

Title of Research Study: Enhancing Perinatal Care Support to Improve Maternal Mortality Disparities

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Supported By: This research is supported by National Institutes of Health (Grant R01 MD016280).

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate.
Detailed information is provided after the summary.

Study Summary

- **WHY?** The purpose of this research study is to test if the **Well-Mama Program** can increase the health care during and after pregnancy for Black, Indigenous and People of Color (BIPWOC).
- **WHERE?** This study is for pregnant people and receiving care at the 3 medical centers doing the study. They are in Chicago, Illinois; Newark, New Jersey; and Baton Rouge, Louisiana.
- **WHO?** People who are 15-49 years old and less than 32 weeks pregnant can join the study.
- **WHEN?** You will be asked to join the study when you are starting your prenatal care in pregnancy. The study will end 1 year after you have delivered.
- **WHAT?** All people in the study will have their medical records reviewed and be asked to do a survey when they join and then 2 weeks, 6 weeks, 12 weeks, 6 months and one year after delivery. In this study, there will be 2 study groups: the Well-Mama Group and the Usual Care Group. You will be put into one of the study groups at random (like flipping a coin) at the beginning of the study. A computer will decide what group you are in. Neither you nor the study team can pick your group.
 - Usual Care Group: You have a 33% chance (1 out of 3) of being in the Usual Care Group. This group will have their pregnancy and postpartum care like normal. They would not join the Well-Mama Program.
 - Well-Mama Group: You have a 66% (2 out of 3) chance of being in the Well-Mama Group. This means you will still have your usual care and also receive the **Well-Mama Program**. The **Well-Mama Program** uses an extra health care team member (who is also a doula) to work with patients and their care team. This person is called a “*Community Doula Navigator*”. The **Well-Mama Program** also uses a checklist to help guide pregnant patients in their prenatal care, postpartum care, and social services. The Well-Mama checklist includes 5 topics that are important to pregnancy health and health after delivery:
 - mental health/depression
 - cardiovascular (heart and blood vessels) symptoms
 - safety (examples: guns at home and intimate partner violence)
 - opioid/substance abuse
 - social support, self-agency, and well-being

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are:

- Between the ages of 15 and 49 years

- Uninsured or have public insurance
- Only having one baby (singleton pregnancy)
- Pregnant and less than 32 weeks into your pregnancy
- Seeking care at either John H. Stroger, Jr. Hospital (Chicago IL), Woman's Hospital (Baton Rouge LA), or University Hospital (Newark NJ)

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide

Why is this research being done?

The purpose of this research study is to improve prenatal and postpartum care for Black, Indigenous and People of Color (BIPOC). Compared with non-Hispanic White women, BIPOC and their babies have worse health outcomes. A clinical trial is important to test if the **Well-Mama Program** can increase the quality of health care services for BIPOC.

How long will the research last and what will I need to do?

We expect that you will be in this research study from the time you start your prenatal care until one year after you give birth to the baby. You will be asked to do surveys during the study. This will happen when you start the study, and at 2 weeks, 6 weeks, 12 weeks, 6 months, and 1-year after you give birth. Your medical records during pregnancy and up to one year after birth will also be reviewed. More detailed information about the study procedures can be found under the section "What happens if I say "Yes, I want to be in this research"?"

Is there any way being in this study could be bad for me?

There are no known physical risks to you by taking part in this study. Some of the questions asked in the surveys may be upsetting, or you may feel uncomfortable answering them. If you feel uncomfortable at any time, you can always choose not to answer a question. The study team will review your medical records. The privacy of your records will be safeguarded to limit any risk for disclosure of that information outside the study team and your care team. More detailed information about the risks of this study can be found under "Is there any way being in this study could be bad for me? (Detailed Risks)"

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved access to health and social services for people in the **Well-Mama Program**. Also, if the **Well-Mama Program** is shown to improve perinatal health outcomes in this study, it could be put into action to improve quality of healthcare for other pregnant people and their babies in the future.

What happens if I do not want to be in this research?

Participation in research is completely up to you (voluntary). You decide whether or not to participate. If you choose not to participate, there will be no penalty to you. There will be no loss of benefit to you if you don't participate. Your alternative to participating in this research study is to not participate.

Detailed Information:

The rest of this document has detailed information about this study.

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by contacting Dr. Damali Campbell-Oparaji the person in charge (Principal Investigator) of this research study at this site. You can call her at 973-972-3173, Monday through Friday from 9am-5pm. You can also call **Rutgers IRB** with questions about your rights as a research volunteer, with concerns about the study, or suggestions about the study. The Human Protections program can be contacted at (973) 973-3608.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect 576 people will participate in the study. The medical centers doing the study are John H. Stroger, Jr. Hospital (Chicago IL), University Hospital (Newark NJ), and Woman's Hospital (Baton Rouge LA).

What happens if I say “Yes, I want to be in this research”?

You will be asked to fill out a form with your contact information. Then, a member of the research team will either email you or contact you via phone to complete a health survey. The health survey topics include demographic (like your age, race, education), mental health, and health behavior information.

You will still have the usual prenatal and postpartum care at your clinic. This includes physical examinations, lab tests, vaccines, nutrition advice, health education, counseling, and screenings. 33% (1 out of 3) of the people in this study will receive usual care only. 66% (2 out of 3) of the women in this study will receive their usual care plus services from the **Well-Mama Program**. This includes navigation services and labor support from a Community Doula Navigator who will use the Well-Mama safety checklist. Whether you are in the group provided a Community Doula Navigator will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what group you get. You will have a two in three chance of being in the **Well-Mama Program** and having a Community Doula Navigator.

