STUDY INFORMATION:

Study Title: CoronaVirus Impacts on Birth Equity (VIBE) Study

Principal Investigator (Head Researcher): Elizabeth Howell MD, MPP

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SUMMARY OF THIS RESEARCH STUDY:

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

The purpose of this research is to study the experiences of pregnant and postpartum persons during the COVID-19 outbreak, and how these experiences may have had an impact on the care and health of women who were pregnant or had a baby during this time. The strain on healthcare providers and pregnant persons may have caused experiences of stress, and strain on the resources available to pregnant persons.

This study may help us have a better understanding of how the COVID-19 outbreak impacted the health and well-being of pregnant and postpartum persons, which may help us understand the needs of pregnant and postpartum persons during a global pandemic.

If you choose to participate, you will be asked to do the following:

- Complete a web-based survey, that asks you about you, your pregnancy, and your thoughts and feelings about the COVID-19 outbreak
- If you are currently pregnant, you'll complete a survey now, and we will be sending you a follow-up survey after your delivery. If you have already delivered, you'll complete one survey at this time.
- Agree to the study team accessing your electronic medical record to collect your pregnancy and delivery information
- You may opt to enter into a raffle for potential compensation
- There is no cost to you as a result of participating in this study

The main risks to you if you choose to participate are minimal, and are related to the emotions that may arise if you decide to answer survey questions about your pregnancy, birth and postpartum period. Participating in this research will not benefit you, but it may help us understand how the COVID-19 illness and outbreak have impacted pregnant and postpartum persons.
You may also benefit from participation in this research if the responses to our survey help us understand the immediate needs of pregnant and postpartum persons during the recent viral outbreak.

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

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you were pregnant or delivered a baby at Mount Sinai Hospital, Mount Sinai West, or Elmhurst Hospital Center during the time of the COVID-19 outbreak.
Funds for conducting this study are provided by the Mount Sinai Hospital System.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last the length of time it takes you to complete the survey, which may take 30 minutes to complete. If you're pregnant at this time, you'll complete the survey now, and a follow-up survey after your delivery. Depending on how far along you are in pregnancy, you'll be enrolled in the study until you complete the follow-up survey (up to nine months).
The number of people expected to take part in this research study at Mount Sinai Hospital, Mount Sinai West, and Elmhurst Hospital is 3600.

DESCRIPTION OF WHAT'S INVOLVED:

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

- Answer questions in our online survey. These questions will ask about you and your family, and your experience during the global pandemic of coronavirus. They will also ask about your pregnancy, your health, your feelings, and mental health. It may take 30 minutes to complete all questions. If you are pregnant now, and taking this survey, we will also send you a follow-up survey by email after your delivery, around one month postpartum. This follow-up survey will ask about how

your delivery went, your experience with coronavirus, your physical and mental health postpartum, and your infant's health.

- If you have already delivered, you will complete this survey once, now.
- Complete this consent form, which includes giving the study team permission to access your electronic medical record. The information we will get from your medical record includes health information related to your pregnancy, which may include medications, and the health of your baby. We will also get information about your birth and postpartum experience in the hospital.
- By signing this consent form, you are also giving the PI, Dr. Elizabeth Howell, permission to use your survey responses and information from your medical record in another ongoing study about the coronavirus and pregnancy outcomes called THE IMPACT OF SARS-CoV-2 INFECTION DURING PREGNANCY ON MATERNAL AND CHILD OUTCOMES (IRB-20-03352) study. Dr. Howell is also a PI on that study, and more information can be obtained by contacting her directly.
- Your participation is over the internet, but you may interact with the study staff by phone or in person if you have questions about participation, or the survey.
- The survey is done over the internet and does not require a visit to any Mount Sinai site.
- You may complete the questions online at your convenience

USE OF YOUR DATA AND/OR SPECIMENS:

Your data will be shared with a link to your identity with Dr. Howell's study "The Impact of SARS-CoV-2 Infection During Pregnancy on Maternal and Child Outcomes (Generation C) Study (IRB-20-03352)". As part of this study, your identifiable information will be shared with the Generation C study, for which Dr. Howell is also a principle investigator. Your data from your survey responses and medical record will be shared with the Generation C study.

The researchers would also like to ask your permission to keep the data collected from you during this study to use them in future research studies. Please tell us how we may use this material in future research studies.

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

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

(2) The researchers can keep your information stored in one of two different ways: one way will store your information in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will store your information anonymously (no one will know who the information is from). It will not be stored both ways, so you must choose

one of these two options. Please note that if you choose to have your information stored anonymously, you will not be able to change your mind to ask for your information to be destroyed at a future date.
How would you like your information stored? Please initial **ONE** choice:

I would like my information stored with a link to my identity_____
I would like my information stored anonymously _____

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

Yes_____ No_____

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

Yes_____ No_____

(5) Do you give the researchers permission to keep the information 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_____

(6) Do you give permission to have portions of the information given **to other researchers,** including those at Mount Sinai, other academic institutions and for-profit companies, for use in research within the limits you have chosen above? Please initial your choice:

Yes_____ No_____

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 web-based survey, that asks you about you, your pregnancy, and your thoughts and feelings about the COVID-19 outbreak. The survey will be sent to you through an email link.
- If you are taking this survey and are still pregnant, you will be asked to take a follow-up survey after the delivery of your baby, around one month postpartum. You'll receive an email link to take this follow-up survey.
- Agree to the study team accessing your electronic medical chart to collect your pregnancy and delivery information
- Agree to giving the PI, Dr. Elizabeth Howell, permission to use your survey responses and information from your medical record in another ongoing study about the coronavirus and pregnancy and infant outcomes called THE IMPACT OF SARS-CoV-2 INFECTION DURING PREGNANCY ON MATERNAL AND CHILD OUTCOMES study. Dr. Howell is also a PI on that study, and more information can be obtained by contacting her directly.
- You may opt to enter a raffle for a cash prize of $150 Amazon gift card
- There is no cost to you as a result of participating in this study

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.

If you agree to take part in this research study, we will enter your name in a raffle. The winners of the raffle will be selected once all data has been collected, or the study has been closed. The raffle winning will be an Amazon electronic gift card for $150, delivered to your email address.

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

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 an understanding of the needs of pregnant and postpartum persons during the time of a pandemic, as well as the effects of the COVID-19 outbreak on pregnant and postpartum persons. We hope that by understanding the needs of people like you, that we will be better able to meet your needs now, and in the future, for example more frequent appointments or referrals.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Psychological risks: Some of the questions in the survey ask about your experience during pregnancy and postpartum, which may bring up feelings of sadness, anxiety, or fear among others. If you would like to talk with someone during or after your survey, please contact Dr. Elizabeth Howell at 212-659-9567.
    - Some of the questions will ask about depression. If your answers show that you are having some symptoms of depression, a member of the study team will contact you either by phone or by email. You may also contact the PI, Dr. Elizabeth Howell at 212-659-9567. If you are feeling very depressed or unsafe, please call 911 or go to the nearest emergency room.
    - One of the survey questions in this survey asks about major stressful life events.
        - The research team may uncover current abuse, neglect, mental health issues or reportable diseases.
        - To lower your risks, our research staff would help you contact social services to provide resources to best help you.

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. Your study data will be secured, physically and electronically. As with any electronic storage means, there may be a risk of data secruity breach. Your name will not be used in any published reports from research done from this study. The research staff will not release any data that could identify you.

- Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. However, because some characteristics are unique to you, 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 also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

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, Elizabeth Howell at 212-659-9567.

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, Elizabeth Howell, or the research staff at 212-659-9567.
If you decide you don't want your data to be used for research anymore, you can contact the researcher by phone or email (elizabeth.howell@mountsinai.org) and ask to have your data removed from future use. If any samples or data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.
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 INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number 212-659-9567

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. The investigators on this research team do not have any financial interests to disclose.

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 shared with others?

As part of this research project, the research team at the hospitals involved in the research will collect your name, address, telephone numbers, dates directly related to you (birth, admission, discharge, delivery date, etc.), email address, medical record number, laboratory (blood tests, nasal swabs) and physiological measurement results (blood pressure, blood loss estimate, etc.), your responses to the questionnaire.

The researchers will also get information from your medical record about your prenatal care, delivery information, and postpartum information. We will access your electronic medical record, with your consent, from your prenatal care provider and delivering hospital.

During the study the researchers will gather information by:

- completing the questionnaires explained in the description section of this consent.
- Reviewing your medical records from your pregnancy, delivery notes, and postpartum notes, including results of the laboratory tests that were completed during your appointments and hospital stay.
- reviewing HIV-related information, which includes any information indicating that you have had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.

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.

In all disclosures outside of Mount Sinai, you will not be identified by your name 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.

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.

ADULT PARTICIPANT:

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

_____ _____ _____ _____

Signature of subject Printed Name of Subject
Date Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____ _____ _____ _____

Signature of consent delegate Printed Name of consent delegate Date
Time