STUDY INFORMATION:

Study Title: FREEDOM COVID Anticoagulation Strategy Randomized Trial

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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 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.

COVID-19 is a new viral infection. Currently, we have no proven medications to treat COVID-19 infections.

Enoxaparin is a type of blood thinner (in the category of low molecular weight heparin) often used in hospitalized patients to prevent and treat blood clots and/or heart attacks. Apixaban is also a type of blood thinner, taken orally and used to prevent and treat blood clots. There is a possibility that you may have received one dose of an anticoagulant before being approached to participate in this research study.

Early evidence suggests that enoxaparin and apixaban might also reduce inflammation and blood clots that could occur in people infected with COVID-19. However, there may be increased risks too, and without a proper study, it is not possible to know if these early observations are correct, which medication should be used, and at whether a higher dose is better than a lower dose in treating COVID-19 disease.

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The Food and Drug Administration (FDA) in the United States, the regulatory body that oversees the use of drugs, has not approved the sale or use of apixaban or enoxaparin for treating COVID-19 disease but has allowed apixaban and enoxaparin to be used in this study.

The purpose of this research study is to understand if a higher (treatment) dose of anticoagulant (also known as a blood thinner) will improve outcomes in patients hospitalized with COVID-19 disease, and if so which medication is the most effective.

Many patients admitted to the hospital in general receive a low (preventive) dose of blood thinners to prevent blood clots from forming. We are testing whether a higher dose of blood thinners is more effective in preventing complications in patients with COVID-19. To do this, some participants will get one of two types of higher dose blood thinners and some will not. Participants who do not get the higher dose blood thinners will receive a low (preventive) dose blood thinner.

- If you choose to allow the research subject to participate, you will be randomly assigned to one of the three study groups listed below:

- STUDY INTERVENTION
    - Group1 Low dose Enoxaparin:
      Doctors often prescribe a low (preventive) dose low molecular weight heparin to patients in the hospital to prevent blood clots. If you are randomized to this group, you will get low (preventive) dose heparin under your skin daily as long as you are in the hospital.
    - Group 2 Full dose Enoxaparin:
      If you are randomized to this group, full dose drug low molecular weight heparin will be given to you under the skin until hospital discharge.
    - Group 3 Full dose Apixaban:
      If you are randomized to this group you will receive Apixaban by mouth twice daily for as long as you are in the hospital.
- After research subject leaves the hospital, they will be called at home (up to 90 days after they have left) to see how they have recovered. They are not required to return to the hospital for follow-up for this trial.
- If they have side effects while they are on this study, the study doctor may make changes to the doses
- There are no additional costs associated with participation. All clinical and professional fees, diagnostic and laboratory tests will be performed as part of normal standard clinical care and will be charged to their insurance.

There is no compensation.

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The main risks to them if you choose to allow research subject to participate is bleeding. Bleeding may range from minor local bruising to major bleeding. Early signs of bleeding may include a nose bleed, blood in the urine or blood in the stool. Major bleeding is very uncommon and typically occurs in less than 2% of patients who receive blood thinners

Participating in this research may not benefit the research subject. Instead of participating in this research, their doctor will choose your treatment based on their best clinical judgment according to standard of care. Other research studies may be available.

The current public health protocol for treating COVID-19 is identifying patients with the disease, isolating them from others, putting them in quarantine to prevent the virus from spreading and providing supportive care as needed (oxygen, dialysis, Intensive care admission if needed).

Treatment guidelines and recommendations from the World Health Organization is that, for COVID-19, treatments with unknown benefit should only be given in a clinical trial. The use of blood thinner medication is not a usual treatment, so these medications are considered a "new treatment

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 been admitted to hospital and you have either tested positive for the new Coronavirus or you are suspected of having the infection. The disease is called COVID-19. This information and consent form provides you with information to help you make an informed decision about whether or not to participate in this study.

Funds for conducting this research are provided Mount Sinai.

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 the research subject. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

This is an international study. The research subject's participation in this research study is expected to last 3 months to complete and the results should be known in about 1 year. The number of people expected to take part in this research study at Mount Sinai is 25. The total number of people expected to take part in this research study across all sites located in countries including the United States and other countries is 3600. This study should take about 3-6 months to complete and the results should be known in about 1 year.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to give permission for the research subject to participate in this research study, the experimental procedures will be to take the drug of the study group into which they are assigned, additionally, there are non-experimental procedures that will be completed. The following information describes what may be involved.

Non-Experimental Procedures

The results of the following tests will be collected for this study. These tests will be done as part of your standard care. Some of these tests may be done more frequently than if you were not taking part in this study, and, if the results show that you are not able to continue participating, the study doctor(s) will let you know.

- Routine blood work (Hematology bloodwork , Biochemistry bloodwork, Troponin, d-dimer)
- Vital Signs (SpO2 and FiO2, heart rate, blood pressure, respiratory rate, temperature)
- Blood (approximately two tablespoons at each blood draw) will be collected for clinical laboratory testing
- All the blood work and vital signs will be done as per the usual standard of care but we will collect the results of those tests for this study. We will also follow up with you at 30 and 90 days.
- Because this project involves the use of medications it is necessary that we make a note of the research subject's participation in the electronic medical record. That way anyone treating you will be aware of the research subject's participation and may be able to avoid any unfortunate outcomes that could arise if the research subject's research participation were unknown.
- The study treatment the research subject gets will be chosen by chance, like picking names out of a hat but done with a computer. Neither the research subject nor the study doctor will choose what experimental study treatment they get. The research subject will have a one-third chance of being given each experimental treatment; low dose blood thinner with an injection under your skin of low molecular weight heparin; full dose low molecular weight heparin with an injection under your skin; or full dose Apixaban given by mouth. The research subject will be told which group you are in.

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- If the research subject is suspected of having COVID-19 infection, you can enroll the research subject in the trial. If the research subject tests for COVID-19 infection is later found to be negative, they will be withdrawn from the clinical trial, treated with medications according to the practice of your attending physician and we will follow the research subject until hospital discharge for safety reasons

Experimental Procedures

The experimental procedures involve randomization to one of three arms: low-dose low molecular weight heparin (enoxaparin), high-dose enoxaparin and full dose apixaban. All blood work and vital signs will be done as per the usual standard of care but we will collect those results for this study. No additional samples will be collected or banked. We will also follow up with you at 30 and 90 days.

For Women:

Since the research subject is participating in a research study that involves drugs or experimental treatment with potential risks to a developing fetus, it is recommended, for the research subject's protection, that the research subject not become pregnant for the duration of the study. The research subject should not participate if she is breastfeeding.

A blood pregnancy test will be done before you begin the study.
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.

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. Research subject should ask study doctor if use of birth control for longer than 30 days after the end of the study is required. If research subject is unsure whether the method of birth control used is acceptable to use while participating in this study, research subject should ask the study doctor before beginning the study. If research subject is less than one year post-menopausal, there is the potential of becoming pregnant. If research subject or their partner becomes pregnant, or may be pregnant, at any time up to the 90 days after the last dose of drugs it is important

that to tell the study doctor immediately. The trial drug may be stopped and a referral may be made to an obstetrician/gynecologist for follow-up. If research subject plans to become pregnant in the year following a clinical trial, they should speak with the study doctor.

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.

For Men:

Since the research subject is participating in a study that involves experimental drugs or experimental treatment with potential risks to a developing fetus, it is recommended that the research subject use a condom and not impregnate a woman or donate sperm while the research subject is taking the study drug, and for an additional 90 days after the research subject stops taking the study drug This is because levels of the study drug may be present in the sperm and/or seminal fluid even after the research subject stops taking the study drug. The research subject is encouraged to tell the research subject's female partner(s) and/or their doctor(s) that he is participating in a clinical trial.

USE OF THE RESEARCH SUBJECT'S DATA AND/OR SPECIMENS:

The researchers would like to ask your permission to keep the data collected from the research subject during this study to use them in future research studies. Please tell us how we may use this material in future research studies.

(1) Will you allow the researchers to store the research subject's information to use in future research studies?

Yes_____ No_____ If no, please stop here. If yes, please continue to the next question.

(2) The researchers can keep the research subject's information stored in one of two different ways: one way will store the research subject's information in a way that it is linked to the research subject's identity (through the use of a code that can indicate the information came from the research subject personally) and the other way will store the research subject's information anonymously (no one will know who the information is from). It will not be stored both ways, so you must choose one of these two options. Please note that if you choose to have the research subject's information stored anonymously, you will not be able to change your mind to ask for the research subject's information to be destroyed at a future date.

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How would you like the research subject's information stored? Please initial **ONE** choice:

I would like my information stored with a link to my identity_____
I would like my information stored anonymously _____

(3) Do you give the researchers permission to **contact you** in the future to collect additional information about the research subject, discuss how the research subject's information might be used, or to discuss
possible participation in another research project? Please initial your choice:

Yes_____ No_____

(4) Do you give the researchers permission to keep the information indefinitely and use them for future studies that are **directly related** to the purpose of the current study? Please initial your choice:

Yes_____ No_____

(5) Do you give the researchers permission to keep the information indefinitely and use them for future studies that are **not related** to the purpose of the current study (for example, a different area of research)? Please initial your choice:

Yes_____ No_____

(5.1) From time to time researchers outside of medicine and related sciences would like to use this information. This might be in the field of anthropology, human origins, mapping human migration patterns etc. Do you give permission to use the research subject's data outside the fields of medicine and biological sciences? Please initial your choice:

Yes_____ No_____

(a) If the future research in a different area can be done without having to know that the information came from the research subject personally, that will be done.
(b) If the future research in a different area requires that it is known specifically who the information came from, then one of the following will be done:
(i) If you allowed the researchers to contact you in the future, they may be able to contact you to explain why the research subject's identifiable information or specimen is needed and what will be done with it. Your permission will be asked to use the research subject's information and/or specimens in that research project.
(ii) If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical, for example, because you have moved, your identifiable

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information and specimens may still be used. The Institutional Review Board (IRB) will be asked for permission to use the information and/or specimens linked to the research subject's identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the information and/or specimens will not be more than a minimal risk to you or the research subject's privacy. The Institutional Review Board (IRB) is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

