

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

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**STUDY INFORMATION:**

**Study Title:** Biologics And Clinical Immunology Cohort at Sinai (BACICS)

**Principal Investigator (Head Researcher):** Rachel L. Miller MD

**Physical Address:** Icahn Medical Institute, 11<sup>th</sup> floor

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**SUMMARY OF THIS RESEARCH STUDY:**

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is establish a bioregistry of patients receiving biologic therapy or infusions at the Mount Sinai Therapeutic Infusion Center and affiliated practices. One goal is to establish a registry of specimens and data that includes information about where people live, their exposures, the activity level of their immune disease over time with treatment. We will ask questions common to other registries so we can make comparisons across cohorts of patients. The second goal is to address specific research questions related to your disorder and/or medication and novel immune biomarkers to assess how well a biologic therapy is working. Most patients will be recruited from the Mount Sinai Therapeutic Infusion Center (TIC), although others receiving infusions elsewhere or at home will be recruited from outpatient Sinai affiliated clinical practices

If you choose to participate, you will be asked to complete a questionnaire, provide a blood, urine and saliva specimens. You will be asked to swab the inside of your cheek three times. You will be asked up to allow 16 small tape strips be applied to the skin and then removed. You will be asked to allow one nasal swab be collected from your nose. This will occur at the first study visit, then 3 months later, then every 6 months for a total of 3 years. Each study visit is expected to last in total about 45 minutes. None of this will affect your standard of care. This study will not result in extra visits nor take much extra time. Samples will be labeled with a code and stored in the laboratory. There are no costs associated with participating in the study. You will be compensated for each study visit.

The main risks to you if you choose to participate are temporary discomfort related to the blood draw, tape strips or nasal swab.

Participating in this research will not benefit you.

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If you are interested in learning more about this study, please continue to read below.

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**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 receiving a biologic medication as part of your medical care at Mount Sinai.

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

Your participation in this research study is expected to last about 45 minutes at each visit. To keep the amount of time low, we will ask you if you want to complete questionnaires and return them to us by fax, mail or email. There will be one visit at enrollment, 3 months later, then every 6 months until three years duration. These will coincide with your medical visits.

The number of people expected to take part in this research study at Mount Sinai Hospital is 3000.

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**DESCRIPTION OF WHAT'S INVOLVED:**

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

At the Therapeutic Infusion Center or at your Sinai Doctor's office, after providing informed consent, we will ask you to:

1. Complete a questionnaire that asks about your medical condition and medications.
2. Contribute three test tubes of blood (about four teaspoons) from a blood draw.
3. Provide saliva into an appropriate container.
4. Swab the inside of your cheek with three separate swabs. You will need to firmly brush the inside of your cheek for one minute for two of the swabs, and for 30 seconds for the third.
5. Avoid applying creams to the skin three days prior to the tape strip procedure.
6. Allow us to place and then remove up to 16 small tape strips on normal appearing skin. Using a pen, we make small marks on the skin after placement of the first tape strip to ensure consistent placement of each subsequent tape strip. The strips will be placed at the same spot in rapid succession.
7. Allow us to swab the inside of your nose.
8. Provide us with a urine sample into an appropriate container.

The skin tape strips, blood test, and swabs of the cheek and nose may be used to measure which genes may be expressed and at what levels. Therefore, these samples will be used as Genetic Tests. These

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tests are being done for research purposes only. The material will be stored for as long as deemed useful for research purposes.

These procedures will be performed by a study investigator and occur during one visit that is expected to last about half an hour in total. The results are not immediately clinically relevant, so they will not be shared with you.

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**USE OF YOUR DATA AND/OR SPECIMENS:**

The researchers would like to ask your permission to keep the data and specimens (like blood, skin tape, swab or urine) collected from you 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 your information and/or specimens 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 your information and/or specimens stored in one of two different ways: one way will store your information and/or specimens in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will store your information and/or specimens 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 your information and/or specimens stored anonymously, you will not be able to change your mind to ask for your information and/or specimens to be destroyed at a future date. How would you like your information and/or specimens stored? Please initial **ONE** choice:

I would like my information and/or specimens stored with a link to my identity \_\_\_\_\_  
I would like my information and/or specimens stored anonymously \_\_\_\_\_

**(3)** Do you give the researchers permission to **contact you** in the future to collect additional information about you, discuss how your information and/or specimens 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 and/or specimens 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 and/or specimens indefinitely and use them for future studies that are **not related** to the purpose of the current study (for

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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 your information and/or specimens 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 and/or specimens came from you personally, that will be done.

**(b)** If the future research in a different area requires that it is known specifically who the information and/or specimens 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 your identifiable information or specimen is needed and what will be done with it. Your permission will be asked to use your 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 data 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 your 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 your 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 specimens and/or information 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 specimens and/or 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 take part in this study, some of your

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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 your information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

This research will not include whole genome sequencing.

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**YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:**

If you decide to take part in this research study you will be responsible for avoiding creams at the site of the tape strips and contacting the study team if there are any questions.

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**COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:**

If you agree to take part in this research study, we will pay you \$20 cash for your time and effort at each study visit.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal \$600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

You should also know that it is possible that products may someday be developed with the help of your specimens and data, and there are no plans to share any profits from such products with you, regardless of whether your identifiable information is removed.

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**POSSIBLE BENEFITS:**

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include knowledge that is eventually advantageous to other immunology patients.

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**REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:**

- 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.

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- Tape strips could cause very mild skin irritation and discomfort which is temporary. The pressurizer which is used to apply equal pressure each time is not an approved medical device.
- The risks associated with the nasal swab includes discomfort or pain, transient nosebleed, tearing of the eyes, runny nose.
- There are no known risks with collection of saliva, urine or cheek swabs.
- 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) will never be placed into a scientific database. 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.

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**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.

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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 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 samples and/or data to be used for research anymore, you can contact the researcher and ask to have your samples and/or data removed from future use. If any samples or data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. Any samples and/or data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your samples and/or data will take place. If your samples have already been deposited in an external repository, the study team will request that your samples be removed.

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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.

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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 212-659-9436.

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.

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**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.

The following investigators receive financial compensation from companies that develop or manufacture biologic and/or immune therapies: Dr. Emma Guttmann, Dr. Fred Lublin, Dr. Saurabh Mehandru, & Dr. Linda Rogers.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at <http://icahn.mssm.edu/>.

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**MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:**

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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/fax number, email, date of birth, medical record number.

The researchers will also get information from your medical record at Mount Sinai Hospital.

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- 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.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project. These sites are available on request.

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- A future sponsoring government agency and/or their representative who may need to confirm the accuracy of the results submitted to the government or the use of government funds.
- 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, 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.

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.

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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.

**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.

<hr/>	<hr/>	<hr/>	<hr/>
Signature of subject	Printed Name of Subject	Date	Time

**PERSON EXPLAINING STUDY AND OBTAINING CONSENT:**

<hr/>	<hr/>	<hr/>	<hr/>
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.

<hr/>	<hr/>	<hr/>	<hr/>
Signature of Witness	Printed Name of Witness	Date	Time

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