THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR AN INCAPACITATED ADULT
TO PARTICIPATE IN A RESEARCH STUDY FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

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
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In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

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 the participants or others. Participation is entirely voluntary. It is completely up to you* whether or not you give permission for the research subject to take part. You can also change your mind at any time and it will not affect your ability, or the research subject's 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 to give permission for the research subject to participate, because they qualify to participate in the trial based on study criteria. Once you give consent, they will be randomly assigned to one of two groups: they will either receive

*Throughout this document "you" refers to the person authorized to provide permission for the research subject

the PMX cartridge treatment plus standard of care OR standard of care alone. The probability of them receiving the PMX cartridge treatment plus standard of care is **TWICE** as likely as receiving standard of care alone. Their participation in the study may to last up 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 their blood into the filter so that the blood flows across the fibers containing Polymyxin B. The bacterial parts (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 the vein. The process is called “extracorporeal hemoperfusion.”

If they 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 their 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).

The research subject 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 their health, and if possible, the study doctor will ask how they have been feeling since last being seen by the research team. The research team will also collect data (information) about the medications that they are currently receiving and any possible side effects from the treatment.

The research subject 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 them.

The possible risks to the research subject if you choose to provide consent 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 the research subject may not benefit as a result of their 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.

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

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

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 give permission for the research subject to participate. Any new information that develops during this research study that might make you change your mind about the subject participating will be given to you promptly.

The research subject may qualify to take part in this research study because they have a medical condition called septic shock. This has been determined because of their signs of infection (such as fever, increased white blood cell count and rapid heart rate), signs that their blood pressure is low and that there is a high level of endotoxin activity in the blood. Endotoxin comes from certain types of bacteria. To confirm if there are endotoxins in their bloodstream a 3mL sample (less than 1 teaspoon) of their 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, they 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. **The research subject will continue to receive the standard of care for septic shock even if you choose not to provide consent for 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.

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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:

The research subject's 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.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to give permission for the research subject 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 the research subject's general medical history, including their past and current medical conditions and medications they are taking.
2. Information will be collected to determine how well their organ systems are functioning.
3. Vital signs will be collected, including heart rate, and blood pressure.
4. Their weight will be measured.

5. Blood samples (about 8 mL, or about 1 tablespoon) will be collected, including a pregnancy test if she is a female that can have children. A woman cannot participate in this study if she is 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 they spend in the Intensive Care Unit (ICU).

Study Treatment and Monitoring

If the research subject qualifies for the treatment and if they 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 their 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 they already have an existing catheter inserted as part of their ongoing standard of care in the ICU, this may be used for the PMX cartridge treatment instead.

Day 1 through Day 3

If the subject is assigned to the PMX cartridge treatment group, they will receive the study treatment in the intensive care unit. On Day 1, they 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 they 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 they spend in the Intensive Care Unit (ICU).
6. Due to the subject's participation in the study, they will be asked about how they feel and will be evaluated for any possible side effects they might have during the study.

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

Day 4

On the fourth day (Day 4), due to their participation in the study, the subject will be asked about how they feel and will be evaluated for any possible side effects they 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 the research subject either in the hospital or at home (if they have been discharged from the hospital) to ask how they are feeling. They will be evaluated for any possible side effects they might have had during the study. The subject will not be required to come in to the hospital for this follow-up visit. If they choose to stop participation in this study prior to Day 28, these questions will be asked at the time of the termination of their 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 the research subject either in the hospital or at home to ask how they are feeling or about their health in general. They 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.

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

Assignment to Study Arm

The study treatment the subject gets will be chosen by chance, like pulling names out of a hat. Neither you nor the study doctor will choose what experimental study treatment the subject gets. The study subject 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 the subject is a woman and pregnant, nursing or intend to nurse a baby, she is NOT eligible to take part in this study. If she is 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 she may become pregnant during the study period, you must notify the study doctor immediately.

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 the research subject begins the study, continuing throughout the study and for one month after the end of the study. You should ask the research subject's study doctor if the research subject should continue birth control for longer than 30 days after the end of the study. If the research subject is unsure whether the method of birth control the research subject uses is acceptable to use while participating in this study, the research subject should ask the study doctor before beginning the study. If the research subject is less than one year post-menopausal, there is the potential that the research subject could become pregnant. If the research subject or the research subject's partner becomes pregnant, or may be pregnant, at any time, it is important that the research subject tell the study doctor immediately.

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

Hormonal birth control, implants, and injections are only considered effective if used properly and started at least one month before the subject begins 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.

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

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USE OF THE RESEARCH SUBJECT'S 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.

RESPONSIBILITIES FOR PARTICIPATION IN THIS RESEARCH:

If you decide to give permission for the research subject to take part in this research study he/she will be responsible for the following things:

- Be honest about their medical history and current condition;
- Tell the study doctor about any problems they have during the study;
- Tell the study doctor if they 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:

The research subject will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you or the research subject.

POSSIBLE BENEFITS:

It is important to know that the research subject may not benefit as a result of their 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, 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.

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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 measurable 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.

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 the research subject is or becomes pregnant, this research may hurt the research subject's baby or the research subject's pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death) for the pregnancy. The research subject 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 choose not to allow the patient take part in this study, the patient 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 allow the research subject to take part in this research study or later stop their participation without any penalty or loss of benefit to which they are otherwise entitled. The choice is totally up to you. Instead of being in this research study, your other choice is the normal standard of care.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

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

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

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If the research subject suffers 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:

- Their injury was not deliberately caused; and
- They 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:

- Their 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 their 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 the subject's responsibility or the responsibility of their 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:

The research subject may stop taking part in this research study at any time without any penalty. This will not affect the research subject's ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which the research subject is otherwise entitled.

If you decide to stop the research subject from continuing to be in the research study, please contact the Principal Investigator or the research staff.

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

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

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop the research subject's 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 the research subject's 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 the research subject, 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.

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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.

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 the research subject takes part in this research project it will be necessary for the research team and others to use and share some of the research subject's 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.

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

As part of this research project, the research team at the hospital(s) involved in the research will collect the research subject's 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 the research subject's medical record at Mount Sinai Hospital.

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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.

Why is the research subject's protected health information being used?

The research subject's personal contact information is important to be able to contact the research subject during the study. The research subject's 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 the research subject is, 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 the research subject 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 the research subject's 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 the research subject's information. If the research subject receives any payments for taking part in this study, the Mount Sinai Finance Department may need the research subject's name, address, social security number, payment amount, and related information for tax reporting purposes. I**f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.**

Who, outside Mount Sinai, might receive the research subject's protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose the research subject's 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.

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- 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, the research subject 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 the research subject without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to the research subject's privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect the research subject's 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 the research subject's 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 the research subject's name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose the research subject's protected health information?

Your authorization for use of the research subject's protected health information for this specific study does not expire.

Will you be able to access the research subject's records?

During the research subject's participation in this study, you will have access to the research subject's 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 the research subject's medical record.

Do you need to give us permission to obtain, use or share the research subject's health information?

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

*Throughout this document "you" refers to the person authorized to provide permission for the research subject

THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR AN INCAPACITATED ADULT
TO PARTICIPATE IN A RESEARCH STUDY FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Can you change your mind?

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

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 the research subject's information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive the research subject's information to continue to protect the research subject's confidentiality.

If as part of this research project the research subject's 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 the research subject. If this research does not involve any review of medical records or questions about the research subject's 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 the participant's HIV-related information without authorization. If the research subject experiences 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 the research subject's rights.

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Form Version Date: [August 2019]

SIGNATURE BLOCK FOR ADULT UNABLE TO CONSENT:

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

Printed Name of Subject			
Signature of Authorized Representative	Printed Name of Authorized Representative	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate	Printed Name of consent delegate	Date	Time

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that he or she cannot reasonably be consulted.

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

*Throughout this document "you" refers to the person authorized to provide permission for the research subject