Consent Form

ACCESS to the cardiac catheterization laboratory in patients without ST-segment elevation myocardial infarction resuscitated from out-of-hospital ventricular fibrillation cardiac arrest (The ACCESS Trial)

Researcher Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Financial Interest Disclosure:

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:
Your doctor, who is also responsible for this research study, 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.

What is research?

Doctors and researchers are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Researchers learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of treatment is to help you get better or to improve your quality of life. Doctors can make changes to your treatment plan as needed.

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 had an out-of-hospital ventricular fibrillation cardiac arrest (an irregular heart rhythm that does not pump blood). This research study is being conducted to see which of two standard treatments has increased survival with good neurological outcomes for patients with out-of-hospital ventricular fibrillation cardiac arrest.

Normally, members of the research team ask for permission (consent) before a person can enter a study. Because a cardiac arrest made you unconscious, the study team could not explain the study to you or get your consent. In place of asking you for consent, we will ask your legally authorized

representative (LAR),usually a family member, to consider your wishes (whether you would want to enter the study or not) or if they do not know what your wishes would be, what they think is in your best interest.

Since the study treatment needs to be started quickly in order to be effective, your LAR must be available within 45 minutes of your arrival for us to have time to ask their permission. In cases where your LAR is not available within 45 minutes of your arrival, we will include you in the study using a Department of Health and Human Services (HHS) approved process for emergency situations called Exception from Informed Consent (EFIC).

As part of the FDA's requirements for an EFIC study, we will continue our efforts to get consent from your LAR, even after we have included you in the study. If they disagree with your participation, we will immediately stop the study.

In order for you/your LAR to be able to decide if you want to participate/continue to participate in this study, you should understand enough about its risks, benefits, and alternatives to make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits, risks, and alternatives of this study.

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?

Patients who are known to have a clot in their heart arteries are taken to the "cardiac cath lab" in order to have an invasive procedure (called "catheterization") to remove the clot and restore blood flow to their heart. Patients are known to have a clot if there are certain signs on their electrocardiogram (ECG). However, previous research has shown that patients that have an out-of-hospital cardiac arrest due to ventricular fibrillation (an irregular heart rhythm that does not pump blood) may be likely to have a clot in their heart arteries but not have signs of a clot on their ECG.

There are currently two standard treatments for these out-of-hospital ventricular fibrillation cardiac arrest patients once they are brought to the hospital:

Standard treatment option 1: Initial transport to the cath lab

Standard treatment option 2: Initial transport to the Intensive Care Unit (ICU) for consultation by a cardiologist who will then make a decision whether or not to transport to the cath lab

There are benefits and risks to both of these treatments. The benefit of option 1 is that if the patient does have a clot, they may have it removed more quickly. However, there is an increased risk of having catheterization (a procedure that has risks of its own) performed without having an actual clot in the heart arteries. The benefit of option 2 is that a cardiologist determines if it is more likely that the patient has a clot before having catheterization performed. However, there is an increased risk of delayed

catheterization to remove a potential clot in the heart arteries, if one is present.

We currently do not know which of these standard treatments has increased survival with good neurological function for patients with out-of-hospital ventricular fibrillation cardiac arrest who do not have signs of a clot on their ECG. The purpose of this research study is to determine if more of these patients do better if initially transported to the cath lab or initially transported to the ICU for consultation by a cardiologist.

We don't know if this study will help you. Your condition may get better but it could stay the same or even get worse. We hope the information from this study will help us develop a better treatment for out-of-hospital ventricular fibrillation cardiac arrest in the future.

How long will the research last?

We expect that you will be in this research study until a 3 month follow-up phone interview is completed.

How many people will be studied?

We expect about 200 people here will be in this research study out of 520 people in the entire study nationally.

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

Because no one knows which of these standard treatment options is best, you will be "randomized" into one of two study groups. One group will be initially transported to the cath lab and the other group will be initially transported to the ICU. Randomization means that you are put into a group by chance. As the trial continues, subjects will have an increased chance to be randomized to the group that shows an increase in favorable outcomes. Neither you nor the study doctor can choose what group you will be in.

