Study Title: Myoelectrolytically controlled device in acute rehabilitation after stroke.

Study PI: Ahlam Salameh MSc, PhD

ClinicalTrials.gov ID: NCT04599036

IRB approval date: August 11, 2022

Participant Name: _____ Date:_____

Title of Study: Myoelectrolytically controlled device in acute rehabilitation after stroke. (Enrollment)

Principal Investigator: Dr. Ahlam Salameh, PhD, MS

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

The purpose of this research study is to test if in the acute rehabilitation setting, individuals with stroke can use and benefit from a myoelectric orthosis, which is a device that detects and amplifies the electrical signals generated by the muscles to move the stroke affected arm. The treatment will consist of targeted motor learning upper extremity exercises while wearing the myoelectric brace which is called a MyoPro. By doing this study, we hope to gather information on the safety and effectiveness of the MyoPro in improving hand and arm function for individuals with stroke by learning two things: 1) can the MyoPro be used for training during the acute rehabilitation stage (less than 6 months after stroke), and 2) does using the MyoPro correlate with the improvements and the speed of the recovery of the weakened arm for individuals in the acute phase of rehabilitation.

You are being asked to participate in this research study because you had a stroke 6 months ago or less and your arm has been affected by your stroke. This study is sponsored by the VA RR&D. The study will be conducted at VA Northeast Ohio Healthcare Systems (VANEOHS; Wade Park). in the Brain Plasticity and NeuroRecovery Research Laboratory of the Cleveland VA FES Center. MRI will be performed at VANEOHS MRI department. We plan to enroll 15 participants with arm weakness due to stroke and 20 participants with no history of stroke.

Your signature on this form means that you have been fully informed and that you freely give your consent to participate. It is also important that you read and understand these principles that apply to all individuals who agree to participate in the research project below:

1. Taking part of this research project is entirely voluntary.
2. You may not personally benefit from taking part in the research but the knowledge obtained may help the health care professionals caring for you to better understand the disease/condition and how to treat it.
3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.
4. If, during your participation in the research project, new information becomes available concerning your condition (disease) or concerning better therapies, which may affect your willingness to continue in the research project, your doctor will discuss the new information with you and will help you make a decision about continuing in the research.

5. The purpose of the research, how it will be done, and what your part in the research will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information, which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions, concerns, or complaints you have about this research with the research staff members.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in this research will last about about 15 weeks. The study has two phases: a screening session, which you have already completed, and the treatment period. The treatment period consists of three parts: baseline testing, 18 therapy sessions, and follow-up testing. You are expected to have about 22 – 30 treatment and testing sessions. The visit sessions will be scheduled at your convenience and breaks will be scheduled for your comfort and as you request. In the therapeutic sessions you will receive 1.5 hours/day, 3 days/week of intensive hand and arm therapy with the MyoPro. This therapy will be provided in addition to your standard care that is assigned for your acute rehabilitation care. Due to the nature of the study, the schedule is subject to change. An example study timeline is preented in the table below.

Study timeline

Part 1: Baseline	Part 2: Therapy/training						Part 3: End		Part 4: Follow up
Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8-11	Week 12
Baseline assessment	3 X 1.5 hour sessions per week						**End-point assessment**	**Unsupervised home ML exercises**	**Final Assessment**
				Mid-point assessment					

Study Part 1. Screening Examination.

As a candidate for participation in this study, you went through a screening process. Based on your medical history and your physical examination you met the criteria for

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study entry to participate in the treatment period. You are being asked to sign this consent form because you have agreed to continue and wish to enroll in the study.

Study part 2. Participation

Treatment sessions: Schedule.

There will be 18 treatment sessions and 5 – 8 testing sessions depending on your tolerance and scheduling. The treatment sessions will be scheduled up to 3 times a week. The sessions will last about 1.5 hours (or 90 minutes). You may rest or end a session at any time that you wish. The testing sessions will be scheduled before treatment sessions (baseline), after treatment sessions , and 6 weeks after you finish all the treatment sessions (follow-up). In addition, for participants who enrolled in the study within the first 3 month post stroke, we will perform a separate testing at 3 months after your stroke.

