Consent and Authorization Document

STUDY TITLE: Serial Echocardiographic and Laboratory Assessments During Mechanical Circulatory Support

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SUMMARY: Serial Echocardiographic and Laboratory Assessments During Mechanical Circulatory Support

A person that you represent is being asked to join a research study. The research is for people who are being treated with extracorporeal membrane oxygenation (ECMO). Before you consider the research, you should be aware of the following information:

- Research is voluntary. The person you represent do not have to be in this study.
- The person you represent will get standard medical care even if you decide not to have them join the study.
- Researchers hope that examining data, such as echocardiograms and laboratory results, from adults being treated with ECMO will help clarify the best clinical outcomes and, from that, assist with developing clinical trials.
- Everyone in this study will receive standard medical treatment in addition to any extra echocardiography and laboratory assessments.
- There is no direct benefit to the person enrolled in this study, but the information we learn may benefit society.
- Please be sure all your questions are answered before you decide whether or not the person you represent should be in the study.
- If you think you want the person you represent to be in the study, you should read the rest of this document and discuss it with the study team. The document explains what will happen to people in the study.
- Risks of participating in the study are described in the document below.

_____
Subject's initials confirming discussion

READ THE FOLLOWING CAREFULLY

This form is for use in a research study that involves participants who are sedated or unconscious and being treated with ECMO and do not have the capacity to consent to take part in the study. You are the legally authorized representative of the patient. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether or not the person you represent should take part. If you decide that the person you represent should take part in this study, you must sign your name at the end of this form. Nothing can be done for this part of the research study until you sign this form.

BACKGROUND

The person you represent is being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is unclear or if you would like more information. Take time to decide whether or not you would like the person you represent to take part in this research study.

Cardiogenic shock is when your heart cannot pump enough blood to your vital organs. It is a very critical medical situation. Cardiogenic shock is sometimes treated with a form of mechanical circulatory support called extracorporeal membrane oxygenation (ECMO). ECMO is the highest form of life support, and it removes blood from the body, oxygenates it, and then returns it to the body. ECMO can save lives but it is also a very invasive and has potential consequences. The purpose of this study is to specifically look at the left ventricle of the heart while a patient is on ECMO. This is done with an ultrasound of the heart as well as with blood tests. The goal of this study is to explore changes over time in common clinical variables (like blood work and heart ultrasounds) in adults being treated with ECMO.

This study is being conducted by Joseph Tonna, M.D. at the University of Utah Hospital.

STUDY PROCEDURES

This is an observational study, meaning we will look at data points gathered during the patient's treatment, but we will not intervene in, or change, the way they are being treated. All patients enrolled in this study will undergo standard treatments and procedures associated with their care. This study is comprised of two times periods: screening and the 7-day observation (+/- 2 days for a window of 5-9 days).

Screening: All adult patients who are admitted to the hospital with cardiogenic shock and who are being treated with ECMO will be eligible for this study. After you consent to have the person you represent enroll in this study, research staff will gather information from the patient's chart, such as their demographic information and medical history.

Observation: All patients will receive standard care for their illness. For seven days after enrollment, we will collect information from the patient's medical chart regarding their ECMO settings, results of

laboratory assessments (blood work), and results of transthoracic echocardiograms, which are ultrasounds of the heart (often referred to as an "echo"). During these seven (+/- two) days, we will collect an extra vial of blood – at least once a day, and as often as every 6 hours – in order to look at biomarkers in the blood. This vial, about 5mls, will be collected at the same time as other labs and will typically be drawn using the patient's central or arterial line. Echocardiograms will be done frequently on the patient to examine their heart function. When an echo is done as standard of care (meaning, the patient's doctors are ordering it) we will simply collect the results from the patient's medical chart. On days when there is not an echo ordered as standard of care, we will order one for the study. An echo is an ultrasound and is not an invasive procedure. After the seven (+/- two) days are finished, we will use the patient's medical chart to gather data such as their outcomes and how long they were hospitalized.

RISKS
The risks of this study are minimal.

Clinical Data Collection: There is no significant procedural risks associated with review of medical records. While there is a potential risk of loss of confidentiality, appropriate measures are in place to mitigate this risk.

BENEFITS
We cannot promise any benefits to you from your being in the study. We cannot promise any benefits to you from your being in the study. The information gathered in this study could add to the knowledge regarding how to most effectively treat patients in these critical situations.