Research study groups
Standard treatment option 1: Initial transport to the cath lab
Standard treatment option 2: Initial transport to the Intensive Care Unit (ICU) for consultation by a cardiologist who will then make a decision whether or not to transport to the cath lab

Summary of Study Procedures:

- Data collection: The research team will collect information from your medical record including medical history, major surgeries/procedures, ECGs, labs, and x-ray reports from the time of your cardiac arrest until you are discharged from the hospital.
- 3-month follow-up phone call: You will be contacted by a member of the research staff 3 months after you leave the hospital to participate in a telephone interview. In this interview, we will ask you a series of questions to find out how you are doing. This telephone call will take about 1 hour.

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

If you take part in this research, you will be responsible to: Provide a phone interview with the study team at 3 months.

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

Instead of being in this research study you will continue to receive regular medical care. The treating doctor will discuss the options available to you.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time. Leaving will not be held against you.

If you decide to leave the research, contact the investigator and/or research team. You will continue to receive your regular medical care.

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. This means 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 information about you may not be removed from the study database.

What are the risks of being in this study? Is there any way being in this study could be bad for me?

There are risks to taking part in any research study. There is a risk that you may get a treatment that does not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet from either treatment. If we learn about new important side effects, we will tell you.

We watch everyone in the study for problems (side effects). **You need to tell the study doctor or a member of the study team immediately if you experience any problems, side effects, or changes in your health.** If you feel that you are experiencing any side effects or have suffered a research related injury, notify your doctor or nurse immediately and have them contact a member of the research team at 612-626-6237.

Risks of Both Treatments

Both of the standard treatments for this study may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.

Risks common to both treatments are infection, damage to the liver, damage to the heart with low blood pressure, damage to multiple organs in the body, seizures, repeated cardiac arrest, survival to hospital discharge with decreased function, and death.

Risks associated with catheterization are heart attack (caused by the catheterization), stroke (caused by the catheterization), injury to the catheterized artery, tear in the heart or heart artery, fluid or blood around the heart, bleeding requiring blood transfusion, kidney damage (caused by contrast dye), and death (as a direct complication of catheterization). The risks of these complications generally occur less than 1 out of 100 times.

Standard treatment option 1 (Initial transport to the cath lab) have an increased risk of having catheterization performed without having an actual clot in their heart arteries.

Standard treatment option 2 (Initial transport to the ICU) have an increased risk of delayed catheterization to remove a potential clot in their heart arteries.

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

Will it cost me anything to participate in this research study?

Both treatments for this study are considered standard of care for your situation and thus would be recommended regardless of your decision to participate in the study. These costs will be billed to you or your insurance carrier. As part of this study no additional test or procedures will be done outside of standard medical care.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you. Your condition may get better, but it could stay the same or even get worse. However, we hope the information from this study will help us develop treatment that has increased survival with good neurological outcomes for out-of-hospital ventricular fibrillation cardiac arrest.

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 privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the National Institute of Health, the US Food and the Department of Health and Human Services (HHS) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at 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.

Who do I contact if I have question, concerns or feedback about my experience?

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to www.irb.umn.edu/report.html. You are encouraged to contact the HRPP 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.

Will I have a chance to provide feedback after the study is over?

After the study, you might be asked to complete a survey about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey after the study is over, but you would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). See the "Who Can I Talk To?" section of this form for study team and HRPP contact information.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include the study doctor believes it is in your best interest, you do not follow study rules, or the whole study is stopped.

What else do I need to know?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Will I be compensated for my participation?

There is no payment for being in this study.

Use of Identifiable Health Information

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. 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. Please read the HIPAA Authorization form that we have provided and discussed.

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

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

Use following section if a witness will observe the consent process. e.g., participant is illiterate, participant physically unable to sign.

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

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