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**UNIVERSITY OF CINCINNATI - MEDICAL**
**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

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| **STUDY TITLE:**<br><br>**ENDOLOW (Endovascular Therapy for Low NIHSS Ischemic Strokes)** | |
| **PRINCIPAL INVESTIGATOR NAME:**<br><br>**Aaron Grossman, MD** | **PHONE NUMBER (24-hour Emergency Contact)**<br><br>**(217) 390-9084** |
| **PARTICIPANT NAME:** | **DATE OF BIRTH:** |
| **Legally Authorized Representative (LAR) NAME (If applicable):** | **Legally Authorized Representative (LAR) Phone Number:** |

## KEY INFORMATION

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| **Purpose of the Study:** | Your physician has determined that you have suffered from a stroke. Stroke most commonly occurs when there is a blockage of blood flow to one of the arteries in the brain. This blockage of blood flow can result in dead brain tissue that is referred to as an infarct. When a blockage is caused by a blood clot, it is called an ischemic stroke.<br><br>The main goal of this study is to determine if patients with mild ischemic strokes that have their clot removed with a device within 8 hours do better than patients receiving only medical care.<br><br>This procedure is called a 'thrombectomy'. It is a standard treatment to reduce disability in patients who have severe strokes. It is not the standard treatment for patients with mild strokes such as yours. Participants in the study will receive standard medical treatment with or without the investigational thrombectomy procedure.<br><br>The first device that will be used in the thrombectomy procedure for this research study is called the EmboTrap® device, and it is used to remove the blood clot in your brain and to help restore the blood flow to your brain. The EmboTrap® device has been cleared for use United States. The FDA's instructions for use are provided below:<br><br>"The EmboTrap® Revascularization Device is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment."<br><br>This study is trying to see if removing the clot with the EmboTrap® will reduce disability in patients with a low stroke scale. This is the reason why this is being consider a study. The device has also been given a CE mark in Europe. |
| **Length of the Study:** | Your participation in this study will last about 3 months from the time of your stroke. |

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| **Risks:** | There may be side effects from the study procedures that are not known at this time. It is also possible that your symptoms may get worse or you could die.<br><br>When randomized to the standard medical care treatment group, there are no additional risks or discomforts that are not associated with stroke and being admitted to the hospital.<br><br>When randomized to the thrombectomy group, the risks associated with procedure are the same risks if receiving the procedure outside of the study. The most common risks and discomforts of being randomized to the thrombectomy group are:<br>• Bleeding or bruising at the top of the thigh where the physician enters the artery in your leg.<br>• Headache / pain during the procedure |
| **Benefits of the Study:** | No benefit is guaranteed. You may experience either no improvement or a worsening of your condition. |
| **Alternative procedures:** | If you decide not to enter this study, You will be provided the established standard treatment for stroke whether you take part in the study or not. This usually includes heart monitoring, physical therapy, or speech therapy. |

## INTRODUCTION:

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. Your participation in this study is entirely voluntary. If you decide to participate, you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

If you are acting as a representative to give consent for another person to participate in this study, "you" throughout this consent form refers to that individual.

The obligation of a representative is to try to determine what the individual would do if competent, or if the subject's wishes cannot be determined, what the representative thinks is in the person's best interest. If possible, an attempt should be made to obtain permission from the individual. Some persons may resist participating in a research protocol that has been approved by their representatives. Under no circumstances may individuals be forced to participate.

## WHY IS THIS RESEARCH BEING DONE?

The main goal of this study is to compare patients with a mild stroke undergoing the thrombectomy procedure within 8 hours to patient receiving only medical care. The researchers will determine if patients who have had the thrombectomy have less disability and better recovery from the stroke than patients who have standard medical care alone.

## WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are 18 years of age or older and you have been diagnosed with a stroke.

## HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately 3 months.

The researcher may decide to take you off this research study at any time.

