Permission to Take Part in a Human Research Study

Protocol Title: Effect of Support for Low-Income Mothers of Preterm Infants on Parental Caregiving in the Neonatal Intensive Care Unit
Principal Investigator: Margaret Parker and Margaret McConnell
Local Study Address: UMass Memorial Medical Center/UMass Chan Medical School, 119 Belmont Street, Worcester, MA 01605
Description of Study Population: Medicaid-eligible mothers with hospitalized preterm infants 24-33 weeks' gestation eligible to breastfeed
Version Date: 30 May 2024

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you and your child to take part in a research study because you have an infant born at 24-33 weeks' gestation.

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 may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study seeks to understand how to support and address challenges faced by families when their infants are hospitalized in the NICU. We hope that the results of this study will inform policies that can better support other mothers of hospitalized preterm infants.

How long will I take part in this research?

We expect that you and your child will be involved in this research for the duration of your infant's NICU stay and approximately 8-12 weeks after their discharge. During this time, you will be asked to participate in surveys administered to you at the hospital or sent to you by text or email to your phone.

What will I be asked to do?

You will be asked to complete a 15-minute survey today. During your infant's hospitalization, every 2 weeks you will be asked to complete a 15-minute survey sent to you by text or email to your

phone. Within a week of your infant's discharge from the hospital you will be asked to complete a 30-minute survey either at the hospital or on your phone. Finally, you will be asked to complete a 30-minute survey 4-8 weeks after your infant's discharge sent to you by text or email to your phone. Surveys will ask you information about yourself, your experiences in taking care of your baby in the NICU and after discharge, challenges you face during hospitalization related to the NICU (experiences with providers) or your circumstances (financial challenges or feelings of stress and depression). Researchers will also track your infant's medical records and financial records related to their cost of care. You will receive a $10-20 gift-card for participating in each of the surveys.

We will invite half of study participants, selected at random, to receive additional financial support during the NICU hospitalization. "Randomly" means by chance, like a coin toss; you have a 50/50 chance of being selected randomly. Neither you, your doctor, nor the researchers may choose your group. If you are selected, you will receive more information about the amount and nature of the financial support.

Finally, a subset of participants will be selected to participate in a 30–60-minute interview. If you are selected to participate, you will receive $40 for participating in this additional interview.

More detailed information about the study procedures can be found under the *"What can I expect if I take part in this research*?" section.

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

You may feel uncomfortable or distressed following surveys that ask about your NICU experience, taking care of your baby at home, or questions about finances, mental health, or experiences of discrimination based on your race or language(s) you speak. If our study team assesses the possibility of extreme depression or self-physical harm, we will immediately intervene by reaching out to offer support and a referral for mental health services.

More detailed information about the risks of this study can be found under the *"What are the risks and possible discomforts?"* section.

Will being in this study help me in any way?

We cannot promise any direct benefits to you or your child from your and your child's participation in this research. We also cannot promise any benefits to others from your and your child's participation in this research. However, possible benefits to others may include the improvement of programs designed to support mothers of hospitalized preterm infants and a better understanding of the economic challenges faced by parents of preterm infants.

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

Participation in research is voluntary. You can decide to participate, not to participate, or stop participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your alternative to participating in this research study is not to participate.

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Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team.

Margaret Parker, MD, MPH: 508-425-1891
Margaret McConnell, PhD: 203-745-8321

This research has been reviewed by a Harvard Longwood Campus Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Regulatory Affairs and Research Compliance (ORARC) at irb@hsph.harvard.edu or 617-432-2157 (toll-free at 1-866-606-0573) for any of the following:

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

Participation is voluntary

You and your child are invited to take part in this research because you have an infant born at 24-33 weeks gestation. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

About 420 people will take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete the following: a baseline survey at enrollment, a short survey every two weeks while your baby is hospitalized, a survey close to your baby's discharge from the hospital, and a post-discharge survey approximately 4-8 weeks after your baby is discharged from the hospital. These surveys will be sent to you via email or text. Surveys will ask you information about yourself, your experiences in taking care of your baby and actions in the NICU and after discharge, challenge you face during hospitalization related to the NICU (experiences with providers) or your circumstances (financial challenges or feelings of stress and depression). Researchers will also track your infant's medical records and financial records related to their cost of care.

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Following the completion of a baseline survey today, we will randomly select half of participants to be invited to receive additional financial support using software installed on this tablet. "Randomly" means by chance, like a coin toss; you have a 50/50 chance of being selected randomly. Neither you, your doctor, nor the researchers may choose your group. If you are selected, you will receive more information about the amount and nature of the financial support.

