STUDY INFORMATION:

Study Title: Mount Sinai Center for Transgender Medicine and Surgery (CTMS) Registry

Principal Investigator (Head Researcher): Dr. Joshua D. Safer, MD, FACP

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SUMMARY OF THIS RESEARCH STUDY:

The purpose of this research study is to develop and maintain a Center for Transgender Medicine and Surgery (CTMS) registry that will be the central source of information for transgender and gender non-binary health care across the Mount Sinai health system. A clinical data registry is an interactive database that collects, organizes, and displays healthcare information.
The CTMS Registry aims to support improvements to patient care as well as ensure high quality outcomes research across the health system.

If you choose to participate, you will be asked to

- Allow us to use your health information regarding your treatment.
- Complete Surveys regarding your health and outcome of your treatments

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. We expect to conduct approximately four surveys each year, none requiring more than half an hour to complete. If you sign this consent, you can say no to our requests, for example, if you are busy or not interested. We are only requesting permission to ask. Investigators will explain their studies at the time, and this consent is only for permission to ask if you would be interested. 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 main risks to you if you choose to participate is the loss of confidentiality, but there are procedures to minimize this risk.

Participating in this research will not benefit you.

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 are a transgender or gender non-binary patient and seek care from Mount Sinai.

Funds for conducting this research are provided by Mount Sinai Health System.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last indefinitely.
The number of people expected to take part in this research study in the Mount Sinai Health System could be 7000 people initially and rise by 3000 people per year.

DESCRIPTION OF WHAT'S INVOLVED:

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

- Research activities will take place in the Mount Sinai Health System clinical care locations.
- You may be asked to complete surveys. This can be done either during a visit or online through secure link sent directly to you.
- The surveys include questions regarding your health and your treatments.
- You will receive surveys online (or if chosen on paper) before your surgical information, 2 weeks post treatment, 3 months post treatment, 6 months post treatment, and 1 year post treatment.
- If you feel uncomfortable to complete the form online, you can do so during your visit to a clinic or over the phone with one of the staff.
- You will also be asked to allow us to access your medical records.

USE OF YOUR DATA AND/OR SPECIMENS:

Your willingness to participate in future research will be maintained along with identifiable information so that approved researchers from Mount Sinai Health System can reach out to you for permission to engage in potential future projects.

In addition, your personal information collected during studies may be stored and used for future research. If used for research, personal identifiers will be removed so that information or samples cannot be linked back to you. The following questions will allow you to specify if we may contact you in the future regarding the use of your information:

1.) Do you give us permission to keep your identifiers (name and medical record number) so that we know you are willing to be part of our research cohort? Please initial your choice:

Yes_____ No_____

2.) Do you give IRB approved researchers permission to reach out to you for research projects? Please initial your choice:

Yes_____ No_____

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: Complete the surveys and allow us access to your medical records.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

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

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be to help us understand your quality of life, as well as our quality of care we are providing to you.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- 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.
- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. However, because your information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. For example, it could be used to make it harder for you to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

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.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

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

ENDING PARTICIPATION IN THE RESEARCH STUDY:

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

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data removed from future use. If any data has already been shared

without your identity, it won't be possible to retrieve them because no one will know who you are. Data that has already been used will not be affected by your decision. Any data that is still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place. If your data has already been deposited in an external repository, the study team will request that your data be removed.

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.

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: 212-604-1730

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

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 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 numbers, date of birth, admission, discharge, medical records number, health plan numbers, and the data from your surveys.

The researchers will also get information from your medical record from Mount Sinai Health System, inpatient billing data, Centers for Medicare and Medicaid (CMS) claims files, NY State Statewide Planning and Research Cooperative System (SPARCS) claims data and claims files returned from other payers.

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.)
- 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 United States Department of Health and Human Services and the Office of Human Research Protection.

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?
Yes. 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.

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

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

Notice Concerning HIV-Related Information

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

Certificate of Confidentiality
Number:
CC-OD-21-1631
Issued To
Icahn School of Medicine at Mount Sinai
conducting research known as
Mount Sinai Center for Transgender Medicine and Surgery (CTMS) Registry

In accordance with the provisions of section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d), this Certificate is issued to *Icahn School of Medicine at Mount Sinai* to protect the privacy of subjects in the above named research study, which is collecting or using identifiable, sensitive information. *Joshua Safer* will serve as principal investigator. If there is a discrepancy between the terms used in this Certificate and section 301(d), the statutory language will control.

Research data and biospecimens containing identifiable, sensitive information collected or used during this study are covered by the Certificate beginning on the later of the approval date of this Certificate or the commencement of the project, until the collection or use of identifiable, sensitive information concludes. Identifiable, sensitive information protected by the Certificate and all copies thereof are protected for perpetuity.

The recipient of this Certificate shall comply with all requirements of subsection 301(d) of the Public Health Service Act. This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services.

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 [Required if used for FDA documentation purposes]

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