There are many reasons why the researchers may need to end your participation in the study.
Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first so that stopping can be done safely. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

If you withdraw, the data collected to the point of withdrawal will remain part of the study data and may not be removed. You may be asked whether you wish to provide further data collection from your routine medical care.

You may be contacted in the future by representatives of the University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes only.

## WHO IS CONDUCTING THE RESEARCH STUDY?

This study is sponsored by Emory University.

The Study is funded by Cerenovus /Johnson and Johnson.

The study is being conducted by Dr. Aaron Grossman at The University of Cincinnati.

Medical supervision for the study is provided by Dr. Aaron Grossman at The University of Cincinnati.

## HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About a total of *200* people will take part across the country *and about 10 people here at The University of Cincinnati.*

## WHAT IS INVOLVED IN THE RESEARCH STUDY?

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group completely by chance. It is like flipping a coin.

You will have the following tests and procedures:

**Group 1** will be treated with standard medical treatment alone such as Aspirin, treatment of your blood pressure and cholesterol to prevent future strokes, and rehabilitation.

**Group 2** will be treated with endovascular thrombectomy (removing a blood clot from a blood vessel in your brain) using the EmboTrap® device plus medical treatment. This includes normal care such as treatment with Aspirin, treatment of your blood pressure and cholesterol to prevent future strokes, and rehabilitation. The EmboTrap® device an investigational device. It is only approved by the FDA for use in this research study. If this device does not work, devices that are FDA approved for treatment will be used.
If you agree to take part in the study, your study doctor will evaluate your stroke symptoms, obtain your medical history and perform a physical exam, including neurological exam. You will have a computed tomography scan (CT scan) performed. A CT scan is a test that produces an image of your body using a small amount of radiation. The image shows the body tissues and structure in three dimensions (“3-D”).

To avoid double testing, results of tests done as part of your standard medical care may be used for study documentation.

If you are a female of childbearing potential, a blood or urine pregnancy test may be done. If you are known to be pregnant you will not be allowed to participate in this study.

If your doctor determines that you qualify for the study and you agree to participate, you will be randomly assigned to one of two groups like flipping a coin. You have an equal (50/50) chance of being assigned to either group.

If you are selected to get routine medical treatment alone, you will receive the usual care and treatment for your condition.

If you are randomly assigned to get treatment with the EmboTrap® device, you will have a cerebral angiogram. This test requires a needle stick to your groin area and dye injected to take pictures of your blood vessel. The EmboTrap® device will be used first to try and grab the blood clot that is blocking the blood flow in your brain and remove it from your body. If the EmboTrap® device does not remove the blood clot completely, you may be treated with other established treatments as determined by your doctor.

You will have two follow-up study visits while you are in the hospital. These happen at 1-2 days and 5-7 days. You will also have two follow-up visits after you leave the hospital. These visits include a short phone call at 30 days and clinic visit at 90 days after you joined the study.

- Within 1-2 days after starting the study, your doctors will order either a CT scan of your brain or an MRI of your brain. This will be determined by the doctors taking care of you. The study will collect this information to look at your stroke recovery.
- 5-7 days after starting the study or hospital discharge (whichever comes first) you will have a test of your stroke symptoms and a test of your stroke recovery. Your appointment for the Day 30 visit will be scheduled at this time.
- Approximately 30 days after starting the study, a member of the study team will call you to check on your stoke recovery. If not already scheduled, your appointment for the Day 90 visit will be scheduled at this time.
- Approximately 90 days (3 months) after starting the study, you will be seen in the clinic for a test of your stroke symptoms and a test of you stoke recovery. This will be your final study visit.

Research will take place at University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC.

Your CT, MR or MRA will be interpreted by a radiologist, placed into your medical record, and used for diagnostic purposes, clinical purposes, and/or to guide your medical care.

## WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Anytime someone has a stroke and is admitted to the hospital, there is a risk that their stroke symptoms could get worse or they could die. In addition, patients could develop an infection or complication in the hospital. These risks are not related to the study.