ALTERNATIVE PROCEDURES
You may choose not to participate in this study. If you do not want to take part in the study, you will be treated with all standard of care treatments available to you.

CONFIDENTIALITY
We will keep all research records that identify you private to the extent allowed by law. Records about you will be kept in locked in filing cabinets and on computers protected with passwords or encryption. Only those who work with this study or are performing their job duties for the University will be allowed access to your information.

Representatives from the study sponsor or their Agent may inspect and/or copy the records that identify you. Results of the study may be published; however, your name and other identifying information will be kept private. We will do everything we can to keep your records private, but cannot guarantee this.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, you can contact:

Principal Investigator: Joseph Tonna, MD
Research Coordinators: Chloe Skidmore, MS, or Margaret Carlson, MPH
University of Utah, Cardiothoracic Surgery
30 North 1900 East SOM 3C-127
Salt Lake City, UT 84132

Phone: 801- 581-5311 / (801) 587-6271 (during business week days 8:00AM to 4:30PM) or you may call the University Hospital operator at 801-581-2121 and have Cardiothoracic team member paged for you, 24 hours a day

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns, which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form, you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.

If you want to stop being in this study, please let the research doctor know. That way you can find out what should be done about your routine care outside of the study.

RIGHT OF INVESTIGATOR TO WITHDRAW

The investigator can withdraw you without your approval. Possible reasons for withdrawal include, but are not limited to:

- It is not in your best medical interest to continue
- The study is terminated

COSTS AND COMPENSATION TO PARTICIPANTS
All standard of care costs associated with patient treatment using ECMO will be billed to you or your insurance company in the ordinary manner. The cost for any additional (non-standard of care) blood work and echocardiograms will be covered by the study, at no cost to you. There is no compensation for participating in this study.

NUMBER OF PARTICIPANTS
We expect to enroll 60 participants at the University of Utah for this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent and authorization form.

This is the information we will use:

- Name
- Address
- Email address
- Telephone number
- Family medical history
- Allergies
- Current and past medications or therapies
- Operative reports, laboratory results, discharge and progress notes
- Any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other medical facilities
- Information from a physical examination, such as blood pressure reading, heart rate, breathing rate, temperature, and physical exam scores.
- X-ray imaging reports
- Answers to questionnaires about pain and function

Others who will have access to your information for this research project are the University's Institutional Review Board (the committee that oversees research studying people) and authorized members of the University of Utah who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research, and for accounting or billing matters).

In conducting this study, we may share your information with groups outside the University of Utah. The information we share may include information that directly identifies you. These are the groups:

- National Heart, Lung, and Blood Institute (NHLBI)
- National Institutes of Health (NIH)
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Information disclosed to groups outside the University of Utah may no longer be covered by the federal privacy protections.

You may revoke this authorization at any time. This can be done verbally or in writing**.** You must either give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to University of Utah 30 N 1900 E SOM 3C-127, Salt Lake City, UT 84132 ATTN: Dr. Tonna. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

This authorization does not have an expiration date.

CONSENT STATEMENTS

PARTICIPANT'S CONSENT (should the participant become cognizant during the study)

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. **I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

_____

Participant's Name

_____

Participant's Signature Date

_____

Name of Person Obtaining Authorization and Consent

_____

Signature of Person Obtaining Authorization and Consent Date

STATEMENT OF LEGALLY AUTHORIZED REPRESENTATIVE

I confirm that I have read this consent and authorization document. I have had the opportunity to ask questions and those questions have been answered to my satisfaction. I am willing and authorized to serve as a surrogate decision maker for

_____.
Participant's Name

I have been informed of my role and my obligation to protect the rights and welfare of the participant. I understand that my obligation as a surrogate decision maker is to try to determine what the participant would decide if the participant were able to make such decisions or, if the participant's wishes cannot be determined, what is in the participant's best interest. I will be given a signed copy of the consent and authorization form to keep.

_____
Name of Authorized Personal Representative

_____
Signature of Authorized Personal Representative Date

Indicate the legal representative's authority to act for the individual:
☐ Spouse
☐ Adult (18 years of age or over) for his or her parent
☐ Individual with power of attorney
☐ Guardian appointed to make medical decisions for individuals who are incapacitated

_____
Name of Person Obtaining Authorization and Consent

_____
Signature of Person Obtaining Authorization and Consent Date