Treatment session. Procedures.

During the 18 treatment sessions, the MyoPro brace will be placed on your stroke affected arm. You will receive individualized motor learning exercises under the direction of a therapist to address the functional needs of your arm. During the session, study staff will instruct you about using the 4 modes of the MyoPro and have you practice using the individual modes or a combination of different modes depending on your hand and arm ability. You may take breaks or end the session at any time. On days when you are not at a treatment session, you will be assigned individualized exercises to help strengthen your weak arm and improve your coordination.

Testing sessions. Schedule.

You will be scheduled for at least 4 testing sessions that could last up to 5 hours (300 minutes) each. The testing sessions may be divided into 2 shorter sessions (lasting up to 2-1/2 hours) on separate days. The first testing session will be scheduled before the first treatment session, the second testing session will be scheduled after session 18. A small third testing session will be scheduled when you are 3 month post stroke if you were enrolled within the first 3 month after stroke. For the fourth testing session you will be asked to come for a follow-up testing session 6 weeks after the last treatment session. During all testing sessions, a break time will be scheduled at your convenience. You may rest or end a session at any time you wish. In addition, there will be two separate MRI test sessions lasting 1.5 hours. One session will be scheduled

before the first therapy session and the second MRI session will be after the last therapy session.

Testing Procedures.

During the testing sessions, we will perform study tests of your arm function and the activity in your brain. The specific procedures are described below. You will be reminded to eat and drink during the longer sessions and you will be able to take a break whenever you would like to do so.

Testing of hand and arm function and sensation.

1- **Hand and arm function tests**. A trained staff member will evaluate your ability to perform some hand and arm tasks. . The tasks will cover the major arm functions that include grasp, grip, pinch and gross movement. The evaluator will score your arm function based on the quality of the task performed.

2- **Hand and elbow joints range of motion**. A trained staff member will measure the angle your arm joints can achieve when you move the joints on your own (active) and when the therapist moves the joints for you (passive).

3- **Abnormal muscle tone**. A trained staff member will move your joint at different speeds and assess the muscle resistance during each movement.

4- **Hand position and sensation test**. To assess your position sense, a trained staff member will move your hand and ask you if you feel the movement and in which direction did your hand move. To assess the sensation, the staff member will touch your hand and arm with a filament (similar to short pieces of fishing line) with different thicknesses. You will be asked to close your eyes and say when and where you feel a touch from the filament.

Testing of brain's structure and activity.

1- **Transcranial magnetic stimulation (TMS) tests.** TMS tests measure how an electrical signal travels between different parts of your brain and between the brain and muscles. The investigator will hold a small coil against your head. The coil consists of loops of copper wire enclosed in hard plastic, and looks like a large figure 8. The coil will be pressed firmly but comfortably against your scalp. The coil will induce a magnetic field around your head. This magnetic field is

converted into an electrical signal in a specific portion of your brain. When the coil is turned on it will feel like a tap or a pinch and you will hear a clicking noise. You may feel a slight contraction of the muscles of your scalp. There will be no electric discharge applied to your head and there will be no electric contact between the coil and you. With one or two TMS coils, we will briefly stimulate a specific portion of your brain that will produce a contraction in a specific muscle of your arm. Muscle contraction will be measured with the electrodes placed on your arms. It may take 60 – 90 minutes to complete the tests. You will be given an opportunity to take breaks, move about and stretch as needed.

2- **Electromyography test (EMG)**. We will test the strength of the electrical signal of your arm muscles. We will use the same electrodes on your arm for TMS and touch your arm at another point with a pair of electrodes delivering a brief shock. When this happens, you will feel a tingling sensation that may or may not be painful. A few brief shocks will be delivered at your elbow. There is no pain between the shocks. EMG is regularly used in clinics.

