Study ID #: [GCO 16-1606, 16-00948] **Form Version Date:** [9/22/2022]

TITLE OF RESEARCH STUDY:

Title: Women with Inflammatory bowel Disease and Motherhood: A Prospective Registry

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Marla C. Dubinsky, MD

Physical Address: Susan and Leonard Feinstein Inflammatory Bowel Disease Clinical Center
17 E. 102nd St, Floor 5
New York, NY 10029

Mailing Address: One Gustave L. Levy Place
Box 1656
New York, NY 10029

Phone: (212) 241-5415

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 determine the outcomes of pregnancies with inflammatory bowel disease. One arm of the study is to look specifically at impact of surgery on infertility in women with IBD. We also aim to examine the other factors that may predict fertility outcomes. Previous research in this field has been compromised by poor research design and outdated surgical techniques. We plan to use the results of our research to inform women and physicians regarding the true effect of surgery on fertility.

You may qualify to take part in this research study because you have been diagnosed with IBD and desire to get pregnant in the next year, or are already pregnant.

Funds for conducting this research are provided by Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your estimated participation in this research study is expected to last up to 12 months if participating in the arm evaluating fertility and IBD, or until you become pregnant.

If you are already pregnant, your involvement in the study will continue from time of enrollment until 6 weeks postpartum or once pregnant 6 weeks postpartum.

You will be contacted on a monthly basis to complete online questionnaires. This means you will be asked to complete up to questionnaires until you become pregnant, or opt out of the study.

The number of people expected to take part in this research study at Mount Sinai is approximately 315. For the arm of the study examining fertility and surgical history the total number of people expected to take part in this research study is 120.

DESCRIPTION OF WHAT'S INVOLVED:

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

After the informed consent process, you will be interviewed by a study coordinator regarding your background and medical information. This interview will take place over the phone and/or through a secure online survey. This will take about 30 minutes. This will include demographics, global health, medications, IBD history, medical history, reproductive health, social history, family history, surgical information, and information regarding your male sexual partner. Your medical chart will be reviewed.

After that, you will receive instructions to complete questionnaires on a monthly basis. This online questionnaire may be completed on your own or you may also be contacted by a study coordinator who may complete the questionnaire with you. The questionnaire will ask questions regarding your general health, reproductive health, sexual function and pregnancy-related information (if you become pregnant or are already pregnant).

The monthly questionnaires will ask you regarding the results of blood and urine tests for ovulation and pregnancy checks you may choose to take at your doctor's office or at home and information on your pregnancy. However, no specimens will be collected for the specific purposes of this study.

The researchers would like to ask your permission to keep data collected from you during this study to use them in future or current research studies. They would also like to know your wishes about how they might use your data in future research studies. You should also know that it is possible that products may someday be developed with the help of your data, and there are no plans to share any profits from such products with you.

(1) Will you allow the researchers to store your data to use in current or future research studies?

Yes_____ No_____ If no, please stop here. If yes, please continue to the next question.

(2) Do you give the researchers permission to **contact you** in the future to collect additional information about you, discuss how your data might be used, or to discuss possible participation in another research project? Please initial your choice:

Yes_____ No_____

(3) Do you give the researchers permission to keep the data indefinitely and use them for future studies that are **directly related** to the purpose of the current study? Please initial your choice:

Yes_____ No_____

(4) Do you give the researchers permission to keep the data indefinitely and use them for future studies that are **not related** to the purpose of the current study (for example, a different area of research)? Please initial your choice:

Yes_____ No_____

(a) If the future research in a different area can be done without having to know that the data 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 data came from, then one of the following will be done:

(i) If you allowed the researchers to contact you in the future, they will be able to contact you to explain why your data is needed and what will be done with it. Your permission will be asked to use your 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 data may still be used. Either all links to your identity will be removed from the data, or an Institutional Review Board will be asked for permission to use the data linked to your identity. The Institutional Review Board (IRB) is a committee of doctors and scientists and non-scientists and people not associated with this hospital or medical school whose job it is to protect people who participate in research. The IRB can give permission for researchers to use and share health information connected to specimens that are linked to people's identities, but only if it determines that doing this will not be more than a minimal risk to people or their privacy.

(5) Do you give permission to have portions of the data **given to other researchers** at Mount Sinai or other institutions for use in research that is either related or not related to the purpose of this study? 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:

Completing an interview via telephone, followed by monthly questionnaires online or via telephone.

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.

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 increased understanding of the IBD or impact of surgery on fertility in women with IBD.

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. At that point, you will be asked to document your withdrawal from the study and will be removed from the study.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

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 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) 824-7785

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.

Dr. Marla Dubinsky (the Principal Investigator in this study) receives financial compensation as a consultant for companies that research and develop therapies used in the treatment of Inflammatory Bowel Disease (IBD).

Dr. Dubinsky is a co-founder, equity owner, CEO, and a member of the Board of Directors for Trellus Health - a public, for-profit company that develops digital health solutions to manage chronic conditions such as IBD.

Dr. Dubinsky is a co-founder, scientific advisor, and equity owner in MiTest Health, a private company that has developed a computer-based tool to predict complications of Crohn's disease. This tool has been licensed to Takeda.

Dr. Michael Dolinger (a co-Investigator in this study) receives financial compensation as a consultant for Neurologica Corp, a company that produces the ultrasound equipment, which is being used to monitor the IBD activity in this study.

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/.

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. This information would only be collected if you provide an authorization to release your medical records for the purposes of this study.

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 will collect your name, dates directly related to the individual (birth, admission, discharge, date of death, etc.), and medical records number.

If you receive care at Mount Sinai, the researchers will also get information from your medical record directly.

During the study the researchers will gather information by:

- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)

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.)

- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the centers: Dartmouth College.
- The United States Department of Health and Human Services and the Office of Human Research Protection.
- Other data sharing centers: Monash Health and St. Vincent's Hospital Melbourne, from Australia.

In all disclosures outside of Mount Sinai, you will not be identified by 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?

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?

If you receive care at Mount Sinai, then 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.

If you do not receive care at Mount Sinai, then you will need to complete an authorization to release your medical records to us.

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.

Signature of subject	Date
Printed name of subject	Time [required if used for FDA documentation purposes]

Person Explaining Study and Obtaining Consent

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

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	Time