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Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 01/10/2022

Protocol Number: 2020P000050

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
01/09/2023
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR: **Zachary Fricker, MD**
PROTOCOL NUMBER: **2020P000050**

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 advanced cirrhosis of the liver and are admitted to the hospital. Liver cirrhosis is extensive scarring of the liver that impairs liver function.

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.
- Your participation is completely voluntary.
- 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.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- 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.

Why is this research being done?

SUBJECT'S NAME:
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PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

Patients with advanced cirrhosis are at increased risk for harmful bacterial infections. Preventing infections might be possible with antibiotics during a hospital admission. We would like to know if this is true and compare the risks of antibiotic use to the benefits. We would also like to determine if any patient characteristics or blood tests can be used to identify patients at greater risk for infection. We would like to answer these questions by studying the effect of antibiotics among this group of patients. We are conducting this preliminary study to determine if a larger, more definitive study is possible.

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

We expect that you will be in this research study for 7-days (during which you may receive antibiotics) and at no longer than 30 days (we may contact you via phone to determine your status after hospital discharge).

We will collect and store a blood sample (approximately 1 tablespoon) for potential future testing, based on the study results, which are unknown at this time. We will store this sample indefinitely.

You will be asked to undergo testing (blood and urine testing and a chest x-ray) to see if you have an infection, if not already done. You will provide blood samples for two extra blood tests for research, and you will be randomly assigned to receive an antibiotic or placebo (inactive fluid).

More detailed information about the study procedures can be found under ***"*DESCRIPTION OF STUDY DETAILS*".***

Is there any way being in this study could be harmful to me?

The most common risks of participating in this study include injury that might occur during testing to determine if you have an infection, if required, (such as bleeding from a needle puncture site, causing an infection), or side effect from the study medication (antibiotic), such as allergic reaction, diarrheal infection, or the development of antibiotic –resistant infection.

More detailed information about the risks can be found under ***"*RISKS AND DISCOMFORTS*".***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to others include improvements in medical care for future hospitalized patients with cirrhosis which may reduce the risk of infection or the unnecessary use of antibiotics.

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

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

DETAILED INFORMATION SECTION

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.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Zachary Fricker, MD and is funded by the American Association for the Study of Liver Diseases Foundation. The funding agency in this study (American Association for the Study of Liver Diseases Foundation) is paying Beth Israel Deaconess Medical Center (BIDMC) to perform this research. Neither BIDMC nor Dr. Fricker has any additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact the Principal Investigator Zachery Fricker at [617] 632-1070.

PURPOSE

We are interested in learning the risks and benefits of providing antibiotics to patients with advanced cirrhosis who are hospitalized. This pilot study is being conducted to determine if a larger, future study would be possible. These future studies would assess whether antibiotic medication can be used to reduce infections that develop in hospitalized patients. We would also like to see whether antibiotic medication affects outcomes, such as length of hospital stay, worsening of laboratory tests, or death. We would also like to assess if patients most likely to benefit from antibiotic treatment can be identified using blood tests.

The treatment proposed is a new use of a commonly used antibiotic medication (Ceftriaxone). It is unknown if using this medication in patients without known infection will be beneficial. Ceftriaxone is an FDA approved antibiotic for the treatment or prevention of infections that are proven or strongly suspected to be caused by bacteria. It has not been specifically approved by the FDA for the prevention of infection in your condition, however, many doctors in the community commonly prescribe ceftriaxone to treat bacterial infections or prevent bacterial infections in patients with cirrhosis and bleeding from the esophagus, stomach, or intestine.

STUDY PARTICIPANTS

You have been asked to be in the study because you have cirrhosis and are admitted to the hospital.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

Approximately 50 people will take part in this study at Beth Israel Deaconess Medical Center. BIDMC is the only site to conduct this study.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you may take the study drug (or placebo) for as long as one week and your medical record may be reviewed by study staff throughout your hospital admission and then for up to one month after enrollment.

After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that are required to determine if you are eligible to take part in the research study. Most all of these procedures will already be completed for your standard care and we will obtain the results from your medical record. If not, they may be required for this research study:
   - **Urine culture** (you will be asked to urinate into a collection container, this sample will be tested for bacteria; requires about 1 tablespoon of urine), and
   - **Blood cultures** (you will have blood drawn from a vein to test for bacteria; requires about 1 tablespoon of blood).
   - **Chest x-ray** (you would be asked to stand still and briefly hold your breath while a radiology technician performs an x-ray),
   - **Study blood tests:** Approximately 2 tablespoons of blood will be drawn to complete study blood test including serum procalcitonin which helps to diagnosis types of infections, and C-reactive protein which helps to identify presence of inflammation and to monitor response to treatment for an inflammatory disorder; and a specimen will be stored for future research.
   - **Clinical lab tests results from routine care**: including but not limited to complete blood count with differential (a measurement of the types of blood cells and their relative proportion in the blood which can indicate infection may be present), blood clotting tests (measurement of the bloods ability to clot), serum creatinine (an estimate of kidney function), bilirubin (an estimate of liver function), sodium (a normal chemical in the blood), albumin (a normal protein in the blood), and pregnancy test results for women who can become pregnant.

2. Randomization Procedures: If there is no sign of infection based on the screening tests above, you will be randomly assigned to receive one of two study treatments.

   It is not clear at this time which of the treatments in this study would be better for you. For this reason, the treatment plan offered to you will be picked by chance [like the flip of a coin].

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

You will not be able to choose which treatment you receive. The chances of receiving either of the treatments are approximately equal. After the randomization, you will be assigned to one of the following groups:

A) Antibiotic (ceftriaxone)

B) Placebo (normal saline fluid)

Placebo: Depending upon the group to which you are assigned, you may receive a placebo instead of the antibiotic ceftriaxone. A placebo is an inactive intravenous fluid (salt and water) 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. 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.

Double-blind study: Neither you nor your physician will know which intervention you are receiving. However this information can be learned in case of an emergency.

3. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures: You will randomly be assigned to receive either the study antibiotic (ceftriaxone) or the placebo once daily for up to 7 days. The study drug will be administered to you intravenously (IV), through a tube inserted into your arm or through a central venous line if you already have one placed. We will record laboratory values and vital signs (e.g. heart rate, blood pressure) in a database for later review. If your physicians feel that you require antibiotics for any period of time, you may receive these as you normally would. We may or may not administer the study medication during this time, depending on the type of antibiotic your doctors feel you require.

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 are listed in the table below. Most of these procedures are completed as a part of your standard care. We will get the results of those procedures and tests from your medical records. If no medical records are available at 30-days after you leave the hospital, a research coordinator from our team will call you to follow-up with you directly to see how you have been feeling since your discharge.

Study Visit / Timeline	Screening	Day 1	Days 1-7	Day 30
Blood and urine collection	X	X	X	
• Blood culture to rule out infection	X	X	X	

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

• Study blood tests	X	X		
• Clinical lab tests	X	X	X	X
• Urine culture and urinalysis to rule out infection	X	X		
• Pregnancy test for women who are able to become pregnant	X			
Chest x-ray to rule out infection	X	X	X	
Study treatment			X	
Possible phone call				X
Review of your medical record	X	X	X	X

Individual Research Results

Your study doctor will disclose any clinically relevant research results to you, including findings from the chest x-ray, and/or blood and urine cultures, if performed. The results of the study tests will be in your medical record and the doctors treating you will have access to all of these results.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The research testing done in this study is just a stepping stone to learning more about liver cirrhosis.

While you should not expect to receive any results from the testing completed only for research, if we find that research results from your sample are of high medical importance, we may attempt to contact your medical provider to discuss the results. In some situations, follow up testing might be needed in a Clinical Laboratory Improvement Amendments (CLIA) certified clinical lab. You and your medical insurer may be responsible for the costs of these tests and any follow up care, including deductibles and co-payments. It is possible that you will never be contacted with individual research findings. This does not mean that you don't have or won't develop an important health problem.

Information and Biological Samples

Your information and biological samples will be used and shared with the researchers involved in this study to conduct the research. The consent form provides information on who will have access to identifiable information and identifiable biological samples during the study. We also want you to know that your information or biological samples may be stripped of any identifiers (for example your name, medical record number or date of birth) and used for future research studies or distributed to

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

another researcher for future research studies without additional informed consent. BIDMC researchers or other third party researchers may use your information and samples in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from the research described in this consent form or from any such work that may be performed by BIDMC or other third parties receiving your information or biological samples. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your information and biological samples may be used for commercial purposes. For example, your samples and information may be used to develop a new product or medical test to be sold. BIDMC and other researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

If your identifiers are removed, we will not be able to destroy or remove your information or biological samples from distributed information or samples. As part of this research program and as further explained in this form, samples of your tissue and/or information about your medical history may be provided to other researchers and/or outside collaborators.

Storing of Identifiable Information and Samples for Future Use

At the completion of this research, we would like to store any remaining sample(s) and information collected from or about you for this research for possible future use. Your sample will be stored in a manner that allows association with your identifiers, such as your name or medical record number. The remaining samples and information may be stored indefinitely and may be used for future research of cirrhosis or infections. The research staff will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If the research investigator distributes your samples to other researchers or institutions, they will be labeled with a research code without identifiers so that you cannot be identified by the other researchers or institutions.

If you have questions about storing samples or information, or would like to request that samples or information be removed from storage, please let us know. It is not always possible to remove samples or information from storage or to retrieve samples or information that have/has already been sent to other investigators.

I agree to allow my samples and information to be stored and used for future research as described above: (please check and initial one to indicate your choice)

_____ YES _____ NO

RISKS AND DISCOMFORTS

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

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.

Regardless of which treatment you are assigned, the study medication will be administered to you intravenously (IV) through a sterile tube placed in a vein in your arm or in a central venous catheter if you already have one placed. The medication you receive will be in an IV medication bag that is labeled in a manner that does not reveal the contents. Side effects rarely observed in patients receiving any type of fluid intravenously include fever, infection at the site of IV insertion, blood clot in the vein, or inflammation of the vein extending from the site of injection, IV fluid leakage into the tissue around the IV insertion, and fluid overload.

If you are randomized to receive the antibiotic **Ceftriaxone**, you may experience side effects that have been observed in prior clinical trials.

- The most common side effects (>10%) observed in clinical trials of ceftriaxone include skin tightness, thickening of the skin, and a warm sensation around the site of the injection when ceftriaxone was administered as an intramuscular injection (injection into a muscle).
- Less common side effects (<10%) included pain and tenderness at the injection site when the drug is given as an intramuscular injection; skin rash, diarrhea, eosinophilia (increase in the number of the white blood cells called eosinophils), thrombocytopenia (decrease in blood platelets; the blood cells that help blood clot), leucopenia (low level of white blood cells in the blood, which can interfere with the ability to fight infection), Increased in the liver enzyme, serum transaminases (suggesting liver injury) and allergic reactions to the drug and increased blood urea nitrogen (a marker of kidney function). Indirect adverse effects of ceftriaxone include development of antibiotic resistance, opportunistic infections which are infections that occur when a person is ill especially when the immune system is weak. Opportunistic infections may be caused by common bacteria (such as the bacteria called C-difficile) and fungi and often cause inflammation of the colon (colitis) and pain such as stomach pain, cramping and diarrhea; diagnostic uncertainty related to treatment of subsequent infections.

If you are randomized to receive **placebo**, you will receive approximately 100 mL (less than 7 tablespoons) of normal saline (salt water). There are no additional side effects expected beyond those listed above.

