Official Title:	Trauma Study: Early Warning of Progression Toward Hemodynamic Deterioration After Trauma
NCT number:	NCT04912232
Document Type:	Informed Consent Form
Date of the Document:	10/13/2022 (ICF) IRB approval Date 08/05/2022 Document Version date

Title of research study: Continued Development of a Multiplex Precision Medicine System for Early Warning of Progression Toward Hemodynamic Deterioration After Trauma

Study Sponsor: Dartmouth-Hitchcock Medical Center

Investigator: Dr. Howard Smithline

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have experienced a traumatic event such as a fall, car accident, etc.

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.
- You will receive the same standard of care if you do or do not participate in this study

Why is this research being done?

The purpose of this research study is to collect information using a new medical device that has electrodes which will be placed on your skin for the duration of your stay in the emergency department (ED). You will have small stickers placed on your chest, arm, and leg that will connect to the study device. You will wear these stickers for up to 6 hours, or until you are discharged home or admitted to the hospital. Participating in this study will not change the standard of care you will receive.

How long will the research last and what will I need to do?

We expect that you will be in this research study for up to six (6) hours or until you are discharged home or admitted to the hospital.

You will be asked to limit movement while the electrodes are in place. We ask that you walk around or move in your bed as little as possible to reduce the risk of electrodes becoming displaced or experiencing interference.

Participation in this study is voluntary and completely up to you. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Conflict of Interest: Dr. Smithline is being paid by Dartmouth-Hitchcock Medical Center for his work on this project.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

You may not want to be in this study if you are uncomfortable with:

- Wearing the study device, or if you have an allergy to the sticker adhesive
- Sharing your private information with researchers

Risks: There are minimal risks to having electrodes on the skin. There may be some minor irritation from the adhesive which will resolve once the pads are removed. We do not know of any serious risks currently. As with any research study, there may be other risks that are not known at this time.

We will take steps to protect your personal information. However, there is a risk of breach of confidentiality.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me or harm me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include helping us gain knowledge that may help diagnose and treat trauma patients more quickly in the future.

Will being in the study cost me anything?

Clinical services provided during a research study are either research-related or related to usual medical care. Research-related services are not the responsibility of you or your insurance. The procedures or items that are considered research-related in this study include the following: the device and *wearing the study device.*

Usual medical care costs include those services that are considered medically necessary to manage your condition. The costs of usual medical care will be the responsibility of you or your insurance and may include deductibles and co-payments. Although unusual, some insurance companies will not pay for usual medical care if you are participating in a research study.

Will you share results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

We can share your individual results with you if you ask. However, because these are researchtests, they are for your interest only. They cannot tell you about your health or diagnose any condition.

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

Participation in research is completely voluntary. You can decide to participate or not to participate. Whether you decide to participate or not, your treatment and care will remain the same.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

How many people will be in this study?

We expect about 480 people here will be in this research study

What happens if I say yes, I want to be in this research study?

If you are found eligible for this study, you will be asked to wear the experimental study device electrodes for no more than 6 hours. The following sensors and monitors will have electrodes that will be placed on your skin, and we will collect its data for our research purposes. If you have a lot of chest hair, we will ask to shave the areas where the electrodes will be placed.

1. ECG
2. Plethysmography
3. O2 Saturation
4. EIT –16 electrodes per location will be placed on your chest across the nipple line, and another will be placed on either your upper abdomen or thigh.
5. EIS – Your torso, chest and arm will have four electrodes each placed on them
6. NIRS – Sensors will be placed on your upper arm, thigh, and chest

Patient identifying information will be removed from this data and the de-identified information may be used for future research without additional informed consent.

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

Your responsibilities as a person taking part in this study

(1) Notify the research team immediately if you suffer any injury or unexpected reaction to the equipment adhesives.
(2) Make reasonable efforts to follow the instructions of the research team.

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

You can leave the research at any time it will not be held against you and your standard care will remain the same. The data collected during your participation will still be used as part of the research.

Is there a possibility being in this study could be bad for me or harm me? (Detailed Risks)

The electrode adhesives used in this study are standard, medical grade, hypoallergenic adhesives. You may still have an allergic reaction or sensitivity that can cause a localized rash or itchiness where the electrodes have been placed.

We will take steps to protect your personal information. However, there is a risk of breach of confidentiality. Any paperwork with your information on it, including this consent form, will be kept in a locked file cabinet in a locked office that only research staff have access to. All of the data being collected by the study device will have all identifiers removed.

This study is federally funded by the Department of Defense and compensation for a research-related injury or illness is not provided by federal law.

If you are injured or become ill as a result of research procedures, you will be provided with medical treatment, but the following organizations do not plan to pay for this treatment.

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College
- U.S. Department of Defense
- Baystate Health, Inc.
- Baystate Medical Center and its affiliates

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 653-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

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 secrecy. Organizations that may inspect and copy your information include the IRB and other affiliates of this organization:

- U.S. Department of Defense
- Baystate Medical and its affiliates
- Food and Drug Administration

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

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.

Federal law provides additional protections of your medical records and related health information. By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this

study at Dartmouth-Hitchcock Medical Center and elsewhere. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Dartmouth-Hitchcock Institutional Review Board (D-H IRB)
- U.S. Department of Defense
- Food and Drug Administration
- Baystate Health, Inc.
- Baystate Medical Center and its affiliates

No publication or public presentation about the research described above will reveal your identity without authorization from you.

Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes.

What else do I need to know?

This research is being funded by the Department of Defense.

Information about the privacy of protected health information

Baystate Health has rules in place to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you that may be collected in this study and who might see or use it.

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form. We may be required by law to report some information (for example, certain infectious diseases, suspected abuse) to a state agency for public health or safety reasons.

The people working on the study will collect information about you. This includes things learned from the procedures described in this consent form and may include information fromyour medical record if needed for the study. They may collect other information including your name, address, date of birth, and other details.

The research team will need to see your information. Sometimes other people at Baystate may see or give out your information. These include people who review the research studies, their staff, administrative personnel, or other Baystate staff.

The fact that you are taking part in this study and information from procedures (such as lab tests) that are done for the research may become part of your medical record.

If we publish information from this research study or use it for teaching, your name will not be used.

People outside of Baystate may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), organizations that accredit hospitals and research programs, study monitors, other hospitals in the study, and companiesthat sponsor the study.

We cannot do this study without your permission to 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 use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside of Baystate who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

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 contacting the Principal Investigator of this study. The Principal Investigator can be reached at:

Howard Smithline, MD

759 Chestnut St, Springfield MA 01199

413-794-8960

If you send a letter, please be sure to include the study name and your contact information.

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.

You can ask to see your research records, but sometimes that can only happen after the research is completed. If you would like to see your research records, please discuss this withyour study doctor or a member of the research team.

Who do you contact if you have study questions or concerns?

If you have any questions about this study, please contact: *Jillian Tozloski at 413-794-4313.* If you experience a complication or injury that you believe may be related to this study, please contact: Dr. Smithline at *413-794-8960.* After hours, please call the operator at 413-794-0000.Ask for Dr. Smithline to be paged with your contact information and he will get in touch with you as soon as he is able.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	