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

IRB APPROVED
Nov 15, 2019

Form Version Date: [October 2019]

STUDY INFORMATION:

Study Title: Evaluating the use of the SAMI RRT unit as a blood pump to perform hemoperfusion using the Polymyxin B cartridge-a substudy to the Tigris clinical trial. An observational study of the safety and utility of the SAMI RRT unit to perform hemoperfusion.

Protocol No.: SDI-PMX-012
WIRB® Protocol #20192861

Sponsor: Spectral Diagnostics Inc

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

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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 observe the performance of the SAMI Renal Replacement Therapy (RRT) instrument, (K170790) for utility and safety in performing hemoperfusion. You are being asked to participate in this study because you qualify for the TIGRIS clinical study, hence, the SAMI RRT instrument will be utilized to perform hemoperfusion for the Polymyxin B extracorporeal hemoperfusion cartridge. Your participation ends when the treatment ends.

If you choose to participate, you will be asked to complete the procedural requirements of TIGRIS before participating in this study using the SAMI RRT device for hemoperfusion. There are no associated costs to you for participating in this study, neither will you be paid for your participation.

The main risks to you if you choose to participate in the SAMI RRT device sub study are the same as other hemodialysis devices used to perform the PMX cartridge treatment. They are very rare in occurrence but include blood loss, blood clotting in the tubing set, or embolism which is air or bubbles traveling into a vein in your body. In addition to the risks named above, use of the SAMI RRT device might have other risks not known at this time.

Participating in this research will not benefit you. Your participation in this research study may help other people with the need for PMX hemoperfusion and use of the SAMI RRT device.

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.

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 meet the requirements for TIGRIS, the main clinical trial for this study.

Funds for conducting this research are provided by Spectral Diagnostics (US) Inc. (Spectral). Spectral designed the study and drafted the study plan and manufactures the SAMI RRT device. The SAMI RRT device is cleared by the US FDA for use as HD (haemodialysis), HDF (haemodiafiltration), HF (haemofiltration) and TPE (total plasma exchange) under K170790.

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 7 people are expected to take part in this research study at Mount Sinai Hospital. About 20 people are expected to take part in this research study across all sites.

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

This study requires observation of the performance of the SAMI RRT device. This device has been FDA cleared for use in hemodialysis; its use for hemoperfusion in this study is investigational. Hemoperfusion is a form of hemodialysis but involves a different set up for blood tubing to accommodate a different path for the flow of blood. The SAMI RRT device works as a blood pump that draws in blood from the dialysis catheter and through the PMX cartridge at a rate of 80-120 mL/minute.

The experimental part of this device involves a different set up for the pump cassette and tubing that connects with the dialysis catheter already in place. There are no different procedures that involve you as a patient but the set up procedure must be followed by the person trained to set up and perform the PMX hemoperfusion using SAMI RRT device for both treatments of the PMX cartridge. Therefore, this study includes treatment similar to what you would receive outside of this study.

There will be specific data collected during the use of the SAMI RRT device such as observing for the functioning of the alarms, and ensuring the pump and the pressure and air monitors are working correctly. This involves observation and data collection for the two treatment sessions of the PMX cartridge that are for up to 2 hours in duration each.

This study will continue at this hospital until there are 7 patients where the SAMI RRT device is used. There is no follow up for this study but the Tigris study includes a follow up at 28 days following the start of that study to ask how you are feeling and you will be evaluated for any possible side effects you might have had during the study and a telephone follow up at 90 days and 1 year. Your participation in this study ends after the treatment sessions ends.

Because this project involves the use of medications or 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.

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:

Your responsibilities in this study are the same responsibilities required of you for participation in the TIGRIS trial.

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:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. Your participation in this research study may help other people with the need for PMX hemoperfusion and use of the SAMI RRT device.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The main risks to you if you choose to participate in the SAMI RRT device sub study are the same as other hemodialysis devices used to perform the PMX cartridge treatment. They are very rare in occurrence but include blood loss, blood clotting in the tubing set, or embolism which is air or bubbles traveling into a vein in your body. In addition to the risks named above, use of the SAMI RRT device might have other risks not known at this time. As this study is connected to the TIGRIS study, the following risks are the same as those from the TIGIRS study:

In human studies of the PMX cartridge administration via hemoperfusion involving patients that had septic shock, 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.

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.

The device has unknown risks when used 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 (or your legal representative) 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.

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. 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.

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 decide not to participate or 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 result in loss of 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.

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 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.

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.

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.

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 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.

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.

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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

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