Partners HealthCare System
Research Consent Form

Subject Identification

General Consent Form Template
Version Date: January 2019

Protocol Title: Brain health Begins Before Birth-I (B4-I): Pregnancy Surveys

Principal Investigator: Joshua Roffman, MD, MMSc & Erin Dunn, ScD, MPH

Site Principal Investigator:

Description of Subject Population: Pregnant women age 18 and older

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about the impacts that certain biological, environmental, social, and behavioral exposures —including but not limited to those related to the COVID-19 pandemic—have on pregnancies and brain development of unborn children.

How long will you take part in this research study?

If you decide to join this research study, it will take you a total of about 4-6 hours over the course of your pregnancy, across five time points, to complete the study.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen: you will be asked to complete a series of surveys at up to 3 time points during your pregnancy and 2 time points after your child is born. These surveys will ask questions about your pregnancy, lifestyle, mental health, and feelings about the COVID-19 pandemic. We will also review your obstetrical medical records for your current pregnancy.

Why might you choose to take part in this study?

You will not directly benefit from taking part in this research study. However, we hope that the study will help us understand how this pandemic is impacting pregnant women and their unborn children and potentially what might be protective to those babies who are developing during this time.

Why might you choose NOT to take part in this study?

Taking part in this research study has minor risks and requirements that you should consider carefully.

Risks and possible discomforts to know about include feeling uncomfortable when answering questions about your pregnancy and physical and mental health. Also, although we make every effort to protect your privacy, there is always some risk to privacy when personal data is shared.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Joshua Roffman is the person in charge of this research study. You can call him Monday to Friday from 9 AM to 5 PM at 617-724-1920. You can also call the study coordinator, Rachel Pride, at 617-398-7459 with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

We are doing this research to learn more about how the prenatal affects brain development in unborn babies. We are particularly interested in stressors related to the Covid-19 pandemic. We will also examine what factors may be protective for the developing baby.

Who will take part in this research?

We are asking you to take part in this research study because you are pregnant during the COVID-19 pandemic. About 1,000 pregnant women will take part in this research study at Massachusetts General Hospital and MGH-affiliated community health clinics. The research study is being paid for by departmental funds.

What will happen in this research study?

The research study will involve you completing a series of surveys throughout your pregnancy and after your child is born. These surveys will ask questions about your pregnancy, lifestyle, psychiatric symptoms, and feelings about the coronavirus pandemic. The schedule of when you will be asked to complete these surveys is provided below:

- Time point 1: About 10 weeks into your pregnancy
- Time point 2: About 20 weeks into your pregnancy
- Time point 3: About 28 weeks into your pregnancy
- Time point 4: At the time your child is born
- Time point 5: 45 days after your child is born

If you are deciding to enroll later on in your pregnancy (for example, during the 2nd or 3rd trimester), you will still be able to participate. Each set of surveys will take from about 15 to 90 minutes to complete, and you will have the option to take breaks and return to complete each survey at a later time.

For time point 4, a member of the study staff will meet with you while you are still in the hospital, after your baby is born. This visit will be brief (about 15 minutes).

You will not be asked to schedule any in-person visits for time points 1, 2, 3, and 5; all of these surveys can be completed at home or wherever is convenient for you. You will be able to choose any of the following methods to complete these surveys:

1. Online – We will send you a secure link via text or email that will bring you to a website where you can complete the surveys online.
2. Hand-written – We will mail hard copies of the surveys to you, along with a pre-addressed, pre-paid envelope for you to return the completed surveys.
3. Over the phone – We will schedule a time for you to speak with a research coordinator over the phone to administer the survey to you.

For these four time points, you will receive a message from our study staff about when it is time to complete the surveys. For each of these time points, you will have a two-week window to complete the survey questions. You do not need to complete all of the questions at once.

We will send you up to three reminders to complete the survey before the end of the two-week window. These reminders can be delivered via phone call, text message, or email. More information about the possible security risks of these methods is below.

Text Messaging

Text messages by mobile/cell phones are a common form of communication. If you so choose, the B4 research study will involve sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Partners Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messages will only be read during regular business hours (Monday thru Friday 9 AM to 5 PM EST). Text messages received over the weekend will be responded to on Monday morning.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."

- Your agreement applies to this research study only. Agreeing to other texts from Partners Healthcare, for example appointment reminders, is a separate process. Opting out of other texts from Partners Healthcare is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

Email

You can also choose to receive survey completion reminders via email. For any emails sent to you concerning this study, the Partners Healthcare standard is for us to encrypt them. Encrypting emails protects your personal information from being accessed and read by unintended recipients. This requires you to set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners Healthcare.

If you prefer, we can send you an unencrypted email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners Healthcare will not be held responsible.

Please let us know your preference for how you would like to receive these reminders:

☐ Over the phone

☐ Via text message (Please read and initial the following:)

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

Initial _____

☐ Via encrypted email

☐ Via unencrypted email (Please read and initial the following:)

I have had the chance to ask questions about unencrypted email with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted email communications associated with this research study.

Initial _____

In addition, we will review your electronic medical records to gather information about obstetrical visits for this pregnancy, and about the health of your baby before and after birth.

In addition, you will be approached towards the end of the research study to see if you would like to participate in a second study focusing on pediatric follow-up with your child.

How may we use and share your samples and health information for other research?

The information we collect in this research study may help advance other research. If you join this research study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified data in other research. It won't be possible to link the information back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

At the completion of this research study, we would like to store and be able to use and share your identifiable health information with researchers at Mass General Brigham for other research related to the COVID-19 pandemic and fetal development during this time. If we share your health information with other researchers outside of Mass General Brigham, we will label the information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your information. We will keep the code in a password protected file on an encrypted computer.

Because this health information is identifiable, we are asking your permission to store, use and share it for other research. You can still take part in the research study whether or not you give permission for the storage, use, and sharing of the health information for other research.

Do you agree to let us store and use your health information for other research related to pregnancy and the baby's brain development?

☐ YES ☐ NO Initial _____

Do you agree to let us re-contact you for additional research studies related to your pregnancy and your unborn baby's brain development?

☐ YES ☐ NO Initial _____

Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the research study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

This research study does not include an intervention and poses minimal risk to participants. However, there may be some discomforts you could experience by participating in our research. It is possible that you may feel uncomfortable answering questions about your physical and mental health or behaviors. You may choose not to answer any question.

A potential risk to your privacy may arise through the review of your electronic medical record by study staff. To reduce this risk, searches through medical records will be conducted only by trained study staff and will be limited to relevant obstetrical data only.

What are the possible benefits from being in this research study?

You will not benefit personally from taking part in this research study. We hope that the research study will provide important insights into how the COVID-19 pandemic and other stressors impact pregnant women and their babies, and what may protect developing fetuses during this time.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be paid $100 if you complete all of the surveys in this research study. If you do not complete all of the surveys, you will receive $25 in compensation for each survey you complete for Timepoints 1 through 3, and upon completion of the surveys administered at Timepoints 4 and 5, one $25 payment will be given.

We may be using an approved, outside vendor make these payments to you via a reloadable credit card-based system, called Advarra Patient Payments. This secure system is similar to a gift card or credit card.

If you are paid by this system, you will be given a Advarra Payments Visa card when you enroll in the study. Once the card is activated, the study team will add a payment after each paid visit you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store. We may need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system.

Reimbursement of expenses will not be made using the Advarra Payments card. However, proof of receipt for something like travel expenses may be covered by our team and will not be considered taxable income.

What will you have to pay for if you take part in this research study?

You will not need to pay anything to take part in this research study. Study funds will pay for all study-related items and services.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records

- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing

list. However, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

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