**Permission to Take Part in a Human Research Study**
***Do not sign this consent if today's date is later than the stated expiration date above.***

***Title of Research Study*:** Development of a Portable Synergy Resistant EMG-driven FES Device for Intuitive Control of Grasp And Release During Functional Arm Activities Following Stroke – Main Consent form

**Investigator:** Jun Yao, PhD

**Supported By:** This research is supported by National Institute of Health.

**Financial Interest Disclosure:** None

**Key Information:**
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

## *Why am I being asked to take part in this research study*?

You are being asked to participate in this research study because you fall into at least one of the following 3 groups: 1) you had a stroke that resulted in insufficient control in one arm, 2) you are a healthy individual at least 45 years old, or 3) you are a physical therapist or a senior physical therapy student with experience in treating individuals with stroke and don't work with any of the listed investigator as part of your coursework or research projects. The purpose of this research study is to develop an assistive device called ReIn-HAND, which will allow individuals with stroke to Reliably and Intuitively use their HAND. ReIn-HAND is based on the muscle activity of your arm and hand, and detects an intent to open, close or relax the hand. The detected activity will be used to drive an electrical stimulation device to assist the performing the desired hand movements. Furthermore, to enable sufficient practice intensity both in the clinic and at home, we will develop the ReIn-Hand device with easy-to-use utilities by developing a user customized forearm/hand orthosis with embedded electrodes. Out of a total of about 100 volunteers with stroke recruited for this study, 20 volunteers with stroke, 10 healthy controls, and 10 physical therapists or senior student physical therapists (PTs/SPTs), who are not members of the study team, will be enrolled and will complete this study.

### What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask questions you want before you decide.

### Why is this research being done?

In order to enable post-stroke individuals who cannot control the impaired hand to sufficiently practice activities of daily living, both in the clinic and at home, we propose to develop a portable device (named ReIn-Hand) with easy-to-use utilities by developing a user customized forearm/hand orthosis with embedded electrodes.

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The ReIn-Hand device is an investigational device that has not been approved by the FDA. It includes an EMG collection unit, an EMG data processor core (ReIn-Hand real time platform), and an output unit (Functional Electrical Stimulator, 300 PV, Empi, Minnesota, USA). While nerither collection unit nor processor core will send any signal to an user, the output unit will send an electrical signal to active the target muscles. The output unit that will be used in this study is an FDA approved device. We will use this output device as indicated by the manufacturer.

## How long will the research last and what will I need to do?

If you are an individual with stroke, we expect that you will be in this research study in part 1: for 4 lab-based visits, each lasting about 3 to 4 hours; and/or in part 2: a home-based practice (1 hour per session, 1 session per day, 7 days per week for 12 weeks) alongside weekly lab visits during the 12-week home-based practice**.** In part 1, you will be asked to learn how to use the developed devices either in the lab or at home, and then provide your feedback. If you participate in the home-based practice, you will also be expected to participate in pre-, post- and follow up measures of brain activity and clinical tests.

If you are a physical therapist (PT), we expect that you will be in part 1 of this research study. You will be asked to learn how to use the developed devices and then to teach an individual with stroke to use it. We also expect you to provide your feedback.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

## Is there any way being in this study could be bad for me?

This study will use the ReIn-Hand device, which uses surface muscle recording electrodes and muscle stimulation electrodes. In addition, during the evaluation sessions on part 2 of the study, surface electrodes for detecting brain activity will also be used. All of these electrodes are surface electrodes with gel, which may produce minor irritation of the skin. The possibility of irritation will be minimized by cleaning the skin after application of the electrodes. Furthermore, the output unit, a 300 PV Complete Electrotherapy System is used to activate targeted muscles via electrical stimulation. Although the 300 PV stimulator is an FDA approved, clinically safe device, the electrical stimulation may cause muscle soreness. The stimulation configuration will be pre-set by clinicians in a safe range to reduce the possibility of muscle soreness.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

## Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, the literature supports the use of an EMG-driven electrical stimulator device, which ReIn-Hand is in this category of, in the treatment of the paretic wrist and forearm. Please note, such benefits are based on statistical data, may not apply to all the participants, and may not continue after the research has ended.

