# 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:** Effect of Neural Constraints on Movement in Stroke

**Principal Investigator:** Julius P.A. Dewald, PT, PhD; Jun Yao, PhD

**Supported By:** This research is supported by the National Institute of Child Health and Human Development and the Department of Physical Therapy and Human Movement Sciences, Northwestern University, Feinberg School of Medicine

**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 have had a stroke. The purpose of this research is to evaluate the effects of the medication, tizanidine (TIZ), on the voluntary movements of your arm. TIZ is approved by the U.S. Food and Drug Administration (FDA) for management of spasticity (involuntary muscle tightness). Your involvement in this study assists in generating a greater understanding of movement impairments following a stroke.

## 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 all the questions you want before you decide.

## Why is this research being done?

We are investigating changes that occur in the brain following a stroke and how they contribute to movement impairments. We are using TIZ. While not FDA-approved specifically for stroke, it is used in practice to treat stroke-related spasticity, given data supporting its use. It decreases the activity of an area of the brain and we are testing how voluntary movement changes as a result. Previous research shows that a particular area (the brainstem) is highly active in controlling movement after a stroke. However, this high activity in the brainstem may also contribute to movement impairments, like spasticity. Understanding how different areas of the brain are involved in movement impairments may help improve rehabilitation efforts and assist in restoring healthy movement in individuals who have had a stroke.

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

We expect that you will be in this study for two to four months. You may be invited back to participate in multiple experiments based on how many experimental protocols you agree to take part in. Each experimental protocol requires two study days (one for each experiment probe). For every additional protocol you enroll in and complete, two more study days will be scheduled. Each visit will last approximately six hours and be separated by at least one week. Prior to starting the measurement visits, you will be asked to complete a medical screening. Your primary care provider will be asked to confirm your eligibility for this study based on medications you are

currently taking. You may be asked to withhold some of your medications on the study days by the study physician.

At each study visit, after completing baseline testing, you will be given either TIZ or a placebo, a lactose pill that contains an inactive substance with no known effects if taken by an individual with no lactose intolerance.

Following administration of TIZ or a placebo pill you will then be asked to rest and allow for the medication to take effect. This waiting period will be approximately 1.5 hours. After this waiting period, we will conduct measurements of your arm movement and muscle activity in the robotic system. These measurements will be the same measurements that were conducted before the drug was administered.

You and the researchers will not know which drug, TIZ or placebo, you will receive at any given session (called "blinding"). If you are involved in the initial round of testing, the medication will not be blinded. You will be told before you enroll whether you will be involved in the blinded or unblinded testing. Additionally, with your approval, testing may be conducted in the absence of any medication or placebo pill.

You can find more detailed information about the study procedures in the **What happens if I say, "Yes, I want to be in this research"?** section.

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

It is possible that you could experience changes in blood pressure and heart rate as a result of taking the drug, and may experience side effects such as dizziness, sleepiness, and dry mouth. Repeated arm movements may result in minor muscle soreness. The use of sticky electrodes on the skin may result in minor skin irritation. The cast may pinch skin, and the cast cutter may burn the skin. Detailed risks for each medication can be found below.

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)" and "What happens if I say 'Yes, I want to be in this research.'"**

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

There is no direct benefit to you by your participation in this research study other than a possible temporary reduction in the tightness in your impaired arm and leg. These procedures are entirely experimental and are not intended to provide any specific medical diagnosis or treatment. It is hoped that this study will enhance our understanding and treatment of movement disturbances following stroke.

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

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Your alternative to participating in this research study is to not participate.

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

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## Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. Dr. Jules Dewald is the person in charge of this research study. You may call him at telephone (312) 908-6788, Monday through Friday from 9am to 5pm. For problems arising evenings or weekends, you may call Dr. Dewald at (630) 854-7708. If Dr. Dewald is unavailable you can call research coordinator Ray Arceo at (312) 908-0847 or team member, Margaret Sereika, at (847) 532-8242.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-1376 or irbcompliance@northwestern.edu if:

- The research team is not answering your questions, concerns, or complaints.
- 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 up to 64 people with stroke will be enrolled in this research study.

