Study ID #: GCO# 18-0003 **Form Version Date: May 4, 2020**

TITLE OF RESEARCH STUDY:

Title: "SAPPHIRE Registry: Safety of Immunosuppression in A Prospective Cohort of Inflammatory Bowel Disease Patients With a HIstoRy of CancEr"

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Steven Itzkowitz, MD

Physical Address: Icahn School of Medicine; Annenberg 5th Floor, Room 12.

Mailing Address: One Gustave Levy Place, Box 1069, NYC, NY 10029

Phone: (212) 241-8788

WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to study the effect of immunosuppression therapy for IBD on incident (new or recurrent) cancers in inflammatory bowel disease (IBD) patients with a previous history of cancer. We have developed a prospective Registry of such patients with IBD who have a history of cancer, and are following them with a yearly questionnaire for the next 5 years to determine whether they development of new or recurrent cancer.

You may qualify to take part in this research study because you 1) have IBD and had your first cancer within the last 5 years, 2) are 18 years or older, and 3) speak English or Spanish.

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

- You will be asked to sign an Informed Consent Form, and in some cases, a medical release form (if your medical records are not in the Mount Sinai Health System).
- You will be asked some demographic and health related questions.
- Your medical record will be analyzed and you will be followed for 5 years to see if you develop a new or recurrent cancer. You will also receive a call every year to update your file.

Funds for conducting this research are provided by the Crohn's and Colitis Foundation.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last approximately 5 years, until your last follow-up call is completed.

The total number of people expected to take part in this research study is 400.

DESCRIPTION OF WHAT'S INVOLVED:

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

If you are a Mount Sinai patient:

As part of your usual care, and after your regular doctor or clinic visits, the research team will examine your medical record to see which medicines you are still taking, and whether you have developed any new or recurrent cancers. If you are hospitalized at Mount Sinai, your in-patient records will also be examined. Your medical record will also be examined for any phone calls to your doctor's office that might be of relevance to the research project. The researchers will be keeping track of whether your IBD is in remission, or whether you are having symptoms. If your IBD flares, the researchers will record any blood tests, x-rays or endoscopies you might undergo as part of your usual care. If you develop a new or recurrent cancer, the researchers will be keeping track of the type of cancer, date of diagnosis, stage and treatment of cancer, and how you are doing. You will need to sign this consent form, or we could provide you a website link so you can sign the electronic version of this Informed Consent Form (*iOPEN e-consenting platform).*

If you are not a Mount Sinai patient:

We will either get your contact information from your doctor (with your permission) or you will contact us directly. One member of our research team will review the study eligibility with you, either over the phone or in person. The researchers will be keeping track of whether your IBD is in remission, or whether you are having symptoms. If your IBD flares, the researchers will record any blood tests, x-rays or endoscopies you might undergo as part of your usual care (if necessary we will need to have copies of your medical records, either provided by you or we will request them directly from your doctor's office). After reviewing the eligibility, we will send you a blank Informed Consent Form, which you will need to sign and send back to us. Alternatively, we will send you a website link so you can sign the electronic version of the Informed Consent Form (*iOPEN e-consenting platform)*. Once you sign the Informed Consent Form, we will ask you to complete the questionnaire (in person or over the phone). If you develop a new or recurrent cancer, the researchers will be keeping track of the type of cancer, date of diagnosis, stage and treatment of cancer, and how you are doing.

No invasive tests (blood tests, x-rays, endoscopies, or other procedures) will be performed for the purpose of this research study. No drugs or devices will be administered to you as part of this study.

The only research related activity will be to complete a questionnaire (demographics and heath related questions) and to complete a yearly follow-up questionnaire (one every 12 months for a period of 5 years), either in person or over the phone, to see if there were changes to your health and/or IBD/cancer conditions.

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:

- Signing the Informed Consent Form, and in certain cases a medical release form if your medical records are outside the Mount Sinai Health System,
- Completing a baseline questionnaire,
- Permitting the researchers to have access to your electronic medical record for the next 5 years, and
- Completing follow-up questionnaires (once a year).

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 will not be reimbursed for your travel or time that may be required for study visits.

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 that the researchers will learn more about whether the medicines used to treat IBD have any impact (positively or negatively) on developing new or recurrent cancer.

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.

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.

You may also 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 the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

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 PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number: (212) 241-8788.

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 disclosed (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, e-mail, and medical records number.

The researchers will also get information from your medical record from Mount Sinai Hospital or your doctor's office if you are not a Mount Sinai patient.

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 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 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.
- Crohn's and Colitis Foundation (Sponsor)
- University of North Carolina (data analysis)

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.

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?

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.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

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.

Signature Block for Capable Adult

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.

DO NOT SIGN THIS FORM AFTER THIS DATE → **4/9/2021**

Signature of subject	Date
Printed name of subject	

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this 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 to consent process	*Date*
Printed name of person witnessing consent process	