A research team member will contact you at five other times to have you fill out more health surveys. This will happen 2 weeks, 6 weeks, 12 weeks, 6 months, and 1-year after you give birth to your baby. Each survey will be about 15 minutes long. Topics include mental health and breastfeeding and other information about you, your pregnancy, and your baby.

A research team member will review your electronic health record when you join the study and until about 1 year after the birth of the baby. Information collected from your electronic health record could include:

- Medical history
- Procedures
- Screening tests and results
- Vaccine records
- Billing information
- Birth control
- Kept/missed appointments

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for filling out the health surveys at 6 different times. These times are: at the time you join the study, then 2 weeks, 6 weeks, 12 weeks, 6 months, and 1-year after you give birth. Each survey will be about 15 minutes long.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not have in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment

You may change your mind and “take back” (revoke) this consent at any time. If you revoke this consent after being in the study, the research team will only use the information collected up until the time you quit the study. By Contacting the Rutgers Study Staff or sending a letter to:

Dr. Damali Campbell-Oparaji
185 South Orange Ave
Newark, NJ 07103

Detailed Risks: Is there any way being in this study could be bad for me?

The risks of participating in the study are:

- Physical risks – There are no known physical risks to participation in this study.
- Psychological risks – Some of the questions asked in the surveys may be upsetting, or you may feel uncomfortable answering them. If you feel uncomfortable at any time, you can always choose not to answer a question.
- Privacy and Confidentiality risks – Your rights as an individual to keep the information you “give the study” (disclose) about yourself will be kept safe. Only the study team will have access to the information you give for the study. Who you are (your identity) will not be disclosed in any study results that are published or otherwise made public. This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: “What happens to the information collected for the research?”
- We will not ask you about child abuse, but if you tell us about child abuse or neglect, we may be required or permitted by law or policy to report to authorities.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

This study presents no physical risks to pregnant women, their fetus, new mothers, or their infants.

Will it cost me anything to participate in this research study?

You and your insurance company will be charged for the health care services that you would normally be responsible to pay. In some cases, insurance will not pay for services normally covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. It will not cost you anything to work with the Community Doula Navigator.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include: improved access to health and social services among women in the **Well-Mama Program**. Also, if the **Well-Mama Program** does improve perinatal health outcomes in this study, it can be added to improve quality of healthcare for other BIPOC and their babies in the future.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study data and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, other representatives of this institution, and the US Department of Health and Human Services.

The study teams, sponsor, monitors, auditors, University Hospital Research, the University Hospital Foundation IRB, the Northwestern University Office for Research Integrity, University Hospital, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. 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.

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

Data Sharing

De-identified data (meaning it does not include information that can identify you, like your name or date of birth) from this study may be shared with the research community to support science and health research. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee secrecy of your personal data.

Can I be removed from the research without my **OK**?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you did not meet the study eligibility criteria.

What else do I need to know?

If you agree to take part in this research study, and are randomized to the intervention group we will pay you \$40 for your time and effort. You will be given a \$20 gift card when you start the study and \$20 when you finish the study. If you are randomized to the control group we will pay you \$120 for your time and effort. You will be given a \$20 gift card when you start the study and \$20 for every survey completed until you finish the study.

HIPAA Authorization

We are committed to respecting your privacy and keeping your personal information confidential. When choosing to take part in this study, you are giving permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Medical history
- Procedures
- Screening tests and results
- Vaccine records
- Mental health information: depression screening
- Billing information
- Birth control

This consent expires on 03/31/2026. After this date, University Hospital Research may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless University Hospital obtains permission to do so from you. Louisiana State Law permits use and disclosure of your mental health information only to the extent specified in this document.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of University Hospital and its clinical partners (or affiliates): the University Hospital and Northwestern University's Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or hospital or University policy.

The following entities may receive your health information:

- Authorized members of the Northwestern University or University Hospital workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Other Northwestern University research centers and Northwestern University or University Hospital contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- National Institutes of Health (NIH), who is sponsoring the study, and NIH's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire on 08/31/2026.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Dr. Damali Campbell-Oparaji
185 South Orange Ave
Newark, NJ 07103

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Optional Elements:

The following research activity is optional, meaning that you do not have to agree to it in order to participate in the research study. Please show your willingness to participate in this optional activity by **placing your initials** next to the activity.

I agree **I disagree**

_____ _____ The research team may contact me in the future to see whether I am interested in participating in other research studies by the investigators of this study.

CONSENT (ADULTS)

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of **Participant**

Date

Printed Name of **Participant**

Signature of **Person Obtaining Consent**

Date

Printed Name of **Person Obtaining Consent**

ASSENT (MINORS)

Your signature documents your permission for the named child to take part in this research.

Signature of **Child** Date _____

Printed Name of **Child**

Signature of **Parent or Individual Legally Authorized** Date _____
to consent for the child to participate

Printed Name of **Parent or Individual Legally Authorized** Date _____
to consent for the child to participate

I attest that the identity of the individual giving consent has been verified.

Signature of **Witness** to Consent/Assent Process Date _____

Printed Name of Person **Witnessing** Consent/Assent Process