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 will be asked to come in for six study visits. 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.

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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).

Whom can I talk to?

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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 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.

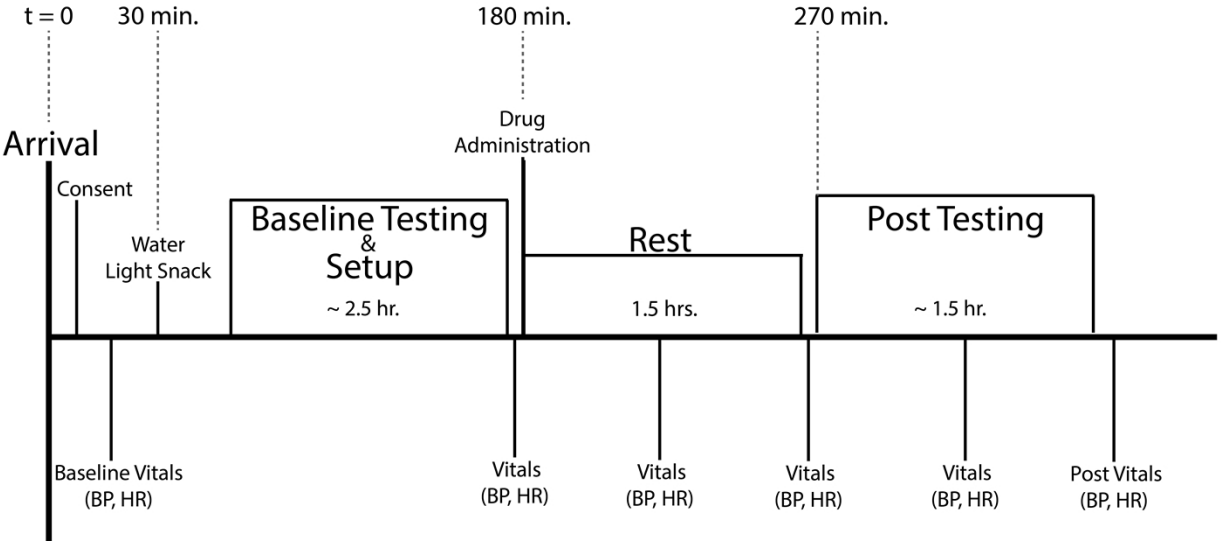

Figure 1: A typical session timeline. Experimental sessions will follow the general timeline shown, repeated for each drug probe and each measurement protocol. Timing is provided as an estimate. BP: Blood Pressure; HR: Heart Rate.

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.

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 session (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.

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.

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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

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 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.

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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.

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.

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.

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If you agree to take part in this research study, we will pay you $20/hour for your time and effort. This will be paid by check via standard mail approximately 3 weeks following each of the visits. 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.

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),

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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.

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.

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I agree	I disagree	
_____	_____	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