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: Altering activation patterns in the distal upper extremity after stroke

Investigator: Elliot Roth M.D.

Supported By: This research is supported by the National Institutes of Health (R01-HD075813-03).

Financial Interest Disclosure:

If your doctor is also the person responsible for this research study, please note that s/he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

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?

We are asking you to take part in this research study because you have experienced a single, unilateral stroke at least 6 months ago and have continued impairment of your hand.

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?

The purpose of this study is two-fold: 1) to investigate a new use of an allergy medicine, cyproheptadine (an anti-histaminic and anti-serotonergic agent), to reduce spasticity and muscle hyperexcitability and 2) to evaluate the effectiveness of a new therapy using active practice of your arm and hand compared to passive stretching.

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

We expect that you will be in this research study for 13 weeks.

This study compares an active drug, cyproheptadine, to a placebo. A placebo is an inactive substance made to look/taste like an active medicine. You will either get the study drug, cyproheptadine hydrochloride, or a placebo. Researchers use a placebo to see if the study drug works better or is safer than not taking anything. Cyproheptadine is FDA approved for treating symptoms of allergic reactions, but has not been used to observe the effects on spasticity and muscle tone.

This is also a double-blinded study, which means that neither you nor the study doctor nor the study staff will know which drug you are receiving. However, in an emergency, the study doctor can get this information.

In addition, two different training therapies to move your arm and hand will be compared. One involves actively trying to control the contraction of your muscles in the hand and arm. The other entails receiving passive stretching of the muscles driving your fingers and thumb. Only you and the study staff administering the hand training sessions will know which treatment (active training or passive stretching) you are receiving and it is important NOT to discuss this with study staff such as the study doctor or evaluators.

You will be randomly assigned a: 1) drug treatment and 2) therapy treatment. Randomization means these two assignments will be based on chance, like drawing lots. Neither you nor the researcher selects these choices. Based on chance, you will be assigned to one of the four groups: drug and active training, drug and passive stretching, placebo and active training or placebo and passive stretching.

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?

The primary risks for involvement in this study are associated with the pharmacological agent to be tested. Although cyproheptadine hydrochloride (study drug) itself is not being used or administered differently than the FDA approved method, it is being used for a potentially different outcome, namely reduced unwanted muscle tone following stroke.

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. Although it has been shown that some benefit may be derived from taking cyproheptadine or from performing repetitive motion tasks or stretching, you may not experience any direct benefit from participating in this research study. Your participation in this study may aid in our understanding of the nature of movement impairment after stroke and may eventually improve rehabilitation of upper extremity function.

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.

You do not have to take part in this research study. Instead of being in this study, other treatment choices available for your condition may include occupational or physical therapy, if prescribed by a physician.

You may not participate in other investigational drug studies or studies treating the upper extremity or hand while enrolled in this study; however, you may take part in other research studies for the lower extremity or for gait training while in this study. Be sure to inform the researcher of your involvement in this study.

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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, talk to the research team at **312-238-2993.**

Dr. Elliot Roth is the person in charge of this research study. You can call him anytime at 312-238-1000 and ask the operator to page him.

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 100 people here will complete this research study

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

If you consent to participate, you will be asked to come to the Arms and Hands Lab (floor 22), in the Shirley Ryan AbilityLab, at 355 E. Erie Street, Chicago, IL 60611 for all training and hand evaluation sessions. You will begin participation with an examination with the study doctor to verify medical appropriateness of your participation. This is also where you will be given your allotment of pills for each change in dosage. Examinations with the study doctor (beginning, middle—at chronic drug dose, and end of study) will last approximately 15 min. In addition, you will be required to have your blood drawn at the beginning of weeks 1 (before beginning drug treatment) and the beginning of week 4 (before beginning therapy treatment) to monitor the drugs effect on your liver function. For these tests, a member of the research staff will escort you to the outpatient laboratory.

Over the course of the study you will participate in a therapy regimen involving either active practice of hand and arm muscle contractions or passive stretching of the digits, while concurrently receiving either cyproheptadine or placebo as part of the drug treatment. You will be randomly assigned a drug treatment (cyproheptadine or placebo) and therapy (active practice or passive stretching).

Over the first 3 weeks, drug dosage will be gradually increased from up to 8 mg per day (up to 4 mg taken 2 times daily) the first week up to 16 mg per day (up to 8 mg taken 2 times daily) the second week and up to 24 mg per day (up to 8 mg taken 3 times daily) the following week. The study doctor will adjust your dosage as needed. It is important for your safety that you do not stop taking the medication without notifying the study doctor, as the dosage should be gradually reduced.

You will maintain this daily dosage at a maximum of 24 mg per day for 6 weeks, during which

time you will come to the laboratory 3 times per week for one hour each session. If you are assigned to the active training, you will alternate between two types of therapy during this period: 1) playing a video game by contracting certain muscles and 2) repetitive task practice while wearing a Voice and EMG-Driven Actuated glove orthosis (the VAEDA glove). Each activity will be controlled by your muscle activity (recorded by electrodes put on the skin over your muscles).

If you are assigned to the passive stretching protocol, you will wear the VAEDA glove for two 20-min stretching stints per session, each followed by 10 min of rest. During this time the VAEDA glove will repeatedly move the digits of your hand from a flexed posture to fully extended posture and back.

You will also be asked to come to the Arms and Hands Lab (floor 22) of the Shirley Ryan Ability Lab for 7 evaluation sessions, each lasting approximately 2 hours. These will take place during the titration phase (baseline and end of weeks 1, 2, and 3), at the midpoint of training (end of week 6), at the end of training (end of week 9), and one month following (end of week 13) (see Fig 1). During this time, we will take a number of measurements. For example, your wrist will be placed in a cast to keep it in a fixed position and your fingers will be attached to a motor which will move them back and forth. On occasion, you will be asked to push against the motor. In addition, we will stimulate your muscle with electrical pulses by means of surface electrodes in order to test your ability to contract it. You will also be asked to perform tasks with your impaired hand and arm and to complete questionnaire rating your sleepiness and mood.

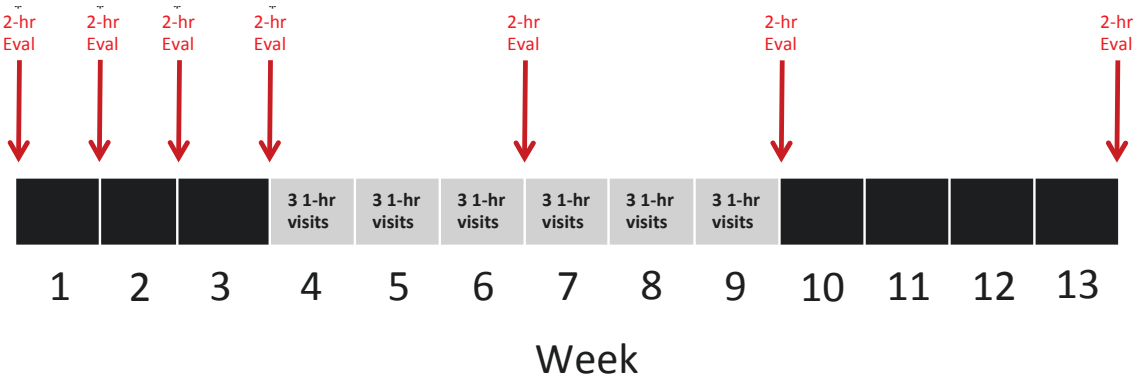

Figure 1: Timeline for evaluation visits (baseline and end of weeks 1-3, 6, 9 and 13)and treatment therapy sessions (3 visits per week for weeks 4-9). Note that you will also need to go to the outpatient laboratory in the hospital at the baseline visit and the end of week 3 (during chronic drug dose) to have your blood drawn.

During any of these visits, we may ask to make audio/video recordings of you both with and without the use of the VAEDA glove for use in scientific publications or presentations. Although these images will primarily focus on documenting hand function they may also include your face or voice. No other personal information about you will be included in the presentation. We will not attempt, however, to remove any identifying features from the photographs or the audio/video recordings, such as prominent scars or birth marks visible in the recordings. Thus, identifiable facial photographs or audio/video recordings may be placed on the Web, which may widely and permanently disclose your identity. These images will be kept after the study is completed and may be viewable indefinitely on electronic media (internet) and print media (scientific journals). Your choice to take part in the audio/video recordings is not related to your participation (you may still participate in the study if you refuse the audio/video recordings).

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The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a 1 in 4 chance of being in each treatment group (drug and active training, drug and passive stretching, placebo and active training or placebo and passive stretching).

Neither you nor the study doctor will know which drug treatment you are getting.

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

If you take part in this research, you will be responsible to arrive on time to your scheduled appointments. If for some reason you are not able to attend a scheduled session, you will be expected to notify study personnel in advance. You will also be expected to follow the prescribed dosages for the study medication. If for some reason you are unable please notify the study team at once.

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 discuss the process to stop study medication and discharge you from the research 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.

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

Your involvement in this study may involve the following risks, some of which may be serious and life-threatening:

As previously stated, the primary risks for involvement in this study are associated with the pharmacological agent to be tested. Although cyproheptadine hydrochloride (study drug) itself is not being used or administered differently than the FDA approved method, it is being used for a potentially different outcome, namely reduced unwanted muscle tone following stroke.

Cyproheptadine is used for treating symptoms of allergic reactions (such as seasonal or food allergies). It is also used to treat mild, uncomplicated hives. It may be used for other conditions as determined by your doctor. Cyproheptadine is an antihistamine. It works by blocking the action of histamine to reduce allergy symptoms.

Do NOT use cyproheptadine if:

- You are allergic to any ingredient in cyproheptadine
- you are breast-feeding
- you are elderly and in poor health
- you have narrow-angle glaucoma; a peptic ulcer; an enlarged prostate; or bladder, stomach or bowel blockage
- you are taking a mono amine oxidase inhibitor (MAOI) (eg, phenelzine) or you have taken an MAOI in the last 14 days.

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Before using cyproheptadine:

Some medical conditions may interact with cyproheptadine. Tell the study doctor if you have any medical conditions, especially if any of the following apply to you:

- if you are taking any prescription or nonprescription medicine, herbal preparation or dietary supplement
- if you have allergies to medicines, foods or other substance
- if you have a history of asthma; bladder, stomach or bowel blockage; glaucoma or increased pressure in the eye; difficulty urinating, prostate problems; kidney problems; overactive thyroid; heart problems; high blood pressure; or seizures

How to use cyproheptadine:

Use cyproheptadine as directed by the study doctor. Refer to the label on the medicine for the exact dosing instructions as it will change throughout your participation.

- Take each dose my mouth with or without food
- If you miss a dose, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

Important safety information:

- Cyproheptadine may cause drowsiness, dizziness, blurred vision or lightheadedness. These effects may be worse if you take it with alcohol or certain medicines. Use cyproheptadine with caution. Do not drive or perform other possibly unsafe tasks until you know how you react to it.
- Check with the study doctor before you drink alcohol or use medicines that may cause drowsiness (eg, sleep aids, muscle relaxers) while you are using cyproheptadine; it may add to their effects. Ask you pharmacist or the study doctor if you have questions about which medicines may cause drowsiness.
- Cyproheptadine may cause you to become sunburned more easily. Avoid the sun, sunlamps or tanning booths until you know how you react to cyproheptadine. Use sunscreen or wear protective clothing if you must be outside for more than a short time. Cyproheptadine may interfere with skin allergy tests. If you are scheduled for a skin test, talk to your doctor. You may need to stop taking cyproheptadine for a few days before the tests.
- Use cyproheptadine with caution in the ELDERLY; they may be more sensitive to its effects, especially dizziness, drowsiness, and low blood pressure.
- Keep cyproheptadine away from children.

Possible side effects of cyproheptadine:

All medicines may cause side effects. Check with the study doctor if any of these most **COMMON** side effects persist or become bothersome:

Blurred vision; constipation; dizziness; drowsiness; dry mouth, throat, or nose; excitability; nausea; nervousness; restlessness

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Seek medical attention right away if any of these **SEVERE** side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); confusion, dark urine; decreased coordination; fainting; fast or irregular heartbeat; fever, chills or persistent sore throat; hallucinations; mental or mood changes; seizures; severe or persistent dizziness, tiredness, or weakness; severe or persistent loss of appetite; severe or persistent trouble sleeping; tremor; trouble urinating; unusual bruising or bleeding; unusual back or stomach pain; yellowing of the skin or eyes.

You have been given a handout with the manufacturers' full prescribing information for cyproheptadine. Please read it thoroughly and discuss any concerns with the study doctor or doctor or pharmacist of your choice.

This is not a complete list of all side effects that may occur. Call the study doctor with any questions about the side effects or for medical advice about the side effects.

Clinical studies of cyproheptadine HCL tablets did not include sufficient a number of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

To minimize these risks, we will begin with low levels of the drug and gradually titrate (increase) up to the optimal target dose for the study, which is still well within the safe level of this drug. You will be evaluated weekly and will be able to contact the study doctor at any time with questions or concerns. There is a potential risk of impaired liver function while taking cyproheptadine. As a precautionary measure, liver profiles (requiring blood draws) will be run prior to initiation of drug administration and at 3 weeks to check drug impact on liver function. If you are feeling too drowsy or dizzy to drive to the AbilityLab during this adjustment period of titration, we will help to arrange transportation. You will also be weighed weekly to monitor weight gain throughout the study.

There are also risks with the use of the actuated hand orthosis, the VAEDA glove, to provide extension assistance or stretching. This device, as well as the motor used during the evaluations, has the potential to cause too much stretching, which may cause pain or damage to the joint. A number of safety features, however, have been implemented to attempt to reduce these risks, such as mechanical stops and limit switches. In addition, you will be monitored continuously by research staff while using this equipment.

The electrical stimulation used to measure muscle activation can cause pain; for some people it is sharp like a prick of a needle. We will use a series of stimulation pulses that we have found to be least painful. Additionally, we will carefully adjust the stimulation level to minimize discomfort.