You may also be contacted to participate in an interview following completion of the post-discharge survey. These interviews will take place either on the phone or on Zoom. Research staff will ask you additional questions about your experiences both while your baby was in the NICU and after he/she was discharged. Interviews will last approximately 30-60 minutes and will be audio-recorded.

What are the risks and possible discomforts?
We will take steps to protect your and your child's personal information. However, there is a risk of breach of confidentiality. You may feel uncomfortable or distressed following surveys that ask about your experiences in the NICU, caring for your baby at home, or questions about finances, mental health, or experiences of discrimination based on your race or language(s) you speak. If our study team assesses the possibility of extreme depression or self-physical harm, we will immediately intervene by reaching out to offer support and a referral for mental health services. Lastly, these surveys will take time away from your other tasks and rest.

Are there any benefits from being in this research study?
We cannot promise any benefits to you, your child, or others from you and your child taking part in this research (clinical or otherwise). However, possible benefits to others may include the improvement of hospital programs designed to support mothers with of hospitalized preterm infants.

What happens if I say yes, but I change my mind later?
You and your child can leave the research at any time it will not be held against you. If you and your child stop being in the research, already collected data may not be removed from the study database.

Can I still get medical care at UMass Memorial Medical Center if I choose not to participate in this research*?*
Yes, you and your child may still get medical care at UMass Memorial Medical Center if you choose not to participate in this study. Your decision will not change the care you and your child receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you and your child may leave/stop the study at any time. There will be no penalty to you or your child and medical care of you and your child will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you and your child stop the study safely.

It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why.

Will I be compensated for participating in this research?
If you agree to take part in this research study, you will receive a $20 gift card for completing each of the baseline, discharge, and post-discharge surveys and a $10 gift card for completing each biweekly survey. The maximum compensation for the completion of surveys is $140. If you are selected to participate in the interview component of the study, you will receive a $40 gift card upon completion of the interview.

In order to receive these payments for study participation, you will need to give us private information like your name, address and phone number. We will then share this information with the business offices and companies that need it to process the payment.

What will I have to pay for if I participate in this research?
It will not cost you anything to participate in this research.

Who has access to my information?
Signing this document means that you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like you and your baby's names, dates of birth, address, telephone number, and email address
- Related medical information like family medical history, and current and past medications or therapies
- Information regarding your pregnancy and delivery and your baby's hospitalization including test results
- If your infant is transferred, researchers may contact the transfer facility to understand when your infant will be discharged.

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsors
- People and companies who work with the research sponsor
- Federal and state government agencies, such as state auditors
- The Institutional Review Board (IRB) that reviewed this research
- The UMass Chan Medical School and UMass Memorial health, including their Institutional Review Board (IRB) and research, billing, and compliance offices
- Health care providers who provide services in connection with this study
- People and companies who work with UMass Chan and UMMH on activities related to the research

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Efforts will be made to limit the use and disclosure of your and your child's personal information, including research study 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 and other representatives of this organizations involved in this research.

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If our study team assesses the possibility of extreme depression or self-physical harm, we will immediately intervene by reaching out to offer support and a referral for mental health services you and referring you to services. This may involve personnel from this research study or other clinical staff in the NICU.

If identifiers are removed from your and your child's identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your and your child's medical records to conduct and oversee the research. By signing this document you are authorizing this access.

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. If you revoke your authorization, you will not be allowed to continue to participate in the study. We will not collect any new information about you. However, information that we have already collected will stay in the study database and cannot be removed in order to maintain the integrity of the research. Your information may still be used and disclosed if you have an adverse event.

You do not have sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you or your child in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your or your child's information from being used for other research if allowed by federal regulations.

Researchers may release information about you or your child when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or any other

persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you or your child. At most, the website will include a summary of the results. You can search this website at any time.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you and your child from the research study without your approval. This may happen if the research is canceled by the sponsor.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the National Institutes of Health.

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Statement of Consent
I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled. I understand that if I am returning this form electronically or remotely that all pages must be sent back to the researchers.

I consent to participate in the study.

SIGNATURE for Child: Parental Permission (will be documented electronically)
Your signature indicates permission for your child (named below) to take part in this research.

_____
Name of child participant

_____ _____
Signature of parent Date

_____ ❑ Parent

SIGNATURE (will be documented electronically)
Your signature below indicates your permission to take part in this research

_____
Name of participant

_____ _____
Signature of participant Date

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent

We would like permission to contact you for future research that expands upon this study. Please check below if you agree to this:

❑ Yes, you may contact me about future studies
❑ No, I would prefer not to be contacted in the future