## What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide whether or not to participate, or only participate part 1 but not part 2. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

You may terminate the experiment at any time for any reason.

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**Detailed Information:**
The rest of this document includes detailed information about this study (in addition to the information listed above).

## Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team. Dr. Jun Yao is the person in charge of this research study. You may call her at (312) 908-9060, Monday through Friday from 8am to 5pm. You may also call Dr. Drogos at (312) 503-3255 or Dr. Carmona at (312) 503-4633, Monday through Friday from 8am to 4pm with questions about this research study. For problems arising evenings or weekends, you may call Dr. Yao at (773) 289-6920.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

## How many people will be studied?

We expect about 40 people, including stroke participants (N=20), Physical therapists or senior student physical therapists (N=10), and healthy control participants (N=10), to take part in this research study.

## What happens if I say "Yes, I want to be in this research"?

As a participant in this study, you will be asked to come to the laboratory at the Northwestern University Department of Physical Therapy and Human Movement Sciences (645 N. Michigan Ave., 11$^{th}$ floor).

If you are an individual with stroke, you will be recruited for either part 1 only or for both parts 1 and 2:

- The part 1 will consist of 2 pre-training test visits, and the 1$^{st}$ and 2$^{nd}$ training sessions on two different days using ReIn-Hand.

  Each of the 4 lab visits will last about 3 hours. The first pre-training visit will focus on the eligibility tests and baseline evaluation of your arm/hand function. The 2$^{nd}$ pre-training visit will focus on determining configurations of the ReIn-Hand device that fits to your situation and also on scanning your arm with the electrodes. Furthermore, the 1$^{st}$ and 2$^{nd}$ training sessions will focus on training you to use the ReIn-Hand device for functional reaching and grasping task.

- The part 2 of the study will be after the part 1of the study as mentioned above, and will additionally involve following activity: home-based daily practice (1 hour per session, 1 session per day, 7 days per week for 12 weeks), weekly lab visits for clinical tests and device adjustment (2 hours per visit), a 2$^{nd}$ baseline arm/hand function evaluation, pre-

and post-training tests using EEG measures to monitor changes in brain activity, and follow up clinical tests at 1 and 3-month after the home-based practice.

If you are a physical therapist (PT) or a senior physical therapy student (SPTs), you will only participate in the 2nd pre-training test and the 1st training session using the ReIn-Hand device in the above mentioned part 1 study.

## What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: respond to phone calls or emails from a member of our research team; visiting the lab as scheduled; and providing feedback as a device user.

## What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can take you out of the contact list for future studies.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for a senior physical therapy student enrolled in a class at NU), or your present or future employment (for employees at NU or its affiliates).

If you stop being in the research, already collected data may not be removed from the study database. An investigator may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.

## Detailed Risks: Is there any way being in this study could be bad for me?

*Performing different movements using your arm:* The repeated movements may result in minor muscle soreness, fatigue and muscle spasms. However, our protocols include many rest periods that should significantly reduce the risk of these adverse effects.

*Surface electrodes:* The self-adhesive surface electrodes used to record muscle activity may produce minor irritation of the skin. The possibility of irritation will be minimized by cleaning the skin with alcohol before and after application of the electrodes.

*Electrical stimulation electrodes:* The self-adhesive electrodes used for electrical stimulation may induce some discomfort, although a comfortable level of stimulation will be found before performing the reaching movements. There will be many rest periods to reduce the possibility of discomfort from the stimulation and the experiment will be discontinued if this discomfort is significant. The possibility of skin irritation will be minimized by cleaning the skin with alcohol before and after the application of the electrodes.

*Using the electrical stimulator:* If the intensity progressively increases during the contraction period, then risk of injury, though minimal, may increase. If a high intensity is applied, you may experience high levels of soreness. We will use 300 PV Complete Electrotherapy System, which is a FDA approved, clinically safe device. The stimulation configuration, including the stimulation intensity, will be pre-set up by clinicians. The clinician will also determine a suggested range of intensities, and setup the maximal stimulation intensity to protect users. When using at home, the

individual with stroke will adjust and determine the required stimulation intensity on a daily basis on the suggested range of intensities from the clinician, with the maximal stimulation intensity pre-set by the clinician.

