Official Title: Promoting Emotional Well-Being in Distressed NICU (Neonatal Intensive Care Unit) Mothers: A Phase 2 Evaluation of a Nurse-Delivered Approach

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INFORMED CONSENT DOCUMENT

Project Title: Mothers Emotional Experiences in the NICU-2: Emotional Support for Mothers in the NICU

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This consent form describes the research study to help you decide if you want you and your baby/babies to participate. This form provides important information about what you and your baby/babies will be asked to do during the study, about the risks and benefits of the study, and about your and your baby's/babies' rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your and your baby's/babies' participation with anyone you choose such as family or friends.
- Do not agree for you and your baby/babies to participate in this study unless the research team has answered your questions and you decide that you want you and your baby/babies to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you and your baby/babies to participate in this research study because you participated in an earlier phase of this study and indicated that you are experiencing symptoms of sad mood in the last week.

The purpose of this study is to assess outcomes associated with two types of emotional support: mental health care provided by NICU social or counseling delivered by a NICU nurse.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 230 women and their babies, who participated in Part 1 of this study, will take part in this randomized controlled trial conducted by investigators at the University of Iowa.

HOW LONG WILL MY BABY AND I BE IN THIS STUDY?

If you agree for you and your baby/babies' to take part in this study, your active involvement will last for eight weeks and involves you completing research assessments at study enrollment, as well as at four and eight weeks after study enrollment. Each assessment will require approximately 30 to 40 minutes to complete. In addition, during this study you will receive mental-health services either from a NICU social worker or a NICU nurse. Those assigned to receive mental-health services from a NICU social worker will meet at least once with a NICU social worker to talk about your well-being and together decide what course of action is needed. For women assigned to this group, the number and length of visits depends on the support options that you and the social worker select. Women assigned to receive Listening Visits from a NICU nurse will meet with the nurse up to six times, every two to three business days, for approximately 45 minutes to an hour in a private place of your choosing within the hospital.

WHAT WILL HAPPEN DURING THIS STUDY?

After study enrollment, you will be invited to complete the first assessment and given a choice of whether to complete the questionnaires online via a tablet given to you by a member of the research team or completing paper copies. The survey questions assess your mood, level of worry or stress, perception of nurse support, use of mental health services and satisfaction with care. You will be randomly assigned (e.g. by chance like flipping a coin) to one of the two groups: mental- health services provided by a NICU social worker or Listening Visits from either a NICU nurse. You will have a 50-50 chance of being placed in either group.

Participants in the Social Work group will:

- Meet with a NICU social worker who will talk with you about your concerns, and if needed facilitate your referral to a mental health specialist.

Participants in the Listening Visits group will:

- Receive 6 Listening Visits from a NICU nurse each visit lasting approximately 45 minutes to an hour, and visits will happen every second to third weekday, depending on your availability and the availability of the nurse

All Participants will:

- Be invited to complete questionnaires at three time-points: immediately after enrollment as well as four and eight weeks post enrollment. You may complete these questionnaires either on a tablet or paper copies. For each assessment there are questionnaires which assess your mood and ask you about your experiences in the NICU. Completing the questionnaires will take approximately 30 to 40 minutes. You are free to skip any question.

- For those preferring to complete these three assessments online, you will receive an email message with a link to the questionnaires. You may complete these assessments at a time that is convenient to you within one week of receiving the link. You may also use the tablet provided by the research coordinator to answer these questions online. You will receive up to three email reminders as well as three phone calls.

- For those preferring to complete paper copies of the questionnaires, a research team will contact you by email and/or phone to 1) let you know that it is time to complete a study assessment and 2) arrange to meet with you to pick up completed questionnaires. Up to three follow-up emails , followed by up to three phone calls will be made to remind you to complete these questionnaires.

- For all participants, if the research team or a clinical staff member of the NICU determines at any time that you are in need of immediate supportive services, they will act to make this referral. They will provide your name to the NICU social work team, who will facilitate appropriate services. The research staff may remove you from the study and facilitate a referral if there is an immediate risk or if you are in immediate need of other treatment. If such an event were to occur, your name will be given to the social work team. If the social worker assesses that you are in danger of hurting yourself or another person, there is also the possibility that you may incur an involuntary hospitalization.

During this study you will be asked to complete questionnaires which ask you about your use of mental-health specialist services and to complete questionnaires to assessing your current emotional well-being.

HIPAA INFORMATION

We will also request access to your baby/babies medical records to record information about their daily infant weight during hospitalization, discharge date, length of stay, and dates of any re-hospitalizations up to 6 months after your infant is discharged from the current admission. You may participate in this study without granting access to these electronic medical records. You will be asked permission to use them below.

Giving permission to access this information is optional. You may still participate in this study even if you do not wish to provide access to your infant's medical record. Please indicate below whether you will permit us to obtain this information from your baby's/babies' health record.. Please check yes or no.

[ ] Yes [ ] No

I give you permission to obtain my baby's/babies' electronic health record as described above.

Audio Recording

One aspect of this study involves making audio recordings of Listening Visits sessions (if you are assigned to the Listening Visits group). Having nurses provide Listening Visits is a new form of care and we are interested in how nurses deliver this support. To assess, an expert provider of Listening Visits will listen to these taped sessions to assess which helping skills the nurse used. Only members of the research team will have access to these audiotapes. Your name will not be provided. The tapes will be identified by your participant ID and session number. The tapes will not be destroyed. Giving permission to audiotape Listening Visits is optional. That is you may participate in this study whether or not you give permission to have Listening Visits sessions audiotaped. Please indicate below whether you agree to having your Listening Visits sessions recorded if assigned to this treatment group.