When randomized to the standard medical care treatment group, the risks above apply. If your symptoms worsen, your doctor may still be able to offer you the thrombectomy procedure as standard stroke care. There are no additional risks or discomforts.

When randomized to the thrombectomy group, the risks associated with procedure are the same risks as if receiving the procedure outside of the study.

The most common risks and discomforts of being randomized to the thrombectomy group are:

- Bleeding or bruising at the top of the thigh where the physician enters the artery in your leg.
- Headache / pain during the procedure

The less common risks and discomforts of being randomized to the thrombectomy group are:

- Infection (at the top of the thigh, or in the blood stream)
- A blood vessel could be damaged (irritated, torn or punctured), causing bleeding, narrowing or blockage of that vessel, or causing an outpouching along the vessel wall (called a pseudoaneurysm).
- Damage to the leg from a clot in an artery of the leg, requiring an additional procedure to remove that clot.
- A new stroke that could make your symptoms worse, causing numbness or weakness, or possible loss of vision or language, or reduction in mental functioning
- Unexpected bleeding that requires surgery or blood transfusion
- Bleeding in the brain
- Risks of being under sedation or anesthesia (temporary confusion or memory loss, dizziness, shivering / feeling cold, nausea / vomiting, sore throat due to breathing tube)
- Risks of having a catheter placed in your bladder (infection, damage to the urinary system)
- Discomfort from equipment used to monitor your condition during and immediately following the procedure
- Discomfort from frequent examinations performed before, during, and after the procedure
- The device could get stuck, or break off, and need to be left in your body
- Allergic reaction to the contrast dye or the metal that the devices are made of may occur. Minor allergic reactions may include a rash or hives. A serious allergic reaction could include shortness of breath and swelling, drop in blood pressure, and even death. The contrast dye can also cause kidney injury mostly if you are diabetic or dehydrated.
- Death
- This research study involves exposure to radiation from a fluoroscopy. The total amount of radiation that you will receive in this study is about 27 mSv or 2700 mrem and is approximately

equivalent to a whole body exposure of 9 years of exposure to natural background radiation. Although radiation may cause cancer at high doses and high dose rates, public health data do not absolutely establish the occurrence of cancer following exposure to low doses and dose rates below about 100 mSv.

There are no known additional risks for patients with low stroke scale scores undergoing the thrombectomy procedure. There may be unknown or unforeseen risks associated with study participation.

## WHAT ARE THE REPRODUCTION RISKS?

If you are a woman: to protect against possible side effects of the study procedure, women who are known to be pregnant or nursing a child may not take part in this study.

## ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

You may experience either no improvement or a worsening of your condition.

Currently, there are limited treatments for ischemic stroke. The information collected from this study may help develop an effective treatment for other people experiencing an acute stroke. The information from this study will help doctors learn more about the use of the EmboTrap® device.

## WHAT OTHER CHOICES FOR CARE ARE THERE?

If you decide not to enter this study, there is care available to you outside of this research study. You will be provided the established standard treatment for stroke whether you take part in the study or not. This usually includes heart monitoring, physical therapy, or speech therapy. If your paralysis persists, every effort will be made to place you into an appropriate rehabilitation facility.

All of this will be done whether or not you choose to participate in this study. The study doctor will discuss these with you. You do not have to be in this study to be treated for ischemic stroke.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

There may be other drugs that could be prescribed for your stroke. Ask your physician.

## WHAT IS THE CLINICAL TRIALS REGISTRY?

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 results. You can search this Website at any time.

## AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

## WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

The study sponsor does not plan to pay for any items or services that you may receive if you take part in this study.

You will have to pay for the items or services that are part of this study. The sponsor will not pay for your regular medical care. If you have insurance, University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC will submit claims to your insurance for items and services that are part of this study.

You or your insurance company will have to pay for all costs related to the investigational thrombectomy procedure.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC and the sponsor will not pay for these costs.