*EEG electrodes:* There is a small possibility of scalp irritation due to the use of EEG electrodes and gel. To hold the EEG electrodes on your scalp, a cap with a strap around the chin will be used. You may find the cap uncomfortable after having it on your head for several hours. We will use cotton or foam underneath the cap to minimize this side effect.

*Using the camera and scanner:* The camera and scanner that will be used for developing your ReIn-Hand device and evaluate your arm/hand function have strong bright light. You will be instructed to close your eyes for all the time. Additional sleep mask may be used to cover your eyes.

This study involves a survey to understand the user feedback for the use of the ReIn-Hand device. There is a risk of discomfort, as you may feel some of the questions involve sensitive issues. You can skip any question that you do not wish to answer, or exit the survey at any point.

We will collect your identifiable, personal information. Therefore, there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

In addition to these risks, this research may hurt you in ways that are currently unknown.

### *What do I need to know about reproductive health and/or sexual activity if I am in this study?*

Due to the potential effect of electrical stimulation on fetus, you or your partner should not be or become pregnant while on this research study.

If you or your partner become pregnant while participating in this research study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

### Will it cost me anything to participate in this research study?

Taking part in this research study may lead to added costs to you. Possible costs include but not limited to: 1), although we provide free parking, we don't compensate gas fee for transportation; 2) in case you feel illness during participating this research, you may visit your medical doctor. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

### Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include: decreasing spasticity, improving muscle strength and range of motion.

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## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. Involvement in this research study may result in a loss of privacy, since persons other than the investigator and research team might view your study records. Unless required by law, only the following people can review your study records and they are required to keep your personal information confidential:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),
- Representatives of the study sponsor, the National Institute of Health
- Representatives of Food and Drug Administration (FDA), and Office for Human Research Protections (OHRP)
- Registries or other research-related databases: the results of your examinations will be kept in a central computer or data registry at the NU Department of Physical Therapy and Human Movement Sciences. These results will be stored by research identifier code for privacy of records and your records will only be accessed by the investigators listed for this study.

The results of this study may also be used for local and regional scientific and healthcare conference presentations, as well as peer-reviewed scientific and medical journal papers. If your individual results are discussed, your identity will be protected by using a study code number rather than your name or other identifying information. We will not ask you about child [or elder] abuse, but if you tell us about child [or elder] abuse or neglect, we may be required or permitted by law or policy to report to authorities.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers 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 researchers will use the Certificate to resist any demands for information that would identify you. 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.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at 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.

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## Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

## Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include: changes in your health conditions or in experimental inclusion/exclusion criteria.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What else do I need to know?

If you become ill or get injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The researchers will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you $10 per hour for your participation of lab visits. For sessions last less than 1 hour, we will compensate your participation time as 1 hour. Please note: your participation of the home-based intervention will be paid to at the 4$^{th}$ week ($100), 8$^{th}$ week ($200) and of the end of 12-week of internvetion ($200) by a check or a pre-load gift card. If you stay here during lunch time, we will provide you a quick lunch at the laboratory. Your cost of using public transportation will also be covered by the research. If you drive, your parking for research visits will be covered by the research. If you decide to use private transportation, such as a cab or rideshare service like Uber or Lyft, please check with a research team member if this fare can be compensated prior to booking the trip. For an approved rideshare service, we will re-imburse no more than $20 per visit.

If you will be paid by check by the Accouting services at Northwestern University. Total payment for multiple-lab visits during a single week will be paid by one check. Payment request will be submitted at the end of the last visit during that week. It usually takes about 4 weeks for you to get the requested check. Alternatively, participants may also be compensated using a pre-stored value card.

The Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

## Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

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| **I agree** | **I disagree** | |
|---|---|---|
| _____ | _____ | The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team. |
| _____ | _____ | The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification. |
| _____ | _____ | The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study. |

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent