Beth Israel Deaconess Medical Center

FOR CCI USE ONLY
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 9/10/18

Protocol Number: 2017P-000436

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
09/09/2019
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Vitamin C, Steroids, and Thiamine in Sepsis and Septic Shock
PRINCIPAL INVESTIGATOR: Michael Donnino, MD (BIDMC) **SITE PRINCIPAL INVESTIGATOR: PETER HOU MD (BWH)**
PROTOCOL NUMBER: 2017P-000436

INTRODUCTION:

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center (BIDMC) or Brigham and Women's Hospital (BWH).

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records. Please keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC [Beth Israel Deaconess Medical Center], BWH [Brigham and Women's Hospital] AND INVESTIGATORS

This study is being conducted by Dr. Michael Donnino and Dr. Peter Hou. This study is funded by the Good Ventures Foundation (Open Philanthropy Project). The funding agency in this study, Good Ventures Foundation (Open Philanthropy Project), is paying Beth Israel Deaconess Medical Center to perform this research. Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Dr. Donnino, and Dr. Hou have no additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you are signing this consent at BIDMC and have any questions, concerns or complaints about this

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: VITAMIN C, STEROIDS, AND THIAMINE IN SEPSIS AND SEPTIC SHOCK
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PROTOCOL #: 2017P-000436

research or experience any problems, you should contact Dr. Donnino at [617] 754-2341. You can also call the ED Research Team at [617] 754-2882 with questions about this research study.

If you are signing this consent at Brigham and Women's Hospital, please contact Peter Hou, MD at (617) 732-6062, Monday – Friday 9 am-5 pm or he can be reached 24/7 via the hospital page operator by dialing (617) 732-5500 and ask to have him paged.

PURPOSE

We are conducting this study to see the effects of Vitamin C, Hydrocortisone and Thiamine administered together on organ injury in people with severe infections. We want to determine if these drugs administered together will be helpful for people with severe infections.

Vitamin C and Vitamin B1 (also called Thiamine) are vitamins which are essential for the function of the cells in your body. Without adequate Vitamin C and Thiamine, certain aspects of energy production would not take place properly. Hydrocortisone is a corticosteroid (a naturally occurring compound in your body) that is commonly used for the treatment of patients with low blood pressure caused by severe infections.

Recent studies have shown that patients with serious infections often have low levels of Thiamine and Vitamin C in their body. In addition, there is some evidence that giving Thiamine to animals with septic shock improves energy production, even in those who are not deficient. Further there is evidence that Vitamin C administered together with Hydrocortisone and Thiamine may improve survival in patients with severe infection.

STUDY PARTICIPANTS

You have been asked to be in the study because you have a serious infection, called Sepsis. Sepsis is a severe infection that causes low blood pressure and critical illness. This is a very serious condition that even with treatment can lead to organ dysfunction and even death.

Approximately 60 people will take part in this study at Beth Israel Deaconess Medical Center and 20 will participate at Brigham and Women's Hospital. A total of 200 people will take part in this study at all study sites.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the

SUBJECT'S NAME:
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PROTOCOL #: 2017P-000436

screening procedure will be a review of your medical record to see if you qualify for the study.

If you are a female aged <45 years, we will ensure that you have had a negative blood or urine pregnancy test performed as part of your care. This will generally be done as part of usual care.

2. Randomization Procedures: You will be randomly assigned (like the flip of a coin) to receive either Vitamin C, Hydrocortisone, and Thiamine or a Placebo. You have a 1 in 2 chance of receiving either the drugs or the placebo. You will not be able to choose the study group to which you will be assigned.

   If one treatment arm is found to be less effective then the other while you are taking part in the study, you will be informed and further treatment will be discussed.

   Depending upon the group to which you are assigned, you may receive a placebo instead of the study drugs. A placebo is an inactive substance that looks like the study drug, but a placebo contains no active medication. Placebos are used to help determine if the results of the study are truly from the study drug. The placebo used in this study will be an intravenous (IV) infusion of 0.9% Sodium Chloride. This is a solution of sodium chloride in water (salt water). You will not know whether you will be receiving the study drug or the placebo. However, this information can be learned in case of an emergency.

3. Research Procedures: Your chart will be reviewed to assure that you are appropriate for inclusion in the study. If you qualify to take part in this research study and you choose to participate you will undergo these research procedures:

   - A blood draw right after you sign the consent to examine chemicals in your blood which tell us something about how it is responding to an infection. We will draw no more than 30 milliliters/2 tablespoons of blood (depending on how much blood is available from clinical blood draws).

   - You will be assigned to one of the following groups:
     - **Vitamin C, Hydrocortisone, and Thiamine group**: If you are assigned to the Vitamin C, Hydrocortisone, and Thiamine group you will receive 4 daily doses of 1.5 grams of Vitamin C, 100 milligrams of Thiamine and 50 milligrams of Hydrocortisone. Vitamin C and Thiamine will be administered intravenously (i.e: into your veins) every 6 hours for a total of 4 days or until discharge from the ICU. Similarly, Hydrocortisone will be administered intravenously for up to 4 days or until you are discharged from the ICU (whatever happens first).

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: VITAMIN C, STEROIDS, AND THIAMINE IN SEPSIS AND SEPTIC SHOCK
PRINCIPAL INVESTIGATOR'S NAME: MICHAEL DONNINO, MD (BIDMC) AND PETER HOU, MD (BWH)
PROTOCOL #: 2017P-000436

  - **Placebo group**: If you are assigned to the placebo group you will receive 4 daily doses of 0.9% Sodium Chloride for up to 4 days or until discharge from the ICU (whatever happens first).

- Blood samples will be drawn at enrollment (0 hours), 24 hours, 72 hours, and 120 hours for a maximum total of 240 milliliters (no more than16 tablespoons total). Portions of your blood collected for research will be used to:
  - Clinical laboratory tests, analysis of cells (how your organs are working), serum, and plasma (parts of your blood). Some of these exams, tests may be done as part of regular care; if so, they may not need to be repeated; this decision will be up to your study doctor.

  - Freeze and store any leftover blood for possible analysis in the future of proteins in your blood called biomarkers that increase and decrease when your body is under stress. This extra blood will be stored at BIDMC and may be kept for up to 10 years. Access to these samples will be limited to the investigator and collaborators. If at any point you choose to withdraw your consent, you may contact Dr. Donnino (BIDMC) or Dr. Hou (BWH) and these samples will be disposed of and will not be used for future research. Genetic testing will not be performed.

- Urine will be collected at enrollment (0 hours), 24 hours, and 72 hours for a maximum total of 30 milliliters. We will study the characteristics of your urine to better understand how your kidneys are functioning. Additional urine will be frozen and stored for possible analysis in the future of proteins in your urine called biomarkers that increase and decrease when your body is under stress. This urine may be stored for up to 10 years and access to these samples will be limited to the investigator and collaborators. If at any point you choose to withdraw your consent, you may contact Dr. Donnino (BIDMC) or Dr. Hou (BWH) and these samples will be disposed of and will not be used for future research. Genetic testing will not be performed.

- Assessment of organ support, which includes, for example, medications to maintain blood pressure, will be performed everyday while you are in the hospital.

- We will also perform a more thorough review of your chart to see how you are doing while you are in the hospital. Information regarding your progress and treatments will be reviewed by the research team. We will collect and record vital signs, laboratory results, treatments you may have received and any other tests done as part of your care. If you were not in this study, we would not be reviewing your medical record.

SUBJECT'S NAME:
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PRINCIPAL INVESTIGATOR'S NAME: MICHAEL DONNINO, MD (BIDMC) AND PETER HOU, MD (BWH)
PROTOCOL #: 2017P-000436

- If you have been discharged from the hospital, you will receive a telephone call at 30-days after enrollment and 90-days after enrollment to see how you are doing after your hospitalization. If we are unable to reach you after two attempts, you may receive a follow-up letter.

4. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called "monitoring" or "follow-up" procedures. For this research study, the monitoring/follow-up procedures include:
   - At each of the blood draws (0 hours, 24 hours, 72 hours, 120 hours) we will follow along in your chart and record lab results from your routine care. When you are discharged, we will record information about your length of stay and signs of organ failure during your hospital stay.

   - If you have been discharged from the hospital, you will receive a telephone call at 30-days after enrollment and 90-days after enrollment to see how you are doing after your hospitalization. If we are unable to reach you after two attempts, you may receive a follow-up letter.

For BWH site: Blood samples and data, with your name and identifying information removed by study staff will be sent to BIDMC analysis center. The BIDMC analysis center will not receive any protected health information.

RISKS AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

Blood Draw Risk:
The risks associated with venipuncture (for blood draws) include momentary pain during needle insertion and bruising at the site of needle insertion. Infection, excess bleeding, clotting, and fainting also are possible, though unlikely. However, it is very likely that you will have an intravenous line from which we may draw, and so the blood draw will be painless. There is a very small risk that air or microorganisms may be introduced in your blood stream, but many steps will be taken to keep this risk at an absolute minimum.

Thiamine Risk:
The only known side effect from Thiamine is the potential for an allergic reaction. Allergic reactions (anaphylaxis) from Thiamine, in general, are very rare. The chance of a serious allergic reaction from Thiamine is approximately 1 in 250,000. There may be a risk of feeling burning at the site of the administration of the study drug.

SUBJECT'S NAME:
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PRINCIPAL INVESTIGATOR'S NAME: MICHAEL DONNINO, MD (BIDMC) AND PETER HOU, MD (BWH)
PROTOCOL #: 2017P-000436

Vitamin C Risk:
In high doses Vitamin C can increase the excretion of oxalate (a chemical substance) in your urine, which, in some cases, raises the risk of kidney stone formation. To prevent this from happening, individuals with a history of kidney stones within the past year will not participate in the study. There is also a chance you will feel dizzy and a rare chance of diarrhea and bloating. Allergic reactions (anaphylaxis) in general, are very rare.

Hydrocortisone Risk:
Multiple studies with the same dosages of steroids in severe infections over a short time course (similar to this study) have been performed and Hydrocortisone is a standard part of care for many patients with severe infections. Hydrocortisone may increase your risk of additional infections, higher blood sugars, higher levels of sodium, bleeding of the digestive tract and muscle weakness (although these effects have not been clearly seen in patients receiving Hydrocortisone for sepsis). In pregnancy, Hydrocortisone may increase the risk of cleft palate and there are concerns about the effects of Hydrocortisone on fetal growth and the adrenal gland function. If you are pregnant, you should not participate in this study.

LOSS OF CONFIDENTIALITY
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center and Brigham and Women's Hospital with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel

SUBJECT'S NAME:
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PROTOCOL #: 2017P-000436

Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. If you choose not to participate in this study, you will continue to receive clinical care from your ICU team as you have been.

It is important to note that it is possible to get Thiamine even if you do not take part in the study. Thiamine and Vitamin C have not been approved by the FDA for treatment of your condition; however, many doctors in the community commonly prescribe these drugs to treat vitamin deficiencies. Please be aware that not all doctors may agree to prescribe this drug for you, and that not all health insurance companies will pay for the drug when it is prescribed by your treating physician for sepsis (although will be provided free of charge to you if given as part of this study).

It is important to note that it is possible to get Hydrocortisone even if you do not take part in this study. Hydrocortisone has been approved by the FDA for treatment of your condition and is already used in certain clinical scenarios in patients with septic shock.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: VITAMIN C, STEROIDS, AND THIAMINE IN SEPSIS AND SEPTIC SHOCK
PRINCIPAL INVESTIGATOR'S NAME: MICHAEL DONNINO, MD (BIDMC) AND PETER HOU, MD (BWH)
PROTOCOL #: 2017P-000436

Medical Center or Brigham and Women's Hospital.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center, Brigham and Women's Hospital or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for the study drugs (Steroids, Vitamin C, Thiamine, Sodium Chloride) or blood tests that are part of this research study. However, you and your insurance company will be charged for other tests, procedures or medications of this study that are considered standard treatment for your medical condition.

CO-PAYMENT/DEDUCTIBLE STATEMENT

You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

PAYMENTS TO YOU:

There is no payment to you for participating in this study.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section "Whom to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION

A description of this clinical trial will be available on 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.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH

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PROTOCOL #: 2017P-000436

INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC, BIDMC] and disclose [to people and organizations outside the BIDMC and BWH workforce identified in this consent] health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information and the results of any laboratory tests as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC AND BWH WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared and used by other health care providers at BIDMC and BWH who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center or the Partners Human Research Committee at Brigham and Women's Hospital, which are responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC AND BWH WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- Other researchers and medical centers that are part of this study.
- People from organizations that provide independent accreditation and oversight of hospitals and research.
- Statisticians and other data monitors not affiliated with BIDMC or Partners.
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company

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PROTOCOL #: 2017P-000436

- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC and BWH may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC and BWH may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's and BWH's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC and BWH General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to:

BIDMC: Dr. Michael Donnino at 330 Brookline Ave., Boston, MA 02215.
BWH: Dr. Peter Hou at Neville House 312C, 75 Francis Street, Boston, MA 02115

Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

Beth Israel Deaconess Medical Center

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: VITAMIN C, STEROIDS, AND THIAMINE IN SEPSIS AND SEPTIC SHOCK
PRINCIPAL INVESTIGATOR'S NAME: MICHAEL DONNINO, MD (BIDMC) AND PETER HOU, MD (BWH)
PROTOCOL #: 2017P-000436

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REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

BIDMC: You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

BWH: If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at [857] 282-1900. You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

ICF REVISION DATES:

10/23/17, 2/2/18, 02/16/18, 06/14/18, 08/07/18, 08/10/18

Beth Israel Deaconess Medical Center

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THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO) at BIDMC.

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center/Brigham and Women's Hospital has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

Informed Consent – Part D
CCI Form: 6-2017
PI Revision Date: 09/10/2018

Beth Israel Deaconess Medical Center

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CONSENT FOR CONTINUED RESEARCH PARTICIPATION

I understand that I am currently participating in a research study. Permission for my participation in this study was obtained initially through from my legally authorized representative (surrogate). I have now recovered to the point where I feel that I can provide direct consent for continued participation in this research study.

I understand that if I decide not to continue in this study, it will not affect my relationship with my doctor or with Beth Israel Deaconess Medical Center and will not result in any penalty or loss of benefits to which I am otherwise entitled.

The study has been described to me and all of my questions have been answered. I have been told what to expect if I take part in this study, including risks and possible benefits.

Any additional questions or concerns about any aspect of this study will be answered by the researchers. Questions I might have about my rights as a research participant will be answered by the Human Subjects Protection Office (HSPO) at [617]667-0469

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

Participant's Signature	Participant's Name (Print)	Date

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

PRINT INVESTIGATOR'S/Co-Investigator's NAME

Informed Consent – Part D
CCI Form: 6-2017
PI Revision Date: 09/10/2018

Beth Israel Deaconess Medical Center

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: VITAMIN C, STEROIDS, AND THIAMINE IN SEPSIS AND SEPTIC SHOCK
PRINCIPAL INVESTIGATOR'S NAME: MICHAEL DONNINO, MD (BIDMC) AND PETER HOU, MD (BWH)
PROTOCOL #: 2017P-000436

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
09/09/2019
APPROVAL EXPIRATION DATE

THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____