

**THE MOUNT SINAI HEALTH SYSTEM  
CONSENT FORM TO VOLUNTEER FOR A RESEARCH BIOREPOSITORY  
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION  
Icahn School of Medicine at Mount Sinai, Mount Sinai West**

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Study ID #: IRB-20-07942

Form Version Date: 08/07/2020

**STUDY INFORMATION:**

**Study Title:** Universal Consent for Mount Sinai Biorepository

**Principal Investigator (Head Researcher):** Rachel Brody, MD, PhD

**Physical Address:** 1468 Madison Ave, Annenberg Building Rm 15-05, New York, NY 10029

**Mailing Address:** One Gustave L Levy Place, Box 1194, New York, NY 10029

**Phone:** 212-241-0678

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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 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 collect medical samples from volunteers to be used in future research projects that may involve genetic testing. We will collect only samples that are taken from you for routine clinical purposes. The samples will be linked to medical information from your medical record, which makes the samples more valuable for research. The samples and medical information are held in a biorepository.

If you choose to participate, you will be asked to review this consent form, ask any questions you may have, and sign to give us permission to collect and use your specimens and data. You will not be required to return to the hospital/doctor's office for specimens as we will only use left-over samples that were already taken for clinical purposes.

The collected samples and information will be banked and used for years, as long as they are useful, or until you cancel your participation. There are no costs to you to participate, and you will not get paid to participate. None of the information that is learned from research with your samples will be given to you.

There is a small risk to the confidentiality of your samples or information by participating in the research biorepository. The risks are mainly those that could result if information about you is revealed, inappropriately or accidentally. Depending on the information, the release could be upsetting or embarrassing to you or possibly affect your insurability or employability. You may also be troubled by not being able to decide which future research projects will use your samples. In fact, if

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you hear about certain research using these samples, you may even find that you would have preferred not participate in the biorepository if you knew the project details.

There are no direct benefits to you expected from participating in this biorepository but the hope is that research done with your specimens will advance medical care for all.

If you are interested in learning more about the research biorepository, please continue to read below.

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**PARTICIPATION IN THE RESEARCH BIOREPOSITORY:**

The research biorepository will be fully explained to you by a member of our team, or through an educational presentation. 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 later that might make you change your mind about participating in the research biorepository will be given to you promptly.

Funds for conducting this research are provided by Mount Sinai.

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**LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:**

Your time required to participate in this project will be limited to the time needed to read and discuss this consent form. We will not ask you back to collect more samples or information. After you grant your consent, we will be able to collect your biospecimen leftovers indefinitely until your consent is withdrawn. It is our hope that you are one of thousands of volunteers who contribute to this biorepository.

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**DESCRIPTION OF WHAT'S INVOLVED:**

During the course of medical care tests, we may collect blood, urine, or other samples from your body during surgery or biopsies. Usually any extra material is thrown away after testing. We are asking your permission to keep this extra material. No additional tissue will be removed, and your procedure or surgery will not be prolonged.

Routine clinical care sometimes requires blood samples to be obtained. Blood can also be utilized for research purposes. When you are having blood drawn for clinical use, we may collect an additional blood sample (no more than 10 mL or 2 teaspoons); this will be approved by your clinical care team. The additional blood sample may be collected more than once, but only when you are already having blood taken for your clinical care. We may also collect left-over samples of urine, saliva, stool, and other biospecimens as part of this study as well.

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In addition to using your left-over samples, including for genetic testing, we also wish to collect information from your medical record maintained within the Mount Sinai Health System. Collected information may include all of your records, existing now or in the future, and may include information that is sensitive, like HIV status, psychiatric and substance use history, sexual history, genetic information, and the like. We will also collect your name, address, age, gender, race and family history. The data from your medical record will be linked to your stored samples to allow us to improve the quality of research performed.

In general, we will not release samples or information that directly identify you. Instead we will use a code that links your samples and information with who you are. We will not release that code. Occasionally some information that could indirectly identify you may be provided to researchers, such as a date of birth or a date of an operation. In those cases, the biorepository will ask the Institutional Review Board (IRB) for permission to use that information. The IRB can give permission for researchers to use and share information that might identify you only if the IRB finds that it will not pose a significant risk to you or your privacy. The IRB is a committee of doctors, scientists and nonscientists, including people not associated with Mount Sinai, who have the responsibility to protect people who participate in research.

The purpose of the biorepository is to share your samples and information with qualified researchers to help advance medicine. We may share your samples and information with scientists and researchers from the Mount Sinai Health System and its affiliates, other universities, government, hospitals, health related companies, including for-profit companies, or research institutes throughout the world. These studies may or may not be related to your particular condition. We will not ask you for permission to use your samples or information for these studies, and it is possible a study may be conducted that you would not agree to, if we had asked.

This research might include genetic research, including “whole genome sequencing,” which is a laboratory process that maps out all of your genetic information.

Reports about research done with your medical information and biospecimens will not be given to you or your doctor. These reports will not be put into your medical record and they will not affect your care.

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 take part in this study, some of your 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 will always have a duty to protect your privacy and to

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keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

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**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.

You should also know that it is possible that products may someday be developed through research that uses your samples or information. There are no plans to share any profits from such products with you.

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**POSSIBLE BENEFITS:**

You are not expected to get any benefit from taking part in this research study. However, research done with the samples and information may lead to a better understanding about disease and what can be done to prevent or treat disease.