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

If you choose to participate in this study, you will be asked to come to Northwestern University's Department of Physical Therapy and Human Movement Sciences at 645 N. Michigan Ave. Each session will last approximately 6 hours. This includes two possible sessions for each of the measurement protocols defined below; one drug and one placebo. An individual session has been allotted for each of these measurements (study portions), though efforts will be made to combine sessions when possible.

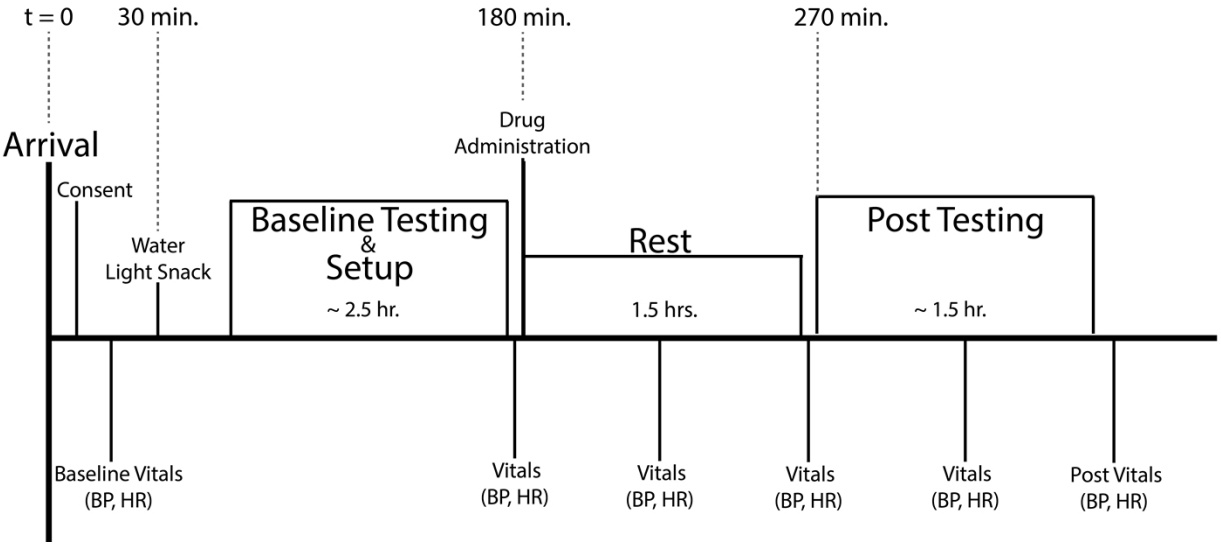



**Figure 1:** A typical session timeline. Experimental sessions will follow the general timeline shown, repeated for each drug probe and each measurement protocol. Timing is provided as an estimate. BP: Blood Pressure; HR: Heart Rate.

A typical session will follow the timeline shown in Figure 1. In each session, you will be seated and at rest in an adjustable chair, and adjustable straps may be placed across your shoulders and waist to maintain proper posture. A custom cast made of fiberglass material may be fit to the

forearm, wrist, and hand of either of your arms. Electromyography (EMG) surface electrodes (stickers placed on skin) may be placed on up to eight arm muscles to measure your muscle activity. Your baseline vitals, blood pressure and heart rate, will be measured and you will be offered a light snack and water. Pre- medication testing measurements will then be conducted. These will include at least one of the five types of measurements listed below.

Throughout each experimental day, your heart rate and blood pressure will be measured. At the end of the experiment day, you will be checked for orthostasis by checking blood pressure and heart rate while you are sitting and standing (3 minutes in between measures). The study team will report blood pressures and heart rates to the study physician, who will decide if you are safe to leave. If you drove, we will encourage you to stay until side effects such as fatigue or dizziness wear off.

Following pre-medication "Baseline" testing, TIZ or placebo will be administered, and a rest period of 1.5 hours will be observed. Following this rest period, "Post" testing measurements will be conducted. These will be identical to the pre-medication measurements.

