Acetaminophen in Sepsis: Targeted Therapy to Enhance Recovery (ASTER)

Study Title: Acetaminophen in Sepsis: Targeted Therapy to Enhance Recovery (ASTER)

NCT04291508

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Part 2 of 2: STUDY SITE INFORMATION

Site Name:	<< insert name of organization>>
Site Principal Investigator:	<< insert name & credentials of responsible PI >>
Site Principal Investigator Contact:	<<insert 10-digit phone for PI>>
Mailing Address:	<< insert PI mailing address>>
Site Study Coordinator (Optional):	<<Name & credentials of alternate POC>>
Site Study Coordinator Contact:	<<insert 10-digit phone for alternate POC>>

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Costs to you if you take part in this study:

Payment in case you are injured because of this research study:

Who to call for any questions or in case you are injured:

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Additional information about your local site:

Confidentiality

The research study Coordinating Center at Massachusetts General Hospital (MGH) in Boston, MA, or the other hospitals involved in this study may share your study information with doctors or researchers using it for other research projects not listed in this form, without any recipients knowing it is related to you specifically. It is possible that other researchers involved in this study may contact you in the future regarding potential participation in other studies and/or to see how you are doing. Other hospitals involved in this study, MGH, and their staff will comply with all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information. Your personal identifiable information will not be shared, unless required by government agencies that oversee or fund research.

Certificate of Confidentiality

We have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects us and you from being forced to release study information as part of a court, legislative, administrative or other proceeding.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH, Department of Health and Human Services (DHHS) or Food and Drug Administration (FDA).

The Certificate also does not stop us from giving information to government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger. We can release some study information, such as laboratory test results, if you wish us to do so and you give permission in writing. The Certificate does not keep you from giving out information about yourself and your treatment in this study. If you would like to read the Certificate or you have any questions, please ask the study doctor or study staff.

Authorization to Use/Disclose Protected Health Information

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally.
All my questions have been answered, and I freely and voluntarily choose to take part in this study.

PARTICIPANT

Participant's Name (Print): _____

Signature (*If able to consent*): _____

Date: ___/___/____ Time: ___: ___ AM / PM

WITNESS

(If Required) Witness's Name (Print): _____

Signature: _____ Date: ___/___/____

Witness to: ❑ Discussion ❑ Signature Time:___:___ AM/PM

STUDY REPRESENTATIVE

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: ___/___/____. **Time** Consent Obtained: ___: ___ AM / PM

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits.
You will get a copy of this form after it is signed.

STATEMENT BY DECISION-MAKER /SURROGATE

SURROGATE / LAR

Legal Representative's Name (Print): _____

Relationship to Participant (Print): _____Date: ___/___/_____

Signature: _____ Time: ___: ___ AM / PM

I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ [participant's name].

I believe receiving such treatment would be in the interests of _____ [participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent.
If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

WITNESS

(If Required) Witness's Name (Print): _____

Signature: _____ Date: ___/___/____

Witness to: ❑ Discussion ❑ Signature Time: ___:___ AM/PM

STUDY REPRESENTATIVE

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: ___/___/____. **Time** Consent Obtained: ___: ___ AM / PM

CONSENT FOR GENETIC TESTING ON STORED SPECIMENS

The purpose of this part of the study is to store samples of your blood. We are looking at genetic factors (such as DNA or RNA) that may cause or relate to severe illness or other diseases.

Description of the Procedures: An extra 1 teaspoon of blood will be drawn and stored for genetic testing purposes. Whenever possible, the blood will be taken with other laboratory test samples to avoid an extra needle stick. Your blood sample will be processed and may be tested and shared for research genetic testing. The sample will be sent to a repository at the NIH. The NIH stores and distributes blood samples and associated data from people with many conditions. The purpose of sending your blood samples to the NIH is to make samples available for future research by investigators not involved in this study. Researchers who use samples from the NIH must request and receive approval to do so from the NIH and from research oversight boards at their institutions.

Confidentiality of Your Blood Samples: We will freeze your samples and store them for years for future studies. We will protect your privacy and give all samples coded study numbers. Only your hospital study team will know your coded study number identity, which will be kept secure. The stored blood samples will not contain your name or identifying information.

How Long Will the Samples Be Stored: The samples will be stored for an unknown period time (usually years). The samples may be thrown away when they are no longer needed. The results of tests run on your samples are not in your normal medical record and neither you nor your doctor will be told of the results. No one else, including relatives, doctors, or insurance companies can get the stored samples or results. Your samples will be used only for research and will not be sold or used directly to produce commercial products.

Risks: One possible risk might be the release of your name, which could link you to the stored samples and/or the results of the tests run on your samples. This could cause problems with insurance or getting a job. You are currently protected from genetic discrimination by employers or insurance companies through the Genetic Information Nondiscrimination Act (GINA 2008). To protect you from this risk we will keep the link between the samples and your personal ID as secure as possible. This link will only be kept by the local study team. The NIH repository and future researchers will not have access to any of your personal information so they will not know who you are or be able to contact you.

Benefits: You will not receive any direct benefit from your samples. Information obtained from the tests may provide useful information to help other patients about the causes, risks, and prevention of severe illness and other diseases.

Voluntary Participation/Right to Withdraw Your Permission for Genetic Testing: Your decision to join this study is completely up to you (voluntary). Your decision will not change the quality of the care you receive. You are still eligible to join the study described in the other consent form even if you do not want your blood samples stored for genetic testing. At any time, you may ask to have your samples destroyed. You should contact Dr. [PI Name] in writing to have your samples destroyed and no longer used for research. We will not be able to destroy

research data that has already been gathered using your samples. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

Costs or compensation of study: There will be no costs or compensation to you.

Commercialization: Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, [Name of Institution], and/or others. If this happens, there are no plans to provide money to you.

PARTICIPANT

Consent: Please *INITIAL* next to ***yes*** or ***no*** and **sign** your name, indicating you have freely given your answers and consent:

- ■ My blood sample may be stored for future genetic research in severe illness. Yes ___ No ___
- ■ My blood sample may be stored for future genetic research involved with other medical conditions (for example, obesity, diabetes, cancer, heart disease, Alzheimer's disease). Yes___ No___

Date: ___/___/____

_____
Signature (Subject OR Surrogate/Legally Authorized Representative) Time___: ___ AM / PM

STUDY REP

_____ _____ ___/___/____
Signature of Person Obtaining Consent *Printed Name and Title of Person* *Date*

Time___: ___ AM/PM

CONSENT FOR CONTINUED RESEARCH PARTICIPATION

You have been taking part in the research study: Acetaminophen in Sepsis: Targeted Therapy to Enhance Recovery (ASTER). Consent for your participation was obtained from your legal representative because you were unable to provide consent at that time. We are now asking for you to consent to continue being in the study. Your continued participation is entirely voluntary. If you decide not to continue in this study, it will not affect your relationship with your doctor or with [Hospital Name] and will not result in any penalty or loss of benefits to which you are otherwise entitled.

STATEMENT OF VOLUNTARY CONSENT

I have read this form and the attached consent or have had them read to me. I have been told what to expect if I take part in this study, including risks and possible benefits. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to continue to be in this research study.

Consent: Please *INITIAL* next to ***yes*** or ***no*** and **sign** your name, indicating you have freely given your answers and consent:

PARTICIPANT

Participant's Name (Print): _____

Signature: _____ **Date**: ___/___/____

Time: ___: ___ AM / PM

- ■ My blood sample may be stored for future genetic research in severe illness _____YES/____NO
- ■ My blood sample may be stored for future genetic research involved with other medical conditions (for example, obesity, diabetes, cancer, heart disease, Alzheimer's disease). ____YES/ _____NO

WITNESS

(If Required) Witness's Name (Print): _____

Signature: _____ Date: ___/___/___

Witness to: ❑ Discussion ❑ Signature Time: ___: ___ AM / PM

STUDY REPRESENTATIVE

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: ___/___/____ **Time** Consent Obtained: ___ : ___AM / PM

You will receive a copy of this form after it has been signed and dated