If you do not have insurance, University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC will review your case as part of its

program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

## WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will not be paid for being in this study.

## WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

In the event that you become ill or injured from participating in this research study, emergency medical care will be provided to you. University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC will decide on a case by case basis whether to reimburse you for your out of pocket health care expenses.

## WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have, nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

## HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your medical and research records related to this study. Agents of the United States Food and Drug Administration (FDA) if the study involves articles regulated by this agency, the University of Cincinnati, and the sponsoring company, University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC. The monitor, the auditor, the Institutional Review Board (IRB), and other regulatory authority(ies*)* will be granted direct access to your original medical and research records for verification of clinical trial (research study) procedures or study data without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this consent form, you or your legally authorized representative are authorizing such access. The data from the

study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law. Your private health information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

## Authorization to Use and Disclose Health Information

A federal regulation known as the Privacy Rule requires that the researchers get your written permission to use your health care information in this research study. If you sign this form, you are giving your authorization for the use and disclosure of your health information for research purposes. You do not have to give this authorization. If you do not give your authorization you cannot be in the research study. However, if you are being treated as a patient here, you will still be able to receive care.

### Who Will Use and Disclose My Health Information?

The study doctor and research staff (the study team) may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication without your permission.

### What Health Information will be Used and Disclosed?

The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms. The study team will send the completed study forms to the study sponsor. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

**Who Will Receive My Health Information?** Your study information or medical records (as described above) or both may be shared with the following people or groups:

- The study sponsor or its representatives, including companies it hires to provide study-related services:
  - Data Coordinating Center: University of Cincinnati, Children's Hospital Medical Center
  - Clinical Coordinating Center: Emory University
  - Data and Safety Monitoring Board
  - Imaging Core Lab: University of Cincinnati
- Researchers who are conducting this study at other study centers
- UC Institutional Review Board and any other committees responsible for overseeing the

research
- Staff of the UC Human Research Protection Program
- University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC. employees providing service or care to you
- Federal and State agencies, such as the U.S. Food and Drug Administration
- (FDA), Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and other US and non-US government bodies that oversee or review research

**Will My Information be protected by the Privacy Rule After it is disclosed to others?**
University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC. required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about drugs, devices or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services.

**What Happens if I Leave the Study Early?** If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

**Will My Authorization Ever Expire?** This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

**May I Take Back My Authorization?** You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this form. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

**May I Look At My Study Information?** You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

Information that could identify you will be removed from the study data. The study data will not be used or shared for future research studies.

## WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, complaints and/or suggestions about this research study or to report a research-related injury, please contact Dr. Aaron Grossman at (*217) 390-3054*.

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

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| **STUDY TITLE:**<br><br>**ENDOLOW (Endovascular Therapy for Low NIHSS Ischemic Strokes)** | |
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| **PRINCIPAL INVESTIGATOR NAME:**<br><br>**Aaron Grossman, MD** | **PHONE NUMBER (24-hour Emergency Contact)**<br><br>**(217) 390-3054** |
| **PARTICIPANT NAME:** | **DATE OF BIRTH:** |

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.

_____

Signature of Participant Date

_____

Print Name

Or

_____

Signature of Legally Authorized Representative Date

_____ _____

Print Name Relationship to Participant

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to

him or her in non-technical terms all of the information contained in this informed consent from, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____

Signature of Person Obtaining Consent Date

_____

Print Name

WITNESS STATEMENT:

The participant was unable to read or sign this consent document because of the following reason:
___The participant is illiterate
___The participant is visually impaired
___The participant is physically unable to sign the consent document. Please describe:

_____

___Other (please specify):

_____
_____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____ _____

(Date) (Printed Name of Witness)

_____

(Signature of Witness)

_____ _____

(Date) (Printed Name of Individual Obtaining Consent)

_____

(Signature of Individual Obtaining Consent)