

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI
THE MOUNT SINAI HOSPITAL
RESEARCH SUBJECT AUTHORIZATION

GCO # _____

Protocol Title: Case Report for publication

Principal Investigator: Dr Dost Sarpel

Co Investigator(s): K.Oikonomou, A. Abrams-Downey, D. Dieterich, A.Mubasher

You have agreed to participate in the study mentioned above and have signed a separate informed consent that explained the procedures of the study and the confidentiality of your personal health information. The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to give you more detailed information about how we intend to use and share your health information in connection with this study. We also need to ask your permission to receive, use and share that information.

You authorize The Mount Sinai Hospital, your doctors and other health care providers to disclose your health information for the purposes described below:

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

- The following personal health information will be collected, used for research and may be disclosed or released in connection with this research study. Medical History (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
 - Medical Record from admissions and clinic visits
 - Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
 - HIV-related information, which includes any information indicating that you have had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV
 - Mental health records
 - Alcohol or Substance Abuse records
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Why is your personal health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use and share the results of these tests and procedures to treat you. The research team may use and share your information to ensure that the research meets legal, institutional or accreditation requirements.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other Mount Sinai Hospital and Icahn School of Medicine at Mount Sinai staff associated with the study).
- The Icahn School of Medicine at Mount Sinai's Institutional Review Board (the committee charged with overseeing research on human subjects) and The Mount Sinai Hospital's and School's Privacy Officers.
- Authorized members of The Mount Sinai Hospital and Icahn School of Medicine at Mount Sinai workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of the Icahn School of Medicine at Mount Sinai and The Mount Sinai Hospital, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above may disclose your personal 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.

- Other collaborating research center(s) and their associate research/clinical staff who are working with the investigators on this project: *Mount Sinai St Luke's-West*
- Journals for case report publication/case reports in conferences
- Research data coordinating office and/or their representative who will be responsible for collecting results and findings from all the centers: *Mount Sinai St Luke's-West*

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- In all disclosures outside of the Icahn School of Medicine at Mount Sinai and The Mount Sinai Hospital, 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.

How long will the Icahn School of Medicine at Mount Sinai and The Mount Sinai Hospital be able to use or disclose your personal health information?

Your authorization for use of your personal 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 have to sign this Authorization?

NO! If you decide not to sign this authorization you will not be allowed 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 personal 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 personal 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 personal 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.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. If you have not already received it, you will also be given The Mount Sinai Hospital Notice of Privacy Practices that contains more information about the privacy of your health information.

By signing this document:

- You are permitting The Mount Sinai Hospital, your doctors and other health care providers to disclose your health information to the researcher for the purposes described above.
- You are permitting the Icahn School of Medicine at Mount Sinai and The Mount Sinai Hospital to use your personal health information collected about you for research purposes within our institution.
- You are also allowing the investigators, Icahn School of Medicine at Mount Sinai and The Mount Sinai Hospital to disclose that personal health information collected about you to outside organizations or people for research purposes as described above.

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- You recognize that your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable) and to run the business operations of the hospital.
- You recognize that once information is disclosed to others outside Icahn School of Medicine at Mount Sinai and The Mount Sinai Hospital the information may be redisclosed and no longer be covered by the federal privacy protection regulations.

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.

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SIGNATURE

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

Signature of Subject or Personal Representative

Print Name of Subject or Personal Representative

Date

Description of Personal Representative's Authority

CONTACT INFORMATION

The contact information of the subject or personal representative who signed this form should be filled in below.

Telephone: _____ (daytime)
_____ (evening)

Email Address (optional): _____

THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.