Consent and Authorization Form

Principal Investigator: Adit Ginde, MD, MPH
COMIRB No: 23-2559
Version Date: 30-SEP-2024
Study Title: An tibiotic Co ncentrations after Ma ssiv E transfusion (ACME)

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Some people in this study may have a medical condition or disability that does not allow them to make important decisions for themselves. If you have been asked to decide for someone else whether they should participate in this study, please read this consent form carefully. In this form, we use the words "you" and "your." If you are reading this form and deciding for someone else, the words "you" and "your" refer to that other person, not to you.

Why is this study being done?

This study plans to learn more about how antibiotic concentrations are impacted by the transfusing of blood products. Doctors and researchers think that transfusing blood products may impact antibiotic concentrations in the blood, but no one knows for sure. Our hypothesis is that antibiotic concentrations are reduced in direct relationship to the volume of blood transfused. We hope to help patients get better faster after a traumatic injury. Getting better faster includes getting off supportive ices and going home from the hospital.

COMIRB
APPROVED For Use
03-Oct-2024 11-Apr-2025

You are being asked to be in this research study because you experienced a traumatic injury and are being treated in the hospital. This document has details that you should consider before you decide to join. When this document is signed, it confirms our promises to you and gives us your permission for the project team to obtain and use your samples and your protected health information.

This is a prospective cohort study. Prospective means you will be followed for the duration of the study (24 hours). Cohort indicates a group of patients, including you, who will participate. This study is NOT a clinical trial, and you will not receive any drug, treatment, or intervention related to this study. The study team will monitor your clinical information through the electronic health record and measure data from blood draws.

Other people in this study

Up to *208* people from your area will participate in the study.

Up to *416* people around the country will be in the study.

What happens if I join this study?

If you join the study, you will receive standard medical treatments for your injury. Your treatment will not be altered or changed in any way by participating in this study.

If you consent to this study, you will be asked to provide up to 6 milliliters (just over 1 teaspoon) of blood specifically for research that will not be used for your medical care. Blood draws will occur six times

during the first 18 hours of your hospitalization. If you leave the hospital before 18 hours, you will not be asked to provide additional blood samples. We will make a reasonable effort to draw blood from your intravenous or arterial access. If this is not possible, we will obtain blood by placing a small needle in your arm, the standard procedure for blood draws at UCH. We will obtain a total of ~one teaspoon of blood throughout this study. Your samples will be collected and frozen at -80 degrees Celsius to preserve their integrity for research and will be discarded at the completion of study.

Additionally, the study team will access and collect data related to this study from your medical record throughout the course of your participation for 7 days or until you leave the hospital, whichever comes first. The study team will check on you while you are in the hospital.

We may have obtained some of the blood samples before approaching you for consent. Because of the emergent nature of your condition, we must often delay the informed consent process. You have the choice to consent to participate in the remainder of the study or decline participation.

What are the possible discomforts or risks?

Risks that have been identified for this study are no more than those of routine clinical care. Discomforts you may experience while in this study include pain, redness, soreness, bruising, or infection may occur at the needle stick site due to the blood draw. Rarely, some people faint.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

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What are the possible benefits of the study?

This study is designed for the researcher to learn more about antibiotic concentrations in trauma patients and how they are impacted by blood transfusion. We will also learn more about how trauma patients can become sick for reasons other than their initial injury. Possible benefits to science and humankind may result from this study.

This study is not designed to treat any illness or to improve your health.

Who is paying for this study?

This research is being sponsored by the Department of Defense (DOD), Congressionally Directed Medical Research Program through The Metis Foundation.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

You will not be charged for any of the study procedures or office visits for the study.

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Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you choose to participate in this study, you can stop at any time. If you decide to withdraw later, you will not lose any benefits or rights to which you are entitled. Leaving the study will not affect your medical care in any way.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call the primary contact, Adit Ginde, MD, MPH, immediately. His phone number is (720)848-0397.

We will arrange to get you to medical care if you have an injury caused by research. However, you or your insurance company must pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Adit Ginde. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Adit Ginde at (720)848-0397. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Adit Ginde with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Adit Ginde, MD, MPH
University of Colorado Department of Emergency Medicine
12401 East 17th Avenue, B215
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research •

The study doctor and the rest of the study team.

- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.
- The Department of Defense (DOD)

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study: • Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.) • Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results.

- Research Visit and Research Test records.

What happens to Data, Tissue, Blood and Specimens that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to research. If you join this study:

- The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.

- Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you. • There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

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HIPAA Authorization for Optional Additional Study Procedures

There are no optional additional research procedures. Your samples will be destroyed at the conclusion of this study.

Agreement to be in this study and use my data

I have read this paper about the study, or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: Date:_____Print Name:

Consent form explained by:_____ Date:

Print Name:_____

----------Use the following only if applicable----------

Signature: Date:_(*Legally Authorized Representative*)

Print Name:_____

[**If Applicable**, add Signature Line for witness; required for consent of non-reading subjects and consent using a short form]

----------Use the following only if applicable---------- **A signature of a witness is required for consent of non-reading subjects and consent using a short form.**

Witness Signature: _____ Date:_Print

Name:_

Witness of Signature

Witness of consent process