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Advancing Perinatal Mental Health and Well-Being: The DC Mother-Infant Behavioral Wellness Program

Informed Consent

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CHILDREN'S NATIONAL HOSPITAL
Division of Diagnostic Imaging & Radiology
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

Consent/Parental Permission to Participate in a Clinical Research Study and Authorization to Use Protected Health Information

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STUDY TITLE: Advancing Perinatal Mental Health and Wellbeing: The DC Mother-Infant Behavioral Wellness Program

PRINCIPAL INVESTIGATOR:
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Director, Institute for the Developing Brain
Division of Diagnostic Imaging & Radiology
Division of Fetal and Transitional Medicine

Throughout this document, "You" always refers to the person (you or your child) who takes part in the study.

SUMMARY AND KEY INFORMTION

We are inviting you to be part of a research study at Children's National Hospital (Children's National). **Taking part in this study is your choice.** You can choose to take part or you can choose not to take part in this study. You also can change your mind about participating at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

To help you decide if you would like to participate, we want you to know why we are doing the study, what you will be expected to do, and the possible risks and benefits of being in the study. This form has information to help you make your choice about whether or not to participate.

The purpose of this research study is to better understand how different types of mental health care can help pregnant women and mothers with infants under the age of 1 feel less stressed. Stress, depression, and/ or anxiety that occurs during pregnancy or after having a baby can affect can have a negative effect on women and their babies. Your participation will help to better understand what types of mental health care are most likely to benefit pregnant women and mothers who are Black/of African Descent who are experiencing stress, anxiety, and/or depression. The study team hopes that your participation shows the effectiveness of different types of services and treatments on improving the outcomes of pregnant women, mothers, and infants born to women who are Black/of African Descent and experience stress, anxiety and/or depression.

If you choose to participate in the study, we will ask you to complete a series of questionnaires aimed at assessing your mood and stress levels as well as gathering other details about your life. Once you complete these questionnaires, we will randomly assign you to 1 of 2 groups (like flipping a coin, so you have an equal chance of being in either group): you will receive either standard prenatal mental health care or a new type of mental health care that involves different types of services and treatment. You will complete either your standard prenatal mental health care or the new treatment throughout the remainder of your pregnancy and the first year of your baby's life.

You may choose to have services or mental health care outside of your standard prenatal care. You can choose not to participate in this study. Your refusal to participate in this study will in no way interfere with any current or future care you or your baby receives at Children's National Hospital.

If you are interested in learning more about this study, please continue reading below. The rest of this form gives you more important information you need to know about the study before you decide if you want to participate. A member of the research team will talk to you about the study and answer all of your questions. We encourage you to discuss this study with your family and anyone else you trust before making your decision. It's important that you have as much information as you need and that all your questions are answered.

Your participation in this research is voluntary.

There will be no penalty or loss of benefits to which you are otherwise entitled if you decide not to be in the study or withdraw from the study later. This means that:

- You do not have to join the study.
- You may change your mind and stop being in the study at any time.
- We will tell you if we make any important changes to the study or if there are any important new findings so that you can decide if you still want to be in the study.

Why is this research study being done?

We would like to invite you and your baby to enroll in a research study being performed at Children's National Hospital, MedStar Washington Hospital Center, George Washington University Hospital, Howard University Hospital and Unity Health Care, a community outpatient health center This research study seeks to better understand how different types of prenatal mental health care can help pregnant women. Stress, depression, and/ or anxiety that occurs during pregnancy or after having a baby can affect can have a negative effect on women and their babies. Your participation will help to better understand what types of mental health care are most likely to benefit pregnant

women and mothers who are Black/of African Descent who are experiencing stress, anxiety, and/or depression.

We are approaching you now because you and your baby are eligible for our study. This is because you are a pregnant woman who is Black/of African Descent and receiving services at one of the four sites listed above and living in the D.C. area.

Catherine Limperopoulos is the person responsible for this research study at Children's National. She is called the Principal Investigator.

The Patient Centered Outcomes Research Institution (PCORI) is paying for this research to be done.

How many people will be in the study?

We hope to enroll a total of 700 mother/baby pairs to participate in this study from four health centers in Washington, D.C.: The George Washington University Hospital, Medstar Washington Hospital Center, Howard University Hospital, Unity Health Care.

What will happen in this research study?

If you agree to enroll in the study, we will randomly assign you to 1 of 2 groups (like flipping a coin, so you have an equal chance of being in either group): you will receive either standard prenatal mental health care or a new, different kind of mental health care, that will include a maternity care specialist who will help provide you with resources when you need it, and other types of mental health services, including group or individual therapy and/or a virtual support group, based on your preference.

If you agree to enroll in this study, we will gather as much information as possible for the study by collecting information that is already being recorded as part of you and your baby's routine care. None of the research procedures will change you or your baby's routine medical care or management. You and your insurance company will not be billed for tests only ordered for the research study.