3- **Magnetic resonance imaging (MRI) test**. MRI is a way of seeing the internal parts of the body using a magnetic field and radio waves and used in clinical practice. The MRI scan is painless and the only discomforts involved are the noise of the equipment and having to lie quietly in a confined space during testing. The enclosed area is a cylinder that is approximately 1 yard wide. The estimated time needed to produce these images is 40 minutes. The procedure involves lying on your back on a table. The technician will slide your upper body into a large cylinder that is the inside of a large magnet. Magnetic and radio waves are used to obtain the images by passing them through the body and recording the radio waves that are released from the body. The behavior of these emitted waves in the presence of the magnetic field allows a computer to reconstruct the image. There are no known side effects or risks associated with MRI although ultimate long-range effects are unknown. Other institutions as well as this facility have performed thousands of MRI procedures on patients with no ill effects. During the test procedure, you can be repositioned for your comfort. During the test, you can verbally request to stop the test at any time. You will also be provided with a hand switch that you can use to tell the staff that you wish to stop the procedure.

4- **Near-infrared spectroscopy (NIRS) recordings**. NIRS is a noninvasive neuroimaging technique that uses the same basic principle used in the pulse

oximeter. It is used to monitor brain tissue oxygenation by measuring the balance between oxygenated and deoxygenated blood to provide a measure of brain activity. During the recording, you will wear a tight-fitting cap holding the NIRS sensors. NIRS will be collected while you are sitting comfortably and you will be asked to move your hand and arm.

5- **Electroencephalography (EEG) recordings**. EEG is a noninvasive neuroimaging technique that measures the electrical activity in your brain using small, metal discs (electrodes) attached to your scalp to provide a measure of brain activity. During the recording, you will wear a tight-fitting cap holding the EEG electrodes. EEG will be collected while you are sitting comfortably and you will be asked to move your hand and arm.

Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research participants.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer for this study because approximately 50–80% of stroke survivors in the acute rehabilitation phase typically suffer muscle weakness and abnormal muscle tone. Studies have shown that the best time to intervene is in the first weeks after stroke. In this study, we are trying to develop better methods to involve the weak arm in intensive targeted exercise during the first weeks after stroke. A myoelectric device may help regain control of the stroke-affected arm. Even though you may or may not benefit from this study, the present study will provide information to help guide future research.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This study is in addition to the therapy you a currently receiving. The study requires you to spend additional time for the treatment with the brace plus time for testing. If you are not currently receiving care as an inpatient at the VA, you will have to travel to the VA for the treatment sessions with the brace and testing sessions.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Ahlam Salameh.

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is:

216-791-3800 ext. 63417

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect. The MyoPro is a relatively new, commercially-available non-invasive arm brace technology. It has been cleared by the Food and Drug Administration (FDA).

In this study we will follow all clinical practice standards for MyoPro use. However, the following side effects are possible:

1. Discomfort due to MyoPro Wear. There is a possibility that some discomfort may arise while wearing the brace. You will be required to wear the device for up to two hours during training. If at any time you feel uncomfortable, please inform the study staff and modifications will be made to the brace fit to improve comfort.
2. Changes in Shoulder Stability/Pain: There is a possibility that if you have ever had issues with shoulder instability or pain, using the orthosis may cause these issues to flare up again. Shoulder stability and pain will be monitored throughout the study to ensure that the device is not causing problems. Development of shoulder pain or instability during the course of the study would result in subject withdrawal from the study if modifications

such as adding a shoulder harness were insufficient to overcome shoulder stability issues.

3. Failure of Safety Mechanisms. The manufacturers of the brace have been careful to ensure that the brace is safe and cannot apply a dangerous amount of force to the arm or hand. Safety mechanisms have been implemented into the control software, the electronics hardware, and the mechanical hardware of the brace. For example, in the software commands that control the brace and the electronics of the brace, there are limits on the amount of force that can be commanded to the system. The mechanical system contains physical limits that prevent the brace from exerting force in an unsafe direction. In the worst-case scenario, if all of these safety mechanisms fail, there is a small risk that your arm could be injured.

4. Skin Irritation. The brace incorporates stainless steel, non-allergenic surface electrodes with no adhesive. It is very rare that these electrodes will cause skin irritation, but they might if you have allergies to certain metals (not including nickel) and/or the brace fit is not correct. Development of skin problems as a result of the orthosis that could not be overcome by modifications to fit or improved donning/doffing procedures would result in subject withdrawal from the study.