**Measurement Protocols:**
By signing this consent form, you are consenting to all the following study portions (measurement protocols). You will be notified which measurement protocol you will be completing and may choose to withdraw participation at any time and do not have to participate in all of the measurement protocols. Upon completion of one measurement protocol, you may be asked to complete a new measurement protocol. Two or more of the measurement protocols may be collected during the same study visit.

**Measurement Protocol 1: Reaching and Hand Opening Experiments**
Your forearm will be fixed to an arm support while you sit in the experimental chair. The robotic version of this device is capable of allowing you to reach towards a target, can stretch your arm, and may make your arm feel heavier or lighter than normal. You will be asked to do a series of reaches which require you to both lift your arm, extend your arm out and open your hand. The robot will adjust the weight of your arm to make it more or less difficult to lift up. Sensors will be attached to your fingers and electrodes attached to your arm. A computer screen placed in front of you will show your arm moving through space, as well as the target you want to reach for. You will be given ample breaks in between reaches.

**Measurement Protocol 2: Stretching Experiments**
Your forearm will be set in a cast for 6 hours and fixed to a robotic system while you sit in the experimental chair. The robot will make a series of stretches at high speeds that move your arm away from you and then towards you. There will also be a period of stretches at slow speeds. Following this, you will be asked to either move your arm on your own or rest your arm. After this period of either movement or rest, the robot will again make a series of stretches at high speeds that move your arm away from you and then towards you, followed by a second period of slow stretches. You will have electrodes attached to your arm.

**Measurement Protocol 3: Tonic Vibration Reflex Experiments**
Your forearm will be set in a cast for 6 hours and fixed to a robotic system in a comfortable position in front of you while you sit in the experimental chair. EMG electrodes will be attached to elbow and wrist flexor and extensor muscles. First while relaxed, a vibrator will be applied to the biceps (half way between your elbow and shoulder) for up to 8 seconds. You will then be asked to

generate force at different efforts (i.e. 5 or 20% of max) while the vibrator is turned on. Approximately 20-30 trials will be performed, with plenty of rest in between each.

**Measurement Protocol 4: Isometric Experiments**
You will be seated in the experimental chair with electrodes attached to your arm. Your arm will be fixed, so without moving your arm, you will increase force in a direction (such as moving your forearm in or lifting at the shoulder) specified by the experimenter. This could either be a steady force for a sustained amount of time, or a gradually increased then decreased force (ramp). A computer screen placed in front of you will provide feedback instructing you to relax, increase force, or decrease force. 3-4 trials will be collected for each movement condition. There will be up to 5 movement directions for both steady, sustained force and for ramp force. You will have ample breaks in between trials.

**Measurement Protocol 5: Electroencephalography (EEG) Experiments**
For the EEG portion of the study, you will wear an EEG cap which measures brain electrical activity. Your forearm will be fixed to a robotic arm while you sit in the experimental chair. You will be asked to do a series of lifting your arm and opening your hand. Sensors will be attached to your fingers and electrodes attached to your arm. A computer screen placed in front of you will show your arm moving through space, as well as the target you want to reach for. You will be given ample breaks in between arm lift and hand opens.

**Pupil Diameter – Used in all measurement protocols**
A pupillometry device will be worn during each experiment to continuously measure pupil diameter (size of eyes). This device is worn on your head with two infrared cameras recording each eye. We ask you to remove your glasses, as the pupillometry device will not fit with them on. Contacts are ok to wear, as the pupillometer can still detect pupils underneath them. The pupillometry device requires initial calibration and instructs you to look at targets on a screen in front of you. During experiment, you will be asked to stare straight ahead at a screen. This may involve the screen changing brightness, or audio tones playing at variable intervals and frequencies to illicit changes in your eyes.

Though you may be asked to complete two experimental sessions (TIZ and placebo) for each protocol, to conserve your time we may combine protocols. This would result in less overall visits to the laboratory. You will be notified when the above protocols will be combined.

Throughout each session, your heart rate and blood pressure will be measured on a routine basis.

With your permission, video recordings may be made of the experimental procedures. If you agree to audio or video recordings (see "Optional Elements" located at end of this document) special consideration will be used to ensure the face is avoided and blurred when necessary.