As part of this research study, we will:

- **Ask you some questions to see if you are a good candidate for the study.** If yes, you'll be asked to complete this consent form. These questions ask about your pregnancy, mood and stress levels as well as your current social support and financial well-being. These questionnaires will take between 20 and 25 minutes to complete. Once these questionnaires are complete, they will be reviewed by a member of the research study staff and you will immediately be notified if you are eligible to proceed with study participation.

- **Randomly assign you to 1 of 2 groups (like flipping a coin, so you have an equal chance of being in either group)**. If you are eligible to participate in the study based on the questionnaires you complete and you are assigned to the first group, you will receive the standard prenatal mental health care that your medical facility provides. If you are assigned to the second group, you will be assigned a Maternity Care Specialist, a person whose job is to provide you with referrals and resources, and receive a prenatal support intervention.

- **Conduct an interview with you.** Regardless of which group you are assigned to, we will conduct an interview with you to gather additional information about you.

- **If you are assigned to the new therapy intervention, we will invite you to participate in Cognitive Behavioral Therapy (CBT), a peer support group or both.** CBT is a type of intervention that has been found to be effective to manage stress, depression, and/or anxiety. There are two types that will be offered in this study: group or individual. Whether you participant in group or individual CBT will depend on your mental health needs. All CBT sessions are conducted by a mental health care provider. There will be 8 total group CBT sessions, 6 while you are pregnant and 2 after you have your baby. Each session is about 90 minutes long. These will be done in person or virtually. If you choose to participate in the CBT individually, there will be 12 50-minute sessions, 8 while you are pregnant and 4 after you have your baby. The individual sessions will also be done in-person or virtually. If you decide to come in person, these sessions will be held at the location where you receive your prenatal care, and transportation costs will be provided for your to attend these sessions. You can also choose to take part in Virtual Mommy Meet Ups in addition to or instead of the CBT sessions. These Meet Ups will be run by mothers like yourself who have experience in this area. There will be 12 total sessions that last 60 minutes long.

- **Ask you to complete questionnaires several times in the first year of your child's life.** These questionnaires will be aimed at assessing your mood and stress levels as well as how you and your child are bonding and interacting when your baby is 2, 6 and 12 months old. These questionnaires will be completed either in-person or remotely.

- **Perform developmental follow-up studies at 12 months**. When your child is around 12 months, at your convenience, we will ask that you visit Children's National Hospital for the developmental part of the research study. On this day the following tests will occur:
    - Developmental testing will be performed by a licensed pediatric psychologist or her designee with particular expertise in testing children.

The testing will take the form of standardized tests where the child will be asked to carry out different motor activities, identify objects or solve age-appropriate questions such as using toys and puzzles, recognizing figures, pencil and paper activities, and language skills depending upon the child's age. These tests will take approximately 45-60 minutes.

- Structured parental interviews will be completed that will allow us to determine how independent your child is in carrying out activities of daily living such as eating, dressing, self-care and social skills relative to his/her age. These questionnaires will take about 15 minutes to complete.

How long will my participation in the research study last?

The initial set of questionnaires you fill out will take about 20-25 minutes to complete. If you are assigned to the new therapy group, each session will last 50-90 minutes depending on your choice of intervention participation. The total study duration is about 2 years: from the time of enrollment through the remainder of your pregnancy until your child is about 12 months old.

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

There are risks to this study that are described below.

- Risks of completing questionnaires and CBT intervention include loss of time, recalling traumatic or distressing events, a sense of invasion of privacy and/or frustration. You are allowed to skip any questions you do not feel comfortable answering.
- Please note that we are required to report any learned instances of child abuse or neglect.

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

- Your participation will help to evaluate the effectiveness of a new mental health services that involves being in contact with a Maternity Care Specialist and different kinds of interventions that will support pregnant women and mothers who are Black/of African Descent experiencing stress, anxiety and depression. The study team also hopes your participation shows the effectiveness of mental health care that is comprehensive on improving the outcomes of children born to women who are Black/of African descent and experience stress, anxiety and depression.

What kinds of information will the study collect? Will any information be shared with me?

- We will collect questionnaire results

- We will collect feedback from you regarding your thoughts about the mental health care you receive.
- We will collect information from you and your baby's medical records, relative to your pregnancy, labor and delivery and the newborn period.

Will the information that I give you be shared with others? How will you protect my privacy?

Efforts will be made to limit the use and disclosure of your personal information, including research records, medical records, and Protected Health Information (PHI), to authorized members of the study team and to people who have a need to review this information. Your identifiable personal information will not be given to anyone unless we get your permission in writing, except as described in this consent form or if the law requires it. This information will also only be given for regular hospital care, payment, and hospital management activities. We will make every effort to keep your information private, but no one's privacy can be totally guaranteed.