You may experience some fatigue, muscle pain or soreness from repeatedly moving your arm and hand. If at any time you feel discomfort or pain, inform the researcher, and we will adjust or stop the experiment.

The cast saw used to remove the fiberglass cast placed around the wrist for the evaluations could produce burns if left for too long in one place. All study personnel will be trained in the proper use of this saw.

Skin irritation could result from the use of self-adhesive surface electrodes. This will be minimized by cleaning the skin with alcohol before and after their application. In case of any incident, emergency medical services are routinely available at the Shirley Ryan AbilityLaband at the adjacent Northwestern Memorial Hospital emergency room.

Some questions we ask may be upsetting or make you feel uncomfortable. If you do not wish to answer a question, you may skip it and go to the next question. Any suicidal ideations will need to be further evaluated by your doctor.

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

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 effects of the study drug, cyproheptadine, on human sperm and eggs have not been studied and are therefore unknown. The effects of cyproheptadine in humans have not shown to cause negative conditions in either the mother or the fetus during pregnancy. However, studies in animals have shown an increased risk of birth defects and fetal hormonal imbalances. The effects of this medication in women who are nursing have been shown to produce hormonal imbalances in the newborn.

If you or your partner become pregnant or are thinking of becoming pregnant while taking a study drug, or if you are nursing, it is important that you notify your study doctor immediately.

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. The cost of the drug, the therapies and the liver tests will be covered by the study.

During the initial dosing phase of the study (weeks 1-3) transportation can be arranged to and from the AbilityLab, at no cost to you, in order to preclude the need for you to drive when you may be experiencing potential side effects of the drug such as dizziness or drowsiness.

During the active/passive training and evaluation sessions you may incur parking or other transportation costs for which you will not be reimbursed. Parking at the AbilityLab for participants in this study is available at a reduced rate of $11, $3 with a valid handicap placard.

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. Additionally, the US Department of Health and Human Services, the sponsor of this research, and other collaborating instutions may request access to your personal infomraiton. Only de-identified data will be kept after the end of the study.

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), 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.

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 can remove you from the research study without your approval. Possible reasons for removal include non-compliance with study procedures or if deemed appropriate for your safety.

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 study doctor about any illness or injury.

The hospital [university, 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.

Following your initial screening with the research staff, further participation will require you to pass a medical examination with the study doctor as well as complete a clinical assessment for randomization purposes. You will be paid $20 for this visit.

If you agree to take part in this research study, we will pay you $20 for each treatment session that you attend and $40 for each evaluation session that you attend. These funds are provided to help support you with time and travel associated with your participation. If a session needs to be repeated at the behest of the study doctor, PI, due to researcher conflicts and/or equipment malfunction the stipend will be duplicated.

The Shirley Ryan AbilityLab will issue you a ClinCard, which is a specially designed debit card for clinical research. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card. The funds will be available within 1 day after being loaded and can be used at your discretion.

You will be issued one card for the duration of your participation. If your card is lost or stolen, please call (866) 952-3795 or ask a coordinator for a replacement ClinCard.

Fees are incurred if used at an ATM (fees vary by location). However, if the card is used for in-store or online purchases via credit or debit, there are no associated fees and no expiration date.

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Please be advised: Inactivity on the card for more than 3 months will incur a monthly fee. However, as long as there is activity on the card within 3 months (funds are added or a transaction is completed), the month period will reset and no monthly fee will be assessed.

If you do incur a monthly fee, please contact Greenphire Support at the number on the back of your card and they will reverse the fee. See "Tips for Using the Attached ClinCard" for more information.

The Finance Department at the Shirley Ryan AbilityLab will be provided with your information, including your Social Security Number, in order to issue payment for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

You may be given access to new inventions that are being developed by the investigator, the study sponsor, or other people involved in the study. Certain laws can make it harder to obtain legal protection for a new invention shared with a study participant, unless the study participant agrees to keep information about the invention confidential. You agree to keep confidential information you may receive about new inventions, such as new drugs, new devices, or new methods.

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
- Mental Health information: In the form of a survey you complete

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

This consent expires on September 20, 2019. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

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).

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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 and the Shirley Ryan AbilityLab 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,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Registries or other research-related databases. 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.

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.

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 expire at the end of the research study. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless it obtains permission to do so from you.

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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: Elliot Roth, MD
Institution: Shirley Ryan AbilityLab
Address: 355 E Erie St.
Suite 14-2118
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.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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.

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Signature Block for Capable Adult:

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

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process

Signature Block for Adult Unable to Consent:

Your signature documents your permission for the named participant to take part in this research.

_____
Printed Name of Participant

_____ _____
Signature of Legally Authorized Representative Date

_____ _____
Printed Name of Legally Authorized Representative Date

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Printed Name of Person Obtaining Consent Date