STUDY INFORMATION:

Study Title: Women with inflammatory bowel Disease and Motherhood: A Prospective Registry

Study site(s): Icahn School of Medicine at Mount Sinai

Principal Investigator (Lead Researcher): Marla C. Dubinsky, MD

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

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. The research team also aims 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 Previous research in this field has been compromised by poor research design and outdated surgical techniques. The research team plans to use the results of the research to inform women and physicians regarding the true effect of surgery on fertility.

If you choose to take part, you will be asked to:

- Complete an interview via telephone or online.
- Complete monthly health questionnaires via telephone or online.
- Allow researchers access to your information in your medical record.
- Agree to have private information (name, address, phone number) and study data collected and stored at Icahn School of Medicine at Mount Sinai
- There are no costs associated participation.
- You will receive up to $100 for taking part in this research.

If you choose to take part, the main risks to you are risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

You will not benefit directly from taking part in this research. However, possible future benefits to others include increased understanding of IBD or the impact of surgery on fertility in women with IBD.

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

STUDY PARTICIPATION:

You may qualify to take part in this research study because you are a woman who has been diagnosed with IBD and desire to get pregnant or are already pregnant.

Your participation in this research study if participating in the arm evaluating fertility and IBD is expected to last approximately 18 months or until 12 weeks after you become pregnant. The research team will continue to review your medical record up to 12 months post-partum.

You will be contacted on a monthly basis to complete online questionnaires. This means you will be asked to complete questionnaires every month until you become pregnant and for the first 3 months (12 weeks) of pregnancy, or opt out of the study.

If you are already pregnant, your involvement in the study will continue from time of enrollment until up to 12 months postpartum. If you are already pregnant, your participation requires permission to review your medical record. You do not need to complete any questionnaires or forms.

There are 1,200 people expected to take part in this research study at Mount Sinai.

Funds for conducting this research study are provided by The Icahn School of Medicine at Mount Sinai, and The Leona M. and Harry B. Helmsley Charitable Trust.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

- You will complete a baseline questionnaire. This will take place over the phone and/or through a secure online survey and will take about 30 minutes. The questionnaire 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 also be reviewed.
- 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 questions 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.

USE OF YOUR DATA:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number) and study 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.

You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

If you are completing the consent document through electronic consent, these questions will appear at the end of the page of the electronic consent.

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

Yes_____ No_____ If you select No, please stop here. If yes, continue to the next question.

(2) The researchers may wish to use your personal contact information to contact you in the future. 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 may 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 data 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 identifiable health information connected to data that are linked to people's identities, but only if it determines that doing this will not be more than 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 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:

- Complete a baseline questionnaire via telephone or online
- Complete monthly health questionnaires via telephone or online
- Allow researchers access to your information in your medical record. If you receive care outside of Mount Sinai, complete an authorization to release your medical records to the researchers.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this study, you will be paid $100 in the form of Amazon gift cards for your time and effort. You will be paid $50 for the completion of the baseline survey associated with this study, and $50 after completion of final survey at the end of study participation.

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 happens 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.

Being in this study will not cost you anything extra. 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.

POSSIBLE BENEFITS:

This study is not designed to benefit you personally. However, possible future benefits to others include increased understanding of IBD or the impact of surgery on fertility in women with IBD.

POSSIBLE RISKS AND DISCOMFORTS:

There are some risks associated with participation in this study:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Group Risks - Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. 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 discrimination.
- Privacy Risks - Your name and other information that could directly identify you (such as an address, date of birth, or social security number) will never be placed into a shared database. However, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher 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 researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher 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 taking part in the research study.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai 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 research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

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 Lead Researcher at phone number 212-824-7785 or the Research Coordinator(s) at 212-824-7786 or email at Wisdom@mssm.edu.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

Dr. Marla Dubinsky (lead researcher this study) and also Dr. Maia Kayal and Dr. Michael Dollinger (researchers in this study) are paid consultants for companies that research and develop therapies for IBD.

In addition, Dr. Dubinsky is a co-founder, equity owner, chair of the Scientific Advisory Board, 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 inflammatory bowel disease. 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.

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

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be 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.
- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)

Why is your PHI being used?

Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. 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 Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants 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.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?

As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, 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 Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- St. Vincent's Hospital Melbourne, from Australia.
- The University of Minnesota (a collaborator with the research).
- The Leona M. and Harry B. Helmsley Charitable Trust (sponsor).

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher 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 (IRB) 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, *OHRP, 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.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI 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 research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, 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?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff.
The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this 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 taking part in the research study.

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 PHI.

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, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

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.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) 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 participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

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 participant, and that consent was freely given by the participant.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time