Lipid Profiles as Predictor of Adverse Maternal and Neonatal Outcomes: A Pilot Study

PI: Samsiya Ona
NCT05535660
Document Date: 3/5/2024

**STUDY INFORMATION:**

**Study Title: Mid- and late-trimester lipid profile as predictor of adverse maternal and neonatal outcomes**

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

**Principal Investigator:** Samsiya Ona, MD

**Research Staff:** Nicola Tavella, MPH Nicola.tavella@mssm.edu
Dayana Mirzaliev dayana.mirzaliev@mssm.edu

**Physical Address:** 5 East 98 Street, Floor 2, New York, NY 10029

**Mailing Address:** 5 East 98 Street, Floor 2, New York, NY 10029

**Phone:** 212-241-3888

**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 research study is to evaluate whether testing for lipids (different types of fats in the blood) in pregnancy can be used to predict outcomes in mom and baby. The high metabolism (or energy usage) state of pregnancy results in changes including BMI (body mass index), blood pressure, glucose (sugars) and components of cholesterol or fats that are all necessary to support the growth of the fetus. Participants between the ages of 18-50 receiving prenatal care at Mount Sinai Hospital will be eligible to enroll. Participants will have blood drawn twice; the first blood work is a fasting blood draw (separate blood draw) around the time of the standard glucose test. The second blood draw is drawn at the time of routine third trimester blood work.

If you choose to participate, you will be asked to:

- Have a fasting lipid panel (one small tube of blood) drawn twice; first around the time of the oral glucose challenge test (24-28 weeks), and again in the third trimester around 36 weeks.
- Give permission to review your medical record to identify delivery outcomes



The main risks to you if you choose to participate are the possibility of a breach in confidentiality or loss of private information, but steps have been implemented to minimize this risk. There is also the discomfort and risks that come along with blood draws such as bruising and discomfort.

You will not benefit directly from taking part in this research. You will not receive any results from the analyses done on samples collected for this study, except in the form of publicly available publications.

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

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**STUDY PARTICIPATION:**

You may qualify to take part in this research study because you are a pregnant patient between the ages of 18-50 receiving prenatal care at Mount Sinai Hospital and plan to deliver at Mount Sinai Hospital.

Your participation in this research study is expected to last about 3 months. It is estimated to take approximately 1 month to enroll an adequate number of subjects in the study, and in total approximately 6 months from enrollment to primary analyses. The number of people expected to take part in this research study is 160.

Funds for conducting this research are provided by the Icahn School of Medicine at Mount Sinai.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**DESCRIPTION OF WHAT IS INVOLVED:**

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

- Have a fasting lipid panel (one small tube of blood) drawn twice; first around the time of the oral glucose challenge test (24-28 weeks), and again in the third trimester around 36 weeks.
- The lipid panel measures different fats in the body including total cholesterol, triglycerides, high density (good) and low density (bad) cholesterol. This blood work is collected fasting, which means it done in the mornings on an empty stomach which is why it should be drawn prior to the glucose challenge test (GCT) which is a test that involves drinking 50g of a glucose drink and having your blood sugar measured 1 hour after. These tests will take place at your OBGYN office lab.
- Give permission to review your medical record to identify delivery outcomes

## USE OF YOUR DATA AND/OR SAMPLES:

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number), study data, and samples (blood, tissue, urine, saliva, or any other body matter.) may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed, and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form, or take part in the study.

By signing this form, you give permission to have portions of your data and/or samples deposited in large public databases (repositories) for use in research with the limits stated above Please read the paragraphs below which explains repositories.

To do more powerful research, it is helpful for researchers to share data and/or samples from the people they study. They do this by putting data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. . Researchers can then use the data and/or samples from multiple studies to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases, but they will not share your direct identifiers (for example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your data, along with that from many other people. Researchers may use your samples for genetic sequencing and other experimental testing. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are always risks associated with data and/or sample collection and sharing. They are described in more detail in the Risks section.

## 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:

Donate one additional tube of blood during fasting lipid panel (extra stick) at the time your scheduled prenatal care appointment. The first sample is collected around the time of the oral glucose



challenge test (24-28 weeks) and the second is collected in the third trimester around 36 weeks, at Mount Sinai Hospital. With participation in the study, you will need to receive prenatal care during your 2nd and 3rd trimester, and also deliver your pregnancy, at Mount Sinai Hospital. However, there will be no repercussions if you are unable to deliver at Mount Sinai Hospital.

**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:**

You are not expected to get any benefit from taking part in this research study. Others may not benefit either.

**POSSIBLE RISKS AND DISCOMFORTS:**

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

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.

Feeling hungry from fasting can be uncomfortable, therefore these sample collections will be scheduled for the morning to minimize fasting time.

**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 you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator. If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments, and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.



## 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 research study, please contact the Principal Investigator or the research staff in writing at the address at the top of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

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 Principal Investigator at phone number 212-241-9247.

If there is an emergency, please call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

## 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 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?

Social history, medical history, age, large gestational age (LGA), maternal and neonatal outcomes, BMI, race/ethnicity, insurance, weight gain, incidence of gestational diabetes, incidence of pregnancy induced hypertension, mode of delivery, maternal and newborn injury, neonatal hyper/hypoglycemia, Apgar's at 1 and 5 minutes, and NICU admissions.

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, education, relationship status, prior pregnancies and their outcomes and dates directly related to you or your baby (birth date, admission date, discharge date, medical record numbers). The researchers will also get information from your medical record at Mount Sinai Health System.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests and procedures explained in the description section of this consent.

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 will 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 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.

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 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 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.

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.

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**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.

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**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 |

***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 |