In the blinded testing, neither you nor the study doctor will know which drug you are getting for a given session. The following may be used.

- TIZ (TIZ) (Zanaflex®) is currently indicated for the management of spasticity (muscle tightness). TIZ acts to decrease the amount of a specific chemical (neurotransmitter, norepinephrine) that is available in your body.

This study uses magnetic resonance imaging (MRI) to look at the brain using magnetic fields and radio waves to create images, without using any radiation like X-rays.

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You may be asked to complete an MRI scan at the Center for Translational Imaging at the Feinberg School of Medicine at Northwestern University, located at 710 N. Fairbanks Ct., Lower Concourse Chicago, Illinois 60611.

MRIs use strong magnets when creating images, so metal in your body that's attracted to magnets can alter the images or even cause metal objects to move. To ensure the MRI is safe, you'll need to fill out a screening form about any metal in your body and questions about your medical history that impact or could lead to harm if you have an MRI. You will be asked to change into a gown to ensure no metal is on your clothing, be visually inspected for any metal, and go through sensitive metal detectors. Be sure to tell the researchers if you have:

- Metal fragments in your eyes or face
- Implants like pacemakers, defibrillators, cochlear implants, or nerve stimulators
- Had surgery on your brain's blood vessels or heart valves
- Claustrophobia (fear of small spaces)
- Body piercings or tattoos

If you have metal in your body, you may not be able to have the research MRI unless the metal is determined to be MRI-safe.

Before the MRI, you'll be given instructions. You'll lie still on a table, and your head will be positioned in a special holder with a foam cushion. The table will slide into the MRI scanner, and the scan will take around 20 minutes.

To get the best images, it's important to stay very still. Let the researchers or MRI technicians know if you feel uncomfortable or if you need to stop the MRI procedure. During the MRI procedure, some people feel fatigued, uncomfortable, or claustrophobic in the scanner. Therefore, you can terminate the experiment at any time by pushing the emergency squeeze ball and by communicating with the experimenter using the 2-way sound system that includes headphones for you. The MRI scanner makes very loud noises, so you'll be given earplugs or headphones to protect your hearing. You'll be able to communicate with the MRI technologist through an intercom during the MRI scan for any reason. These headphones will also significantly reduce the scanner noise. Finally, there are 2 digital cameras located inside the magnet room (MRA Inc, Pittsburgh, PA). They provide continuous monitoring of the whole room and a close-up view of the participant for safety purposes.

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

If you take part in this research, you will be responsible to return to the lab for all five sessions.

## 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 will no longer contact you for this study. 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. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

If you agree, this data will be handled the same as research data.

You may choose to withdraw from a session for any reason, such as side effects, but return on another day to participate with another drug/placebo. You may also choose to withdraw from a protocol or from the entire study. The data that is collected up until the time of withdrawal may still be used in the analysis. All files and records will continue to be confidential.

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

*Surface electrodes:* The self-adhesive EMG surface electrodes and stimulator electrodes may produce minor irritation of the skin; there is also the possibility of an allergic reaction to the electrode paste. The possibility of irritation will be minimized by cleaning the skin with alcohol before and after the application of the electrodes. There is a similar possibility of scalp irritation due to the use of EEG electrodes. 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 place cotton or foam underneath the cap to minimize this side effect. There is no known increase in risk in performing an EEG recording on individuals with stroke.

*Reaching movements:* Although the movements of your arm will not meet or exceed your elbow's normal range of motion, repeated motions may cause minimal temporary discomfort in your arm by the end of the study session. This potential discomfort will be addressed by stretching or massaging your arm prior to and following the experiment.

*Fiberglass cast:* The fiberglass cast used to prevent movement of the hand and wrist will be applied and then later removed with a cast cutter. It is possible for the cast cutter to burn your skin. The possibility of a skin burn from the cast cutter is minimized by careful and experienced removal of the cast by trained personnel.