(6) Do you give permission to have portions of the information or data given **to other researchers,** including those at Mount Sinai, other academic institutions and for profit companies, for use in research within the limits you have chosen above? Please initial your choice:

Yes_____ No_____

(7) Do you give permission to have portions of the data **deposited in large public repositories, (explained below)** for use in research with the limits you may have chosen above? Please initial your choice:

Yes_____ No_____

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to give permission for the research participant to take part in this study, some of the research subject's genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai or another institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use the research subject's information, along with that from many other people. Researchers will always have a duty to protect the research subject's privacy and to keep the research subject's information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

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

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will be responsible for the following things: Tell the study doctor about your current medical conditions;

- Tell the study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbals, and check with the study doctor before starting, stopping or changing any of these. This is for your safety as these may interact with the intervention you receive on this study.
- Tell the study doctor if you are thinking about participating in another research study

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

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.

POSSIBLE BENEFITS:

Research subject is not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others may allow the Study Doctor and their team to discover new information about COVID-19 or how best to provide care to future patients with the disease.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The research subject may experience side effects from participating in this study. The main risks and side effects related to the use of blood thinners is bleeding. Other side effects are known and are listed below, but there may be other side effects that are not expected. You should discuss these with the study doctor.

Other risks include:

- Pain and mild irritation may follow the subcutaneous injection.
- Bruising at the injection site (>10%).
- Thrombocytopenia or Heparin induced thrombocytopenia - a blood condition associated with low platelets (blood cells responsible for clotting) and is also called Heparin-Induced Thrombocytopenia (HIT) (<1%). Patients in the low molecular weight heparin groups are at risk for this condition since the use of heparin is standard practice in acutely ill patients. As per usual practice, the medical team will be monitoring your blood daily for this potential complication.

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- It is possible that other drugs (prescription and non-prescription drugs), vitamins, or herbals can interact with the study intervention. This can result in either the intervention not working as expected or result in severe side 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.

Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to allow the research subject to take part in this research study without any penalty. The choice is totally up to you. Instead of being in this research study, research subject's choices may include: undergoing routine clinical care under the supervision of your physician. If you choose not to participate in this trial, you may still receive anticoagulation at a dosage per the current standard of care for patients at Mount Sinai.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that the research subject have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

If the research subject is injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to the research subject or the research subject's insurance in the ordinary manner and the research subject will be responsible for all treatment costs not covered by the research subject's insurance, including deductibles, co-payments and coinsurance. This does not prevent the research subject from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

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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

If 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. Research subject may be asked whether the study doctor can collect information from routine medical care. If agreed, this data will be handled the same as research data

If research subject decides not to allow data to be used for research anymore, you can contact the researcher and ask to have the research subject's data removed from future use. If any 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 they are. Data that have already been used will not be affected by your decision. Any data that are still linked to research subject's identity by a code the researcher has will be withdrawn so that no future sharing of the 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:

- Research subject is unable to tolerate the study intervention
    - New information shows that the study intervention is no longer in your best interest
    - The study doctor no longer feels this is the best option for you
    - The Sponsor decides to stop the study
    - The Regulatory Authority/ies (for example, FDA) or research ethics board withdraw permission for this study to continue
    - If research subject plans to or become pregnant
- Heparin induced thrombocytopenia (deficiency of platelets in the blood which causes bleeding into the tissues, bruising, and slow blood clotting after injury) or other heparin allergy/hypersensitivity
- Thrombocytopenia if platelet count <50 x109/L
- Major Bleeding
- Coagulopathy (impaired blood clot formation). associated with an elevated INR (e.g. >2.0)

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- (INR stands for International Normalized Ratio. Doctors measure a patient's INR level during a PT-INR test. The PT stands for prothrombin time. The test measures how much time it takes for a patient's blood to clot) or hypofibrinogemia (an abnormal deficiency of fibrinogen a protein involved in forming blood clots in the blood)
- Following invasive procedures where heparin is deemed unsafe to re-institute
- Patients requiring systemic fibrinolytic (process that prevents blood clots from growing) therapy

If this happens, it may mean that research subject would not receive the study intervention for the full period described in this consent form.

If research subject is removed from this study, the study doctor will discuss the reasons with you and plans will be made for the continued care of the research subject outside of the study.

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 212.241.7300.

If the research subject experiences an emergency during the research subject's participation in this research, contact 911 or go to the emergency room, etc.

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.

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 the research subject's physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

There are no financial conflict of interests for the researchers at Mount Sinai Health System for this study

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.

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

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, etc.), e-mail/ medical records number, and other unique codes

The researchers will also get information from the research subject's medical record at Mount Sinai Health System and from your physician or other facilities if you receive care for a relevant condition.

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.

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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 receive 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. If 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.)

- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the centers: InCHOIR at Icahn School Of Medicine at Mount Sinai
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- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the centers: InCHOIR at Icahn School of Medicine at Mount Sinai
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration
- The United States Department of Health and Human Services and the Office of Human Research Protection.

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.

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.

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

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

----------FOR IRB USE ONLY----------

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Icahn School of Medicine at Mount Sinai

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