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**POSSIBLE RISKS AND DISCOMFORTS:**

There are no physical risks associated with taking part in the biorepository.

There is some risk to the confidentiality of your samples or information by taking part in the biorepository. In the unlikely event that there is an accidental disclosure of information that could be used to identify you, it could embarrass you, or cause fear or guilt, or damage to your social standing or reputation or your family relationships. It could also cause others to discriminate against you or impact your employability and earnings.

The use of large databases, especially of genetic data, increases the privacy risks and has additional risks:

- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will not be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is small but has been growing. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) 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,

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stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

- **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.

**Insurance Risks** – There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most larger employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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**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.

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**ENDING PARTICIPATION IN THE RESEARCH BIOREPOSITORY:**

You may stop taking part in the research biorepository 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 samples and/or information to be used for research anymore, you can contact the Principal Investigator and ask to have your samples and/or information removed from the research biorepository so that no future sharing happens. If your samples or information have already been shared with researchers, we will ask those researchers to stop using them. However, if your samples or information have been shared without a code that links them to you, it won't be possible to stop the research because no one will know who you are. Samples and information that have already been used will not be affected by your decision.

The Principal Investigator or Mount Sinai may stop your involvement in the research biorepository at any time. This may be because the biorepository research is stopped, the investigator believes it is in your best interest, or for any other reason.

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If specimens or data have been stored as part of the research biorepository, they too can be destroyed for any reason, without notice to you and without your consent.

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**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 212-241-0678.

An Institutional Review Board has reviewed and approved this research biorepository. You may reach a representative of the Program for Protection of Human Subjects for Mount Sinai Health System at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office can also help to direct your call to the right person within the Mount Sinai Health System if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

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**MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:**

The Health Insurance Portability and Accountability Act (“HIPAA”) requires Mount Sinai Health System and each of its entities to protect the privacy of information that relates to your past, present, and potential future medical condition (the law calls this “protected health information” or “PHI”). As you take part in this Biorepository the research team and others will have to use and share some of your private protected health information. Consistent with HIPAA, we are asking your permission to receive, use and share that information, as explained below.

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

As part of this research Biorepository, the research team will collect any and all information in your medical records that are held by Mount Sinai Health System (which includes Mount Sinai Hospital, Mount Sinai Beth Israel, Mount Sinai Brooklyn, Mount Sinai West, Mount Sinai St. Luke’s, New York Eye and Ear Infirmary of Mount Sinai, and Icahn School of Medicine at Mount Sinai). This information may include, for example, information from clinical laboratory testing; imaging studies

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(such as ultrasounds, CT scans, MRIs, X-rays, nuclear medicine, etc.); clinical pathology; doctors' and nurses' clinical notes; medication and prescription information; and any clinical information related to your biospecimens.

Also included is information that some will see as being particularly sensitive, such as:

- Birth control and abortion (family planning)
- Mental health conditions
- Alcohol or drug use problems
- Genetic (inherited) diseases or tests
- HIV or AIDS
- Sexually transmitted diseases
- Employment Information
- Living Situation
- Social Supports
- Insurance Claims Encounter Data

The information collected for this Biorepository could include information created before and after the date you sign this form.

Why is your protected health information being used?

The main reasons for using or sharing your personal contact information includes the following:

- To conduct the study, as described above, and to determine research results
- To contact you during the study
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research data bases, so that scientists can design better research studies to develop new therapies for patients and to improve their understand of diseases
- To help with Mount Sinai medical treatment, billing or healthcare operations.

Research results using your samples or information 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 research team and other authorized members of 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.

Who, outside Mount Sinai, might receive your protected health information?

To allow the research Biorepository to fulfill its purpose, it will be sharing your tissue, blood samples, and protected health information with Mount Sinai collaborators, business partners, subcontractors,

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and agents and their research/clinical/other staff. These may be located anywhere in the world and they may be academic, public, private, not for profit, or for profit. This list will change from time to time, but now it includes Surveillance Research Program (SRP) in the National Cancer Institutes' Division of Cancer Control and Population Sciences (DCCPS). Some of these organizations may not be covered by the same federal privacy protection regulations (HIPAA) that apply to Mount Sinai. In all cases organizations receiving information from the Biorepository will be contractually obligated to protect your privacy and use your information as described in this consent.

Information might also be released to federal and state agencies and other government bodies, if required by law or necessary for them to oversee the research, including:

- Office for Human Research protections (OHRP) of the US Department of Health and Human Services (HHS)
- US Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Other agencies that oversee research

There will be research disclosures that either include certain types of personal protected health information, such as a 5-digit zip code or the date of a hospital visit, or have enough different types of protected health information that re-identification of the information becomes too easy. These disclosures are also covered by HIPAA privacy protections. Much information sharing will have limited or no identifiers and will not be covered by HIPAA. In all cases organizations receiving information from the research Biorepository will sign a contract and commit to protect your privacy and use your information as described in this consent. It is possible that the shared records and information will be supplied with a unique code number. In these instances, Principal Investigator will make sure that the key to the code will be kept securely and not shared with these outside entities. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy.

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?

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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 Biorepository may still use your information if that information is necessary to complete any studies already in progress. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the Biorepository. You can also tell us you want to withdraw from future contributions of data or samples to the Biorepository without canceling the Authorization to use the data already in the medical record. Your decision will not impact your ability to get medical care.

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**Notice Concerning HIV-Related Information**

By signing this authorization, 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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**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

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