

THE UNIVERSITY OF TEXAS



## Informed Consent

### INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Early Metabolic Resuscitation: A Potential Solution to Multi-Organ  
Dysfunction Syndrome in Septic Shock

2018-0986

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Study Chair: Diego de Villalobos

Participant's Name \_\_\_\_\_ Medical Record Number \_\_\_\_\_

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

#### STUDY SUMMARY

The goal of this clinical research study is to learn if patients in septic shock can benefit from liquid nutrition therapy when it is added to the standard of care treatment for septic shock.

**This is an investigational study.** Liquid nutrition therapy is FDA approved and commercially available. Combining liquid nutrition therapy with the standard of care therapy is investigational. The study doctor can explain how the liquid nutrition is designed to work.

Receiving liquid nutrition may help to lower the effects of septic shock in your body. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience fluid overload, electrolyte disturbances, high or low sodium, and high or low blood sugar.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

Your participation in this study will last up to 7 days. After 7 days, if you are still in the ICU you will continue to be treated for your condition but not as part of the study. You will not receive any more liquid nutrition. You may be taken off study early if intolerable side effects occur.

You and/or your insurance provider will be responsible for the liquid nutrition treatments you receive during this study.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive the standard of care treatment for septic shock only. You may choose to receive other investigational therapy, if available. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

## 1. STUDY DETAILS

### **Screening**

If you can become pregnant, you will have a urine pregnancy test. To take part in this study, you must not be pregnant.

### **Study Groups and Procedures**

If you are eligible to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one study group is better, the same, or worse than the other group.

**Group 1** will receive the current standard of care treatment that is provided to septic shock patients for 7 days.

**Group 2** will receive the standard of care treatment for septic shock and liquid nutrition therapy for up to 7 days. The liquid nutrition will be given by vein continuously during this 7-day period.

If you are in Group 2, blood (about 4 teaspoons) will be drawn on Days 1-7 to check your blood oxygen and sugar levels. These tests may help the doctor make any needed changes to your liquid nutrition therapy.

Up to 112 participants will be enrolled in this study. All will take part at MD Anderson.

## 2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any concerns you may have about the study itself or procedures during the study.

Receiving **liquid nutrition** may cause low blood sugar, high blood sugar (possible diabetes), high blood levels of sodium (possible weakness and/or swelling), and/or low blood levels of sodium (possible headache, confusion, seizures, and/or coma). It may also rarely cause allergic reactions

**Blood draws** may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

This study may involve unpredictable risks to the participants.

### **Pregnancy Related Risks**

Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant or breastfeed a baby while on this study. You must use birth control during the study if you are sexually active.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant may result in your removal from this study.

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### **3. COSTS AND COMPENSATION**

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

### **Additional Information**

4. You may ask the study chair (Dr. Diego de Villalobos, at 713-792-5040) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.
5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.
6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.
7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.
8. MD Anderson may benefit from your participation and/or what is learned in this study.

### **Future Research**

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

## **Genetic Research**

Samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment.

### **Authorization for Use and Disclosure of Protected Health Information (PHI):**

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**CONSENT/AUTHORIZATION**

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

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SIGNATURE OF PARTICIPANT

DATE

**LEGALLY AUTHORIZED REPRESENTATIVE (LAR)**

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

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SIGNATURE OF LAR

DATE

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RELATIONSHIP TO PARTICIPANT

**WITNESS TO CONSENT**

I was present during the explanation of the research to be performed under Protocol 2018-0986.

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SIGNATURE OF WITNESS TO THE VERBAL CONSENT  
PRESENTATION (OTHER THAN PHYSICIAN OR STUDY  
CHAIR)

DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

**PERSON OBTAINING CONSENT**

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

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PERSON OBTAINING CONSENT

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DATE

## **TRANSLATOR**

I have translated the above informed consent as written (without additions or subtractions) into \_\_\_\_\_ and assisted the people (Name of Language) obtaining and providing consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

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SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION  
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,  
OR STUDY CHAIR) DATE