*Pupillometry device:* The pupillometer stays on your head similar to a pair of glasses. If worn with an EEG cap, you may experience discomfort from pressure behind your ears. Additionally, staring at a screen may induce eye strain. Both potential side effects can be minimized by taking breaks and removing pupillometer, or only wearing pupillometry device during applicable trials.

*Medications*: The medications used in this study may produce side effects that should be reported immediately to the research team (See contact information under "**Who can I talk to?"**). Potential side effects include:

Tizanidine

- TIZ may cause hypotension (low blood pressure), syncope (fainting due to low blood pressure), dizziness, bradycardia (slow heart rate), dry mouth, asthenia (weakness/fatigue), difficulty passing stool, vomiting, blurry vision, flu-like symptoms, nervousness, dyskinesia (abnormal body movement), hepatotoxicity (liver injury), sedation (drowsiness), urinary tract infection, rhinitis/pharyngitis (inflammation of nose/throat), hallucinations(false perceptions involving your senses) or psychosis (losing contact with reality) (found in 3% of patients studied), hypersensitivity reaction (allergic reaction that could include rash, itching, trouble breathing), anaphylaxis (life-threatening allergic reaction)
- There are less common (<3%) reactions of Steven Johnson Syndrome (rare reaction with fever, rash, blisters on mouth), allergic reaction to the medication, seizure (abnormal brain activity that may involve spasms), depression, ventricular tachycardia (heart arrhythmia, irregular beat), tremors (shakiness), arthralgia (aching joints), that were reported by people who were taking TIZ, which may or may not be due to the medication.

- There is a risk in patients with liver or kidney problems, so you should not take this medication if you have any liver or kidney problems.
- The risk of adverse effects and/or duration of effects may increase in older adults (≥65 years of age)

Lactose Placebo
For individuals with lactose intolerance, potential side effects of ingesting the placebo pill are:

- Abdominal pain and bloating
- Excessive flatus
- Watery stool

Drug holding

- Your daily medications are taken into account for inclusion/exclusion and whether your participation is safe to enroll in this study. Study physician, Dr. Urday, may deem you safe to enroll but advise holding a medication (e.g. on the day of the study or taken in the evening rather than the morning)
- This is usually in the case of blood pressure or sedating medications, so symptoms of increased or decreased blood pressure or drowsiness are not compounded on experiment day.
- Potential risks include change to blood pressure which we will monitor throughout the study day to ensure it stays in safe range.

*MRI:* Some people cannot have an MRI because they have metal in their body. This includes things like pacemakers, artificial heart valves, metal implants (e.g., ear implants, bullet fragments), and devices like chemotherapy or insulin pumps. If you are aware that you have any type of metal in your body, tell the research team so that they can assess whether it is safe for you to have an MRI.

During the MRI, you'll lie in a small, enclosed space inside a large magnetic tube. Some people feel anxious or claustrophobic in this small space. The scan doesn't hurt, but it can be uncomfortable to lie still for a long time. Let the researcher know if you're concerned about claustrophobia or staying still during the test.

The MRI makes very loud banging noises, so earplugs or special headphones will be used to reduce the noise.

Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable, please notify the MRI technician or the researcher.

Most studies of MRI during pregnancy show no evidence of risk to the fetus. However, given the limited data and the vulnerability of the fetus, persons who are pregnant should not participate in MRI studies. You can withdraw from the study at any time, if you have any concerns, without penalty.

Other risk: In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

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This study involves the use of your identifiable, personal information and 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?".**

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

The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. You should not be or become pregnant during this research study, with incomplete sessions and intentions to finish.

If you are a participant of childbearing age and could become pregnant, you will be asked during the phone screening prior to enrollment if it is possible that you are pregnant. If there is a chance you could be pregnant, you may be asked to take a qualitative urine human chorionic gonadotropin test (over the counter pregnancy test) on the day you come in for your in-person screening and consenting visit. You must provide evidence of a negative pregnancy test in order to continue participation in this study.

If you are sexually active, both men and women should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or your partner become pregnant while participating in this research study or for 1 month after you complete the study, it is important that you tell the research team immediately (See contact information under "**Who can I talk to?"**). You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

If you or your partner [are/is] considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. 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 will not lead to any costs to you.