5. Device Malfunction. If at any time during the use of the device, you notice any of the following, you should immediately discontinue use and seek guidance from the researchers:

- Unusual noises from the orthosis (i.e. skipping, clicking.)
- Smells from the orthosis (i.e. smoking, burning plastic.)

6. Videotaping of Brace Use. Your functional performance of your arm both with and without the brace will be videotaped during some of the outcome evaluations. Your upper body, head, and neck will be visible in the video tapes. The tapes will be stored in a locked cupboard. The only people with access to the cupboard will be study staff. If study personnel identify that your video tape shows functional benefits that would be useful to illustrate the benefits of the study treatment to the to the scientific community, we would like to use a short portion of your video record for the purpose of illustrating the good results of the study treatments for persons with arm impairment.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you by the VA Northeast Ohio Healthcare System while you are participating in this study. You also authorize disclosure of the picture and/or voice recording to the research team at LSCVAMC. The said picture, video, and/or voice recording is intended for the following purposes: to evaluate your arm function, to help educate new invistigaters, and to be used for presentations in scientific conferences and scientific talks.
The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled.

Signature: _____ Date: _____

7. Inclusion of Women of Childbearing Potential

The safe use of MRI in pregnant women and nursing mothers has not been established. Consequently, there may be risks to you (or to your embryo or fetus) if you are or may become pregnant that are unknown. Women of childbearing potential enrolling in this study must (i) have been using a birth control measure (an intrauterine device (IUD), birth control pills, a condom, diaphragm, or abstinence) for the previous three months, (ii) must have a negative pregnancy test if such testing was indicated, and (iii) must agree to continue to use a birth control measure for the duration of the study. If, while participating in the study, you suspect you have become pregnant, please contact the study physician immediately. Women are considered to be of childbearing potential unless they have been surgically sterilized (for example tubal ligation or hysterectomy) or are post-menopausal, that is, no menstrual period for more than 6 months. Nursing mothers may not participate in this study.

Risks associated with MRI, TMS and EMG test.

1. MRI Testing, Lying Quietly in A Confined Space and Loud Noise

The MRI testing includes lying quietly in a small space for about 40 minutes. Some patients complain of claustrophobia or the sensation of being enclosed in a small space. You will be able to speak to the research team members using a microphone and you can hear the research team members through the earphones that will be provided.

The MRI testing also entails loud noises that occur when the MRI equipment is testing. The earphones for communicating with the research team reduce the level of the noise. If the noise is still too loud for you, cotton earplugs will also be provided. If you become uncomfortable, you can use the call button that will be provided for you to hold in your good hand. Using the call button or the microphone, you can alert the team that you wish to cancel the test. You can do this at any point during the testing procedure.

2. TMS tests-non-invasive measurement of brain function. TMS has been used in growing number of laboratories worldwide since 1984, and safety guidelines have been developed. In this study we will use all recommended safety precautions for TMS. The following side effects are possible although very unlikely with this level of stimulation.

- Headache You may have a headache following TMS. Headache is thought to be due to muscle tension. In case of a headache you will be offered acetaminophen or aspirin, which in all prior cases of headaches induced by TMS have promptly resolved the discomfort. The risk of headache is estimated to be approximately 25%.
- Seizure: You may have a seizure induced by TMS. If seizure occurs, it will occur during the TMS application itself, not after. This is a very rare complication. Only two people have had seizures following TMS among many hundreds of thousands of subjects who have undergone TMS worldwide. Furthermore, we will use precautions to further reduce the risk. Nevertheless, a seizure may occur. Should a seizure occur, you would receive prompt treatment from a neurologist (Dr. Pundik). Experiencing a seizure induced by TMS does not mean that you will ever have another seizure. It does not make you an epileptic person, and it will not mean that you would have to take medication to prevent seizures in the future. The people who had seizures induced by TMS in the past have not had any health problems following this event that could be related to the seizure.

- Loud click: TMS produces a loud clicking sound. To prevent any discomfort you will wear earplugs during TMS.

3. Discomfort associated with the EMG test. You may or may not experience discomfort during brief electrical shocks to your arm. The investigator will use the lowest needed shock strength for the tests. The investigator performing the testing will assure that you can tolerate the testing and will stop if you request. These tests are routinely used in clinical settings and usually well tolerated.

Other potential/theoretical risks.

Although the myoelectric arm brace has been used since 2007 in both studies and clinical practice, it is possible that there may be other risks that we cannot predict.

Although the MRI and TMS tests have been used around the world extensively, there may be risks that we don't know about.

One of the potential/theoretical risks is a risk for pregnant women and an unborn fetus. Therefore, if you are a woman and capable of becoming pregnant, you must agree to use adequate birth control for the duration of the study. For the purpose of this study, adequate birth control includes one of the following: oral contraceptives (birth control pill), implanted hormonal contraceptive (Implanon, intramuscular progesterone injection), diaphragm with spermicide, condoms, intra-uterine device or abstinence.

If you believe that you have become pregnant while participating in this study, you must inform study investigators immediately. They will have you take a pregnancy test. If results show that you are pregnant, you must withdraw from the study and the study investigator will monitor your pregnancy by contacting your OB provider.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

ALTERNATIVE PROCEDURE(S) / TREATMENT(S):

If you do not wish to participate in this study, the following alternative treatments are available: standard-of-care physical and occupational therapy without a brace.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to participate. You will not lose any services, benefits or rights you would normally have if you choose not to participate.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include enhanced muscle strength and coordination and increased joint range of motion. Both lead to improved hand and arm function. In addition, the information we get from this study might help others with your condition.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices such as standard-of-care physical and occupational therapy without a brace. You may discuss these options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At

most, the website will include a summary of the results. You can search this website at any time.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, and lab results.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include; Institutional Review Board (IRB), study's sponsor (VA RR&D), Food and Drug Administration Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address: 10701 East Boulevard, Cleveland, OH 44106. B-E251. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Salameh and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked previously.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WHAT ARE THE EXPECTATIONS FROM ME IF I TAKE PART IN THIS STUDY?

If you take part of this study, you are expected to adhere to the study schedule and attend all the therapeutic and testing sessions. It is your responsibility to come to Cleveland VA Medical Center. If you are unable to have reliable transportation to and from Cleveland VA Medical Center, the research team will evaluate your case and determineif they may be able to arrange transportation service for you.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you sustain injury as a direct result of your study participation, medical care will be provided by the VA Northeast Ohio Healthcare System at no cost to you. Financial compensation for such things as lost wages, disability, or discomfort due to an injury may not be available.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

__Dr. Ahlam Salameh___ at __201-791-3800 ext. 63417___ and

AFTER HOURS:

__Dr. Ahlam Salameh___ at ___330-634-4989_____.

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to participate. You will not lose any services, benefits or rights you would normally have if you choose not to participate.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The investigators may stop your participation in this study without your consent, for example, if they think that it will be in your best interest, if you do not follow the study plan, if you experience a study-related injury, or for any other reason.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

To answer questions about the research or if you sustain a research related injury contact the following:

- During the Day: Dr. Ahlam Salameh, 216-791-3800 ext. 63417
- After Hours: Dr. Ahlam Salameh, 330-634-4989

For answers to questions about rights as a research participant or to voice a concern or complaint contact the following:

- The Research Administrative Officer at (216) 791-3800 ext. 64657
- The VA Northeast Ohio Healthcare System Patient Representative at (216) 791-3800 ext. 61700

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Institutional Review Board at (216) 791-3800 X64658 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

New findings developed during the course of the research that may affect your willingness to continue participation in this research study will be provided to you.

Participant Name: _____ Date:_____

Title of Study: Myoelectrolytically controlled device in acute rehabilitation after stroke. (Enrollment)

Principal Investigator: Dr. Ahlam Salameh, PhD, MS

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

_____has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study titled Myoelectric upper limb orthosis in rehabilitation of individuals with acute and sub-acute stroke and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.		
_____	_____	_____
Participant's Name	Participant's Signature	Date