee before being undertaken.

Confidentiality
The following procedures will be followed to keep your personal information confidential in this study. We will comply with any applicable laws and regulations regarding confidentiality. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked files and unless you give specific consent otherwise, only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when the results of this study are presented or published. The Georgia Institute of Technology IRB, the Office of Human Research Protections, and/or the Food and Drug Administration may look over study records during required reviews.

Costs to You
There are no costs to you, other than your time, for being in this study. Parking will be provided at no charge.

Questions about the Study
If you have any questions about the study, you may contact Dr. Minoru Shinohara at telephone (404) 894-1030 or shinohara@gatech.edu.

In Case of Injury/Harm
If you are injured as a result of being in this study, please contact Dr. Minoru Shinohara at telephone (404) 894-1030. Neither the Principal Investigator nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.

Questions about Your Rights as a Research Participant
- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

If you have any questions about your rights as a research participant, you may contact Georgia Institute of Technology Office of Research Integrity Assurance at IRB@gatech.edu.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____
Participant's (Subject's) Name

_____	_____	_____
Participant's (Subject's) Signature	**Date**	**Time**

_____	_____	_____
Signature of Person Obtaining Consent	**Date**	**Time**