## 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: Your arm may feel looser after stretching and reaching protocols and your movements may improve temporarily with medication.

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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.

If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Please note that any research information shared with people outside of Northwestern University will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office]**.**

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share information with others without your separate permission. The results of this study may also be used for teaching, publications, or presentations at scientific meetings but your private health information will not be identified.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for Human Research Protections (OHRP), and 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.

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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.

## Will my data or samples be used for future research?

This study is collecting data and samples from you. We would like to make your data and samples available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data and samples may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data and samples for 5 years. To get your data or samples, future researchers must seek approval from this institution and review by an IRB may be required.

We will protect the confidentiality of your information to the extent possible. Your data and samples will be coded to protect your identity before they are shared with other researchers. Only the study team will have a code key that can be used to link to your identifying information. The code key will be securely stored.

Your name and identifying information will be removed from any data and samples you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and samples. 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 not being able to properly perform the protocols or having an adverse reaction to the medication.

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 are 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 research team about any illness or injury (See contact information under "**Who can I talk to?"**)..

The hospital [Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), Northwestern University, researchers, study physician] will not pay for medical care required because of a bad outcome resulting from your participation in this research study.

You will receive $50 for the consenting and screening visit, which determines eligibility and enrollment in the study. This visit will last approximately 2 hours. In the event that the duration of the visit is an hour or less, you will receive $25.

After enrollment, you will be compensated using one of the following two methods, whichever results in the smaller total amount:
- $150 per experimental visit (typically lasting about 6 hours) for participation in one experimental session of the study. If a visit exceeds 6 hours, you will receive an additional $20 per hour for the extra time. Time will be rounded up if the additional duration is 30 minutes or over the hour mark. For example, if the visit is 6 hours and 45 minutes, you will be paid $150 for the first 6 hours and $20 for the additional 45 minutes. If the duration is 29 minutes or less over the hour mark, time will be rounded down to the nearest hour. For example, if the visit is 6 hours and 20 minutes, the participant would be compensated $150.

- $25 per hour for the total duration of the visit. Time will be rounded up if the duration is 30 minutes or over the hour mark. For example, if a visit is 2 hours and 45 minutes, the participant will be paid for 3 hours. If the duration is 29 minutes or less over the hour mark, the time will be rounded down to the nearest hour. For example, if a visit is 2 hours and 20 minutes, the participant will be paid for 2 hours.

This will be paid by check via standard mail approximately 3 weeks following each of the visits. The research team will determine the payment schedule, not the participant. 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 $2000 or more in a calendar year.

Reimbursement for public transportation will be added to the $150 per visit or $25 per hour compensation. If you would like the research team to order a Lyft for you to take to and from the lab, please call the research team so they can coordinate the ordering of the Lyft for you.

You are encouraged to bring a pre-prepared lunch from home on the days that you are scheduled for experimental visits (usually around 6 hours, typically from 9am-3pm). We also provide snacks and water during the visit. If you are unable to bring lunch from home, the research team will coordinate ordering lunch for you to have at lab, up to $25 (with tax).

If you drive to or are dropped off at the lab by a family member or friend, one parking voucher will be provided per visit to use at specific garages near the lab. Participants are responsible for their own gas expenses. In special circumstances—such as severe weather events—the study team may cover the cost of a private rideshare service (e.g., Lyft or Uber), at the discretion of the Principal Investigator (PI).

Please note that communication-related expenses (e.g., phone calls) will not be reimbursed.

## HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations

- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information
- Mental Health information

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- 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.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly
- Registries or other research-related databases: The Clinical Neuroscience Research Registry. The results of your examinations will be kept in a central computer or data registry at the Shirley Ryan AbilityLab, Chicago, IL. These results will be stored by research identifier code for privacy of records and to allow others to contact you for participation in similar research studies.

**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.***

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Julius Dewald
Institution: Northwestern University
Department: Physical Therapy and Human Movement Sciences
Address: 645 N Michigan Ave, Suite 1100, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

## 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.

| 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

_____

**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.***

Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent