

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 1 of 16

Form Version Date: [August 2019]

STUDY INFORMATION:

Study Title: A Prospective, Multicenter, Randomized, Open-Label Study to Evaluate the Efficacy and Safety of PMX Cartridge in Addition to Standard Medical Care for Patients with Endotoxemic Septic Shock: TIGRIS TRIAL

Protocol No.: SDI-PMX-NA003
WIRB® Protocol #20191517

**Principal Investigator
(Head Researcher):** Roopa Kohli-Seth, MD

Physical Address: Mount Sinai Hospital; Surgical Intensive Care Unit, 1468 Madison Avenue, 6th Floor, New York, NY 10029

Mailing Address: One Gustave L Levy Place Box 1264, NY, NY 10029

Phone: 212-241-8867
212-241-0809
646-385-4839 (24 hours)

SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to evaluate the effectiveness and safety of the investigational PMX Cartridge, a device designed for the removal of endotoxins, in addition to standard medical care for patients with endotoxemia and septic shock. You are being asked for consent because you qualify for this trial based on study criteria. If you give consent, you will be randomly assigned to one of two groups: You will either receive the PMX cartridge treatment plus standard of care OR standard of care alone. The probability of you receiving the PMX cartridge treatment plus standard of care is **TWICE** as likely as receiving standard of care alone. Your participation in the study may last up to 12 months.

The PMX cartridge contains the antibiotic Polymyxin B that is attached to fibers of a blood filter. It is used much like a dialysis procedure where a tube inserted in a large vein carries some of your blood into the filter so that the blood flows across the fibers containing Polymyxin B. The bacterial parts

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 2 of 16

Form Version Date: [August 2019]

(endotoxin) in the blood are captured by the Polymyxin B and stays in the filter. Polymyxin B forms a very strong link to endotoxin and can keep it from floating back in the bloodstream. Then the remaining blood flows back into your vein. The process is called “extracorporeal hemoperfusion.”

If you are assigned to the PMX cartridge treatment, you will receive two treatment sessions with the PMX cartridge, each to be administered over 1.5 to 2 hours within a 24 hour period. The PMX cartridge treatment may be interrupted at any time, if deemed necessary, by the ICU doctor or the study doctor. If interrupted, the PMX cartridge treatment may be re-started at the discretion of the ICU doctor.

Blood samples will be collected and used to measure the levels of factors in the blood that will give the study doctors information about septic shock, such as the way the organs in the body work. The amount of blood that will be drawn over the entire study period for study purposes will add up to less than 45 mL (which is approximately 3 tablespoons). Blood samples will not be stored as these tests are done as part of standard medical care.

When possible, blood samples will be collected from an existing catheter (tube) in one of your veins or arteries to reduce the need for additional needles. If this is not possible, blood will be drawn by a routine needle puncture of a vein (usually in the arm).

You will be followed up after 4 days, 28 days, 90 days and 12 months of enrollment in the study. At each follow up call, the study doctor or their staff will ask questions about your health, and if possible, they will ask you how you have been feeling since last being seen by the research team. The research team will also collect data (information) about the medications that you are currently receiving and any possible side effects from the treatment.

You will not be paid or otherwise financially compensated for participating in this research study. Being in this research study will not lead to extra costs to you.

The possible risks to you if you choose to participate are reactions or discomforts with the PMX cartridge. There are other risks associated with dialysis catheter insertions such as air in the bloodstream and other risks associated with heparin use.

It is important to know that you may not benefit as a result of your participation in the study. Others may not benefit either. However, this study may be helpful for others with septic shock or endotoxemia in the future.

Instead of participating in this research, you may choose to undergo normal standard of care.

If you are interested in learning more about this study, please continue to read below.

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 3 of 16

Form Version Date: [August 2019]

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you have a medical condition called septic shock. This has been determined because of your signs of infection (such as fever, increased white blood cell count and rapid heart rate), signs that your blood pressure is low and that there is a high level of endotoxin activity in the blood. Endotoxin comes from certain types of bacteria. In order to confirm if there are endotoxins in your bloodstream, a 3mL sample (less than 1 teaspoon) of your blood was used for a test that is called the Endotoxin Activity Assay, or EAA, which is a U.S. Food and Drug Administration cleared blood test. Since the level of endotoxin activity was found to be between 0.6 to less than 0.9 Units, you are eligible to participate in this research study.

This is an investigational research study where the PMX cartridge is being tested for use in the treatment of septic shock. "Investigational" means that the PMX cartridge has not been approved by the United States Food and Drug Administration (FDA) as a treatment for septic shock. The PMX cartridge has been used in patients in Japan and countries in Europe for more than 20 years. Additionally, a research study using PMX cartridge has recently been completed where 450 patients were enrolled in the United States and Canada. This is the second study of the PMX cartridge for safety and effectiveness in patients in the United States. This study of the PMX cartridge will be conducted in multiple hospitals in the United States. **You will continue to receive the standard of care for septic shock even if you choose not to participate in this study.** Standard of care is how patients would be treated for their condition whether or not they were in a study.

Funds for conducting this research are provided by Spectral Diagnostics (US) Inc. (Spectral). Spectral designed the study and drafted the study plan and has licensed the device for use in the United States. The PMX cartridge is manufactured in Tokyo, Japan by a company called Toray Industries.

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.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last up to 12 months.

Approximately 15 people are expected to take part in this research study at Mount Sinai Hospital. About 150 people are expected to take part in this research study across all sites.

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai**

Page 4 of 16

Form Version Date: [August 2019]

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

The study will take place in six ICUs:

- Surgical Intensive Care Unit, 6th Floor East, Guggenheim Pavilion
- Cardiac Intensive Care Unit (CICU), 6th Floor Klingenstein Clinical Center
- Cardiothoracic Intensive Care Unit (CSICU/CTICU), 5th and 6th Floor Center, Guggenheim Pavilion
- Medical Intensive Care Unit (MICU), 5th Floor West, Guggenheim Pavilion
- Cardiovascular intensive care unit (CVICU), 5th Floor Center, Guggenheim Pavilion
- Transplant Intensive Care Unit (TICU), 6th Floor Center, Guggenheim Pavilion

Pre-Treatment Procedures

Before being given the study treatment, the following study-related procedures will happen (in no particular order):

1. Information will be collected about your general medical history, including your past and current medical conditions and medications you are taking.
2. Information will be collected to determine how well your organ systems are functioning.
3. Vital signs will be collected, including heart rate, and blood pressure.
4. Your weight will be measured.
5. Blood samples (about 8 mL, or about 1 tablespoon) will be collected, including a pregnancy test if you are a female that can have children. You cannot participate in this study if you are pregnant.
6. The research team will check the type of medical care that is being used, such as blood pressure medication, I.V. fluids and length of time you spend in the Intensive Care Unit (ICU).

Study Treatment and Monitoring

If you qualify for the treatment and if you are assigned to the treatment arm, a doctor will need to insert a dialysis catheter (needle) into a central blood vessel (vein) as part of the investigational procedure (i.e. not part of standard of care), for administration of PMX cartridge treatment. After completion of your PMX treatment sessions, the doctor may choose to remove this catheter or leave it in place to be used for other standard of care procedures. If you already have an existing catheter inserted as part of your ongoing standard of care in the ICU, this may be used for the PMX cartridge treatment instead.

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 5 of 16

Form Version Date: [August 2019]

Day 1 through Day 3

If you are assigned to the PMX cartridge treatment group, you will receive your study treatment in the intensive care unit. On Day 1, you will first receive the treatment for 1.5 to 2 hours. A second treatment will be given over another 1.5 to 2-hour period, within 24 hours of the first treatment. Standard of care for septic shock will continue for both study groups.

On the day of study treatments (Day 1), and the two days after the treatment (Day 2 and Day 3), the following study-related procedures will be performed on each day:

1. A blood sample (3 mL) will be tested using the Endotoxin Activity Assay, or EAA.
2. Vital signs, including heart rate and blood pressure.
3. Review of medical records by the research team to collect data about medications you are taking.
4. Blood samples will be collected (about 8 mL, or about 1 tablespoon) for laboratory testing on each day.
5. The research team will check the type of medical care that is being used, such as blood pressure medication, I.V. fluids and length of time you spend in the Intensive Care Unit (ICU).
6. Due to your participation in the study, you will be asked about how you feel and you will be evaluated for any possible side-effects you might have during the study.

The procedures discussed above will be completed for both study groups and will only be done while you are still a patient in the hospital. It is possible that you will not have procedures or assessments done on each of these days.

Day 4

On the fourth day (Day 4), due to your participation in the study, you will be asked about how you feel and you will be evaluated for any possible side effects you might have during the study.

Day 28 or Early Termination

On Day 28 the study doctor or one of the research team members will contact you either in the hospital or at home (if you are discharged from the hospital) to ask how you are feeling and you will be evaluated for any possible side effects you might have had during the study. You will not be required to come in to the hospital for this follow-up visit. If you choose to stop your participation in this study prior to Day 28, these questions will be asked at the time of the termination of your participation.

Day 90 and 12 Month Follow-up

At approximately Day 90 of the study and at 12 months the study doctor or one of the research team members will contact you either in the hospital or at home to ask how you are feeling or about your health in general. You will not be required to come in to the hospital for the follow-up visits.

A blood pregnancy test will be done before the study treatment begins.

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 6 of 16

Form Version Date: [August 2019]

Because this project involves the use of a medical device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

Assignment to Study Arm

The study treatment you get will be chosen by chance, like pulling names out of a hat. Neither you nor the study doctor will choose what experimental study treatment you get. You will be twice as likely of being placed in the PMX plus standard of care group.

Risks to Reproduction

For Women:

The PMX cartridge has not been tested in pregnant women. If you are a woman and are pregnant, nursing or intend to nurse your baby, you are NOT eligible to take part in this study. If you are a woman of childbearing potential (capable of having children), you must discuss using a medically acceptable, non-hormonal method of contraception with the study doctors. Before the beginning of the study, a pregnancy test will be done for women who are able to become pregnant. If you suspect that you have become pregnant during the study period, you must notify the study doctor immediately. Therefore, practicing effective birth control is important. No individual birth control is 100% effective.

Recommended methods of birth control are:

- The consistent use of an approved hormonal birth control (pill/patches, rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual intercourse) or
- Sterilization.

No individual birth control is 100% effective.

Hormonal birth control, implants, and injections are only considered effective if used properly and started at least one month before you begin the study, continuing throughout the study and for one month after the end of the study. You should ask your study doctor if you should continue birth control for longer than 30 days after the end of the study. If you are unsure whether the method of birth control you use is acceptable to use while participating in this study, you should ask your study doctor before you begin the study. If you are less than one year post-menopausal, there is the potential that you could become pregnant. If you or your partner becomes pregnant, or may be pregnant, at any time, it is important that you tell your study doctor immediately.

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 7 of 16

Form Version Date: [August 2019]

Should you become pregnant, regardless of the outcome, the sponsor may ask for information on your pregnancy, even if you are withdrawn from the study. Your written consent will be obtained separately in the case that this happens.

USE OF YOUR DATA AND/OR SPECIMENS:

The private information and/or samples collected as part of this research will never be used or shared for future research, even if the identifiable information is removed.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

- Be honest about your medical history and current condition;
- Tell the study doctor about any problems you have during the study;
- Tell the study doctor if you have been in a research study in the last 30 days or are in a research study now.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you.

POSSIBLE BENEFITS:

It is important to know that you may not benefit as a result of your participation in the study. Others may not benefit either. However, this study may be helpful for others with septic shock or endotoxemia in the future.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

As with any treatment, it is possible that the PMX cartridge could cause reactions or discomforts and there may be risks to patients participating in this study. Polymyxin B is an antibiotic. Patients should not receive Polymyxin B if there has been a previous reaction to Polymyxin B. As of January 1st, 2019, more than 150,000 adult patients with septic shock have been given the PMX cartridge treatment,

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 8 of 16

Form Version Date: [August 2019]

including approximately 10,000 patients who received the PMX cartridge in research studies. In general, the PMX cartridge has been well tolerated in subjects that have completed previous research studies.

In human studies of the PMX cartridge administration via hemoperfusion involving patients that had septic shock, all possible side effects included:

- Fever, low platelet count, low white blood cell count, decreased blood pressure, mild allergic reaction (skin redness and rash), a severe allergic reaction that may be life threatening (rapid heart rate and rhythm disturbance, with decreased oxygen in blood); shock (decreased blood pressure along with shortness of breath, rapid heart rate, palpitations, chills, chest pain, vomiting, bluish skin discoloration), blood clots, stroke, anemia (low hemoglobin count), low potassium level, low phosphate level.

The antibiotic Polymyxin B has been in use for many years, however it is not approved by FDA to be given directly into a vein. This is because there can be side effects to the kidneys (low urine output, inability to filter blood) or the brain (general weakness, numbness, blurred vision, drowsiness). In rigorous lab testing using the PMX cartridge there has not been proof of Polymyxin B released into the blood in measureable amounts. However you will be watched by study personnel for any of these side effects on a daily basis during the treatment.

The potential risks (side effects) of extracorporeal hemoperfusion can also be related to the procedure used to bring blood outside the body. This is done by inserting a tube (catheter) into a vein that is connected to tubing that is attached to a pump.

Dialysis Catheter Insertion

Risks associated with the dialysis catheter insertion are rare but may include:

- Air in the bloodstream, collapsed lung, infection of entry site of dialysis catheter, catheter malposition, blood vessel damage, puncture site bleeding and bruising, blood clot formation in the vein around the catheter that could dislodge, irregular heartbeat, local nerve damage, bleeding within the abdomen, and low blood flow to the legs.

Heparin Use

Heparin is a medication that is used to prevent blood from clotting. Heparin may be used during PMX cartridge treatment to prevent blood clots within the cartridge. This decision will be made by your doctor. Risks associated with heparin use include:

- Bleeding that is not normal which may cause bruising, skin discoloration, low hemoglobin, bleeding from puncture sites, bleeding from the stomach, blood in the urine, bleeding around the brain, low blood pressure including decreased blood flow to the liver, low platelet levels (known as heparin induced thrombocytopenia), a sensitivity reaction to heparin may include itching, rash, hives, shortness of breath, or even, in rare circumstances, a severe allergic reaction, blood clots (stationary or moving), and inflammation of the pancreas.

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai**

Page 9 of 16

Form Version Date: [August 2019]

Other risks of taking part in this study may include the following:

- In addition to the risks named above, PMX cartridge treatment and the study procedures might have other risks not known at this time. The unknown risks might be minor or might be major (death). At any time during this study, you (or the patient) might experience a return or worsening of symptoms related to sepsis. Your doctor, nurses and other research staff will be following you closely to look for and treat any possible adverse events (bad effects).
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.
- If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death). You should not become pregnant or father a baby while on this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.

OTHER POSSIBLE OPTIONS TO CONSIDER:

The alternative is not to take part in the study. If you (or the patient's authorized representative) choose not take part in this study, you will continue to receive the same standard and level of care at this hospital as any patient with septic shock.

VOLUNTARY PARTICIPATION:

You may decide not to take part in this research study or later stop taking part without any penalty or loss of benefit to which you are otherwise entitled. The choice is totally up to you. Instead of being in this research study, your other choice is to undergo the normal standard of care.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, medical care will be provided. The sponsor will reimburse your reasonable and necessary medical expenses for diagnosis and treatment of a research-related injury or illness.

This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 10 of 16

Form Version Date: [August 2019]

If you suffer a physical injury as a direct result of the study treatment, or the conduct of a procedure required to be conducted by the study protocol, the sponsor (Spectral Diagnostics (US) Inc.) will provide reimbursement for the reasonable and necessary medical costs related to that injury if:

- Your injury was not deliberately caused; and
- You followed the medical advice of the study doctor; and
- The injury was not the result of negligence or misconduct of any agent or employee of the institution or hospital.

The sponsor (Spectral Diagnostics (US) Inc.) will not provide reimbursement if:

- Your injury was deliberately caused
- The injury was the result of negligence or misconduct of any agent or employee of the institution or hospital

The cost of any medical treatments or procedures required for any illness, injury or complication related to your septic shock, or any other medical problem not related to the study treatment, or to a procedure required to be conducted by the study protocol, will remain your responsibility or the responsibility of your health insurance company.

The Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare and Medicaid programs, has stated that payments by a clinical trial sponsor for injuries related to a trial are a form of liability insurance that must be reported to CMS. As a result, if the sponsor pays for any medical expenses to treat a trial-related injury, the sponsor may have an obligation to determine whether you are covered by CMS, and, if you are, the sponsor may be required to make a report to CMS. In order to perform these tasks, the sponsor (or its delegate) must have certain individually identifiable information about you, such as your name, date of birth, Social Security Number, CMS Claim Number, date of injury and description of injury. Because the sponsor would not normally receive such identifiable information about you, the sponsor (or its delegate) has agreed to use this information only for the purposes described in this paragraph or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. You will receive only the standard of care.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**
Icahn School of Medicine at Mount Sinai

Page 11 of 16

Form Version Date: [August 2019]

asked whether the study doctor can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your samples and/or data will take place.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include if you do not follow the procedures described in this informed consent or if you are lost to follow-up.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number **(212) 241-0809, 212-241-8867, or 646-385-4839 (24 hours)**.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**
Icahn School of Medicine at Mount Sinai

Page 12 of 16

Form Version Date: [August 2019]

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than \$5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk to your physician/researcher or visit our website at <http://icahn.mssm.edu/> where Mount Sinai publicly discloses the industry relationships of our faculty.

The company sponsoring this research study owns the exclusive license to the device being tested and so has a financial interest that could be affected by the outcome of this research study.

The Principal Investigator's Department is being paid by the research study sponsor to conduct this research. The costs of doing this research are paid based on the number of patients enrolled.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death), and medical records number.

The researchers will also get information from your medical record at Mount Sinai Hospital. During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai**

Page 13 of 16

Form Version Date: [August 2019]

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. **If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.**

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration): Spectral Diagnostics (US) Inc.
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The U.S. Food and Drug Administration (FDA).
- The United States Department of Health and Human Services and the Office of Human Research Protection.
- Western Institutional Review Board® (WIRB®)

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 14 of 16

Form Version Date: [August 2019]

allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, **the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.** We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 15 of 16

Form Version Date: [August 2019]

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of subject

Printed Name of Subject

Date

Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate

Printed Name of consent delegate

Date

Time

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 16 of 16

Form Version Date: [August 2019]

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

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

Printed Name of Witness

Date

Time