Blood draw and receiving medication intravenously: The risks and discomforts of drawing blood from a vein include the possibility of pain or bruising at the site of the blood draw, occasional feeling of lightheadedness, and rarely, infection or blood clotting at the site of the blood draw.

If not already completed for standard care and treatment, you may need one or all of the following tests for the study:

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

Chest X-Ray/Radiation Risk:

Some patients may get a chest x-ray to rule out infection at screening if one has not been completed as standard care. In this instance you would receive radiation exposure that is not necessary for your medical care. This exposure would be in addition to any exposure you receive as part of your routine medical care.

Radiation exposure from a single chest x-ray will deliver approximately 0.2 milliSieverts, a measure of radiation exposure. For comparison, the average person in the United States receives a radiation exposure of 3.2 milliSieverts per year from natural background and exposures we encounter in our everyday life. One possible effect from this additional radiation exposure is an increase in the risk of cancer. The estimated increase in the cancer risk due to this radiation exposure is 0.002%.

If you are pregnant, you will not be able to participate in this research study. It is best to avoid radiation exposure to unborn children because they are more sensitive to radiation than adults.

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 about you during this research program will be maintained confidentially by the research staff as described in this form.

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, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center. 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 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.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

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. Instead of being in this study, you have the following options: not participating and receiving routine medical care as you otherwise would.

It is important to note that it is possible to get ceftriaxone even if you do not take part in the study. Ceftriaxone has not been approved by the FDA for the prevention of infection in your condition, however, many doctors in the community commonly prescribe ceftriaxone to treat bacterial infections or prevent bacterial infections in patients with cirrhosis and bleeding from the esophagus, stomach, or intestine. 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 for prevention of infection.

This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

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 Medical Center.

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 or the funding source may stop the study at any time.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for diagnostic tests required only by virtue of participation in this study or the antibiotic or placebo 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:

You will not be paid 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.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH 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.

DESCRIPTION OF PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose 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 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 with and used by other health care providers at BIDMC 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, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

PEOPLE/GROUPS OUTSIDE OF BIDMC TO WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE DISCLOSED (SHARED) AND WHO MAY USE YOUR PROTECTED HEALTH INFORMATION

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 research study:

- The funding source of this study (American Association for the Study of Liver Diseases Foundation) and, where applicable, the people and companies that the sponsor uses to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- Other research collaborators and supporting research team members taking part in this study
- Any external health care providers who provide services to you in connection with this

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- Your health insurance company
- 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

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.

PURPOSE: WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC 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 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 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 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

Zachary Fricker, MD; LMOB 8th Floor, 110 Francis St; Brookline Ave., Boston, MA 02215.

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

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

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

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.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

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).

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 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.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

VERBAL CONSENT PROCEDURES WITH LEGALLY AUTHORIZED REPRESENTATIVE

If consenting over the phone ask the LAR:
Do you have any questions or concerns before you provide consent on behalf of the patient? If you would like some time to think about this, please let me know and we can arrange another time to talk.

If LAR consents: Thank you.

TO BE FILLED OUT BY RESEARCH STAFF

☐ LAR provided verbal consent for the patient to participate in the study

☐ LAR declined to provide consent for the patient to participate in the study

_____
PRINT LEGALLY AUTHORIZED REPRESENTATIVE'S NAME

_____
RELATIONSHIP OF LEGALLY AUTHORIZED REPRESENTATIVE TO SUBECT

_____
PRINT INVESTIGATOR'S/Co-Investigator's NAME

_____
SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

Gave verbal consent form to Legally Authorized Representative:

In person ☐ Mail ☐ Email/text ☐

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A pilot study of the effect of prophylactic antibiotics on hospitalized patients with advanced cirrhosis
PRINCIPAL INVESTIGATOR'S NAME: ZACHARY FRICKER, MD
PROTOCOL #: 2020P000050

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: _____