Your medical record is confidential but, just like any medical record, there are some exceptions under state and federal law.

There are some third parties such as government agencies or other groups within Children's National that may check records that identify you without your permission. They might review the study records and your medical records to make sure we are following the law and protecting the people in the study and to make sure our results are correct. The agencies or groups who might see these records are*:* the Department of Health and Human Services Office of Human Research Protections, and the Children's National Hospital Institutional Review Board (the ethics board that reviewed and approved this research study) and the Office for the Protection of Human Subjects.

The results of this research may be presented at meetings or in publications. You will not be personally identified. If identifiers like your name, address, date of birth and phone number are removed from the data and samples that are collected during this research, that information or those samples could be used for future research studies or given to another investigator for future research studies without your additional informed consent.

What other choices do I have if I don't want to take part in the study?

You have the alternative to obtain mental health care outside of your standard prenatal care through private means. You have the alternative not to participate in this study. Your refusal to participate in this study will in no way interfere with any current or future care you or your baby receives at Children's National Hospital.

Will it cost me anything to take part in the study?

All mental health care is being done only because you are taking part in this study. You or your insurance company will not have to pay for that care.

You or your insurance company will have to pay for the costs of any routine or standard medical care that is not part of the study. This may include, but is not limited to, visits to the clinic, having to stay in the hospital, laboratory tests, x-rays, or other tests. If your insurance company does not pay for the routine or standard care, you will be responsible for paying for it.

Will I be paid for taking part in this study?

Depending on which group you are assigned to, you may receive between $275-$395 after finishing this research study. You will receive $15 for completing the first set of questionnaires. You will receive $20 for completing the interview and at 3 OB visits between 24 and 40 weeks. You will receive $30 at your 2- or 6-week postpartum visit as well as the 2 month, 6 month and 12 month visit. You will receive $60 for attending the developmental follow-visit when your child is 12 months old. If you are assigned to the prenatal support intervention, you will receive $10 per session for transportation.

You will receive your study payments through a “ClinCard” debit card. ClinCard follows laws, like HIPAA, which protect your identifiable information. After each completed study visit for which you will be paid, the payment amount will automatically load onto your card within 3 business days. You can use your ClinCard at an ATM or bank to get cash, or at any store to make a purchase. There is a fee for using the card at an ATM machine and there may be other fees, like monthly fees.

The study team will give you a ClinCard and forms with more information about how to use it and about specific ClinCard user fees.

The Internal Revenue Service requires that any monetary payments totaling $600 or more in a calendar year must be reported for tax purposes.

Your information and samples (both identifiable and de-identified) may be used to help researchers create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you or to pay you or your family.

What happens if I get hurt or sick because of taking part in this research study?

Children's National Hospital cannot promise that the risks we have told you about or other unknown problems will not happen. If you think that you are hurt, sick, or

otherwise harmed because of something to do with the study, please call the Principal Investigator, Catherine Limperopoulos, at 202-476-5293.

- In case of a medical emergency, call 911 or go directly to the hospital. Be sure to tell the Emergency Room personnel and your doctor that you are in this study.
- If you have any non-emergency side effects or bad reactions, call the Principal Investigator, Catherine Limperopoulos, at 202-476-5293 right away.

We will give you any urgent medical care needed because of your participation in this research study if reported in a timely manner. Children's National will seek payment from your health insurance company or other third-party payer for any medical care or services you receive. Children's National has no program to provide you with any additional payments for any injuries.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or PHI). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize the Principal Investigator, Catherine Limperopoulos, and her research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

- Information that identifies you such as name, address, telephone number, date of birth, Social Security number, and other details about you
- Information that relates to your health or medical condition from your medical records
- Information obtained from the study procedures outlined in this consent form, for example: things done to see if you can join the study such as physical exams, blood and urine tests, x-rays and other tests, and any other medical information we learn from you about your health history and family history
- Laboratory results obtained on specimens collected from you (blood, saliva, hair)
- Questionnaires or surveys you complete

The Researchers may use and share my Protected Health Information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study
- Government agencies that have the right to see or review your PHI including, but not limited to:
  - The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP)
  - The Food and Drug Administration
- Children's National Hospital Institutional Review Board
- Children's National Hospital Institutional Quality Assurance Program
- Other staff in the Human Research Protections Program at Children's National Hospital

Also, your primary physician will be contacted if during the course of the study the researcher learns of a medical condition that needs immediate attention.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

Storage of PHI in a Database:

We would like to store personal health information collected from you in this study in a database for future research. The database is maintained by the Department of Radiology at Children's National Hospital.

Please indicate your approval of any or all of the following by checking a box next to each statement and initialing your choice:

- My personal health information may be stored in the above named database for future analysis related to this study.

  ☐ Yes ☐ No Initials _____

- My personal health information may be stored in the above named database. Researchers may contact me to request my authorization for future studies that are not related to this study or the disease named above.

  ☐ Yes ☐ No Initials _____

- My personal health information may be stored without any of my identifying information for use in other studies of other diseases.

  ☐ Yes ☐ No Initials _____

If you agree to participate in this research study, the research team, the research sponsor (when applicable) and the sponsor's representatives may use Personally Unidentified Study Data. The Personally Unidentified Study Data does not include your name, address, telephone, or social security number. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials, and dates you received medical care. Personally Unidentified Study Data may also include the health information used, created, or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others to perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, or use it to improve the design of future studies. They may also publish it in scientific journals, or share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

You do not have to sign this Consent/Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

After signing the Consent/Authorization, you can change your mind and revoke this Authorization.

- If you revoke the Authorization, you must send a written letter to the Principal Investigator to inform her of your decision.

  Catherine Limperopoulos, PhD
  Children's National Hospital
  Department of Diagnostic Imaging & Radiology
  111 Michigan Avenue, N.W.
  Washington, DC 20010-2970

- If you revoke this Authorization, researchers may only use and disclose the PHI that was collected for this research study before you revoked the Authorization.
- If you revoke this Authorization, your PHI may still be used and disclosed if you should have an adverse event (unexpected side effect).
- If you change your mind and withdraw the Authorization, you will not be allowed to participate in the study.

You will be allowed to review the information collected for this research study.

This Authorization does not expire.

If you have not already received a Notice of Privacy Practices from Children's National Hospital, you may request a copy and will be given one. If you have any questions or concerns about your privacy rights, you may contact the Children's Hospital Privacy Officer at 202-476-6464.

Whom can I call if I have questions about this research study?

We want you to ask questions about any part of this research study at any time.

- For questions about the study or the information in this informed consent/parental permission document, call the Principal Investigator, Catherine Limperopoulos, at 202-476-5293.

Whom can I call if I have questions or concerns about my rights as a research study participant?

The Children's National Office for the Protection of Human Subjects is available to talk with you about:

- Your rights as a research participant
- Your concerns about the research
- A complaint about the research

This is the administration office for the Institutional Review Board, which is a group of doctors, nurses, and non-medical people who review research studies for safety and the protection of people who participate in research. You can call the Office for the Protection of Human Subjects at 301-565-8447.

Children's National has a research participant and family advocate. The advocate is here to answer your questions or concerns about taking part in this research. The advocate does not work for the doctors who are doing this research and is not paid by the researchers. The advocate is here only to help and protect you during any research.

You may contact the research advocate at any time. This can be done before you decide to take part in the research, during the study, or even after you finish the study. You can contact the research advocate at 202-476-5586 or by email at RSA@childrensnational.org. In urgent situations the research advocate and pediatric ethics program team can be reached at the pager number: 202-259-2082.

CONSENT/PARENTAL PERMISSION:

- I am the study participant or I am authorized to act on behalf of the participant.
- I have read this consent form or had it read to me.
- I have been invited to take part in a research study. I was told why the research is being done and how long my participation in the study is expected

to last. I was told about what will happen in the study and if there are any procedures or drugs that are experimental.

- I was told that taking part in this research is voluntary. I also was told that I can decide not to take part or stop being in it at any time without any penalty to me or any change to the quality of care I receive at Children's National.
- I was told about the risks and possible discomforts of taking part in this research study. I was also informed if there are any possible benefits to me if I am in this study.
- I have been given the chance to ask questions about the study, and my questions have been answered. If I have questions later, I can ask one of the people listed in this form.
- I agree to take part in this research study.
- I will receive a signed copy of this Informed Consent/Parental Permission form to keep.

Signature of adult participant (18 years of age and older)/Parent(s)/Guardian(s)

Printed Name of Participant:_____

Medical Record Number: _____

Printed Name of Parent(s)/Guardian(s):

Signature of Participant: _____Date: _____

(Participant must be 18 years of age or older)

Signature of Parent(s)/Guardian(s): _____

Date and Time: a.m. / p.m. (circle one)

Signature of language interpreter (if applicable)

Printed Name of Interpreter:

Interpreter's Signature:

Language: Date and Time: a.m. / p.m. (circle one)

AFFIDAVIT OF PERSON OBTAINING CONSENT / PARENTAL PERMISSION:

I certify that I have explained to the above individual(s) the nature and purpose of the study, possible risks, and potential benefits associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Person Obtaining Consent:

Research Role:

Signature:

Date and Time: a.m. / p.m. (circle one)

Signature of Witness to Consent Process (if applicable)

Printed Name of Witness:

Witness's Signature:

Date and Time: a.m. / p.m. (circle one)