[ ] Yes [ ] No I give you permission to make audio recordings of Listening Visits sessions during this study.

It is possible that we may also want to contact you about new studies on parents of hospitalized newborns. We would like to keep your contact information (e.g., name, address, and email) as well as the data that you provide on these questionnaires. Agreeing to participate in this study does not obligate you to participate in these future studies. We would be required to invite you to participate in future studies and provide a separate Informed Consent Document for participation in these future studies.

WHAT ARE THE RISKS OF THIS STUDY?

You and your baby may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You may feel embarrassed about discussing mental health issue. You may not wish to take extra time to

participate in either intervention option or may feel uncomfortable discussing your concerns with either type of provider. There is a risk of loss of confidentiality. The procedures we have put in place to protect confidentiality are described in the 'What About Confidentiality' section later in this document.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you or your baby/babies will benefit from being in this study.

However, we hope that, in the future, other mothers of hospitalized newborns/infants might benefit from this study by learning about effective models of emotional support.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

You may receive standard mental health services from the NICU social work team without enrolling in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You may have costs for being in this research study. If you are assigned to meet with a NICU social worker about how you are feeling, the social worker will help you to decide if you want to see a counselor and, if yes, then connect you with a counselor. The costs of these counseling services will not be paid by the study. You may submit these expenses to your insurance company. It is important to note that depending on your coverage, your insurance may or may not cover the cost of the services. The social worker will help you assess your insurance coverage and payment options. There may also be options for support that do not require payment that the social worker can describe.

You and/or your medical/hospital insurance carrier will remain responsible for your and your baby's/babies' regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be compensated for your participation. You will receive a check for $25.00 for completing each of the study assessments. In total, participants completing all three assessments will receive $75.00. You will need to provide a postal address so that a check can be mailed to you. You will be paid after completing each assessment.

WHO IS FUNDING THIS STUDY?

The National Institute of Nursing Research is funding this research study. This means that the University of Iowa is receiving payments from the National Institute of Nursing Research to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Institute of Nursing Research for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your and your baby's/babies' participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your and your baby's/babies' participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you and your baby.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and

- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your and your baby's/babies' confidentiality, we will store your and your baby's/babies' data on a password protected computer only accessible to members of the research team. Data for this study will be stored electronically using the REDCap platform. In REDCap, primary data and data backups are secured in two separate data centers. (Primary data is secured in HCIS Pomerantz Data Center. Data backups are secured in ITS Lindquist Data Center.) Operating system security includes secure logins, remote system logging and configuration, and change management. Data encryption occurs and copies of data are replicated to the remote data center every 15 minutes to facilitate data recovery.

At enrollment, all participants will be assigned a study ID. The list linking the name of the participant to the study ID will be stored on a password protected computer.

Paper copies of the Informed Consent Document will be electronically scanned and stored on the PI's password protected computer in a file that is accessible only to members of the research team. Paper copies will be stored in the PI's office, in a locked cabinet. These paper copies will be placed in a security protected shredder at the time that all data collection is complete. Electronically stored copies of the Informed Consent Document will be maintained.

If you complete paper copies of the study questionnaires, the completed questionnaires will be kept in a locked file cabinet in the PIs research cubicle, which is located in a locked research suite. These completed questionnaires will also be scanned and stored on the password protected computer. A member of the research team will enter your responses into the study database. The database is stored on a password protected computer that can only be accessed by members of the research team.

If you complete the study questionnaires on the tablet the data will be stored electronically using the REDCap platform.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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. At most, the website will include a summary of the results. You can search this website at any time."

WILL MY BABY'S/BABIES' HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about your baby for purposes of this research study. Protected health information is information that personally identifies your baby /babies and relates to your baby's/babies' past, present, or future physical or mental health condition or care. We will access or create health information about your baby/babies, as described in this document, for purposes of this research Once University of Iowa Health Care has disclosed your baby's/babies' protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your baby's/babies'

confidentiality as described under "Confidentiality."

We may share your baby's/babies' health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff,

Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about your baby/babies.

Although you may not be allowed to see study information until after this study is over, you may be given access to your and your baby's/babies' health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your and your baby's/babies' health information for this research study by sending a written notice to Lisa Segre PhD, College of Nursing, University of Iowa, 50 Newton Road, Iowa City, Iowa 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your and your baby's/babies' health information to a third party, such as the study sponsor, or we have removed your and your baby's/babies' identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is voluntary. You may choose for you and your baby/babies not to take part at all. If you and your baby/babies decide to be in this study, you may stop participating at any time. If you decide for you and your baby/babies not to be in this study, or if you stop participating at any time, you and your baby/babies will not be penalized or lose any benefits for which you and your baby/babies otherwise qualify.

What if I Decide to Drop Out of the Study?

Leaving the study early may cause you to experience the following harms or discomforts: psychological distress. If you decide to leave the study early, we will ask you to **contact Cheryl Carter, the study coordinator to indicate that you wish to end your participation. Her phone number is 319-331-8083.**

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we will promptly provide you with that information.

If a member of the research team has concerns about your emotional well-being or if your responses on the study questionnaires indicate that your mood has significantly deteriorated, you may be removed from the study and referred to specialist services

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers or the National Institute of Nursing Research might decide to end your participation in this research study earlier than planned. This might happen because in our judgment it would not be safe for you to continue, because your condition has become worse, because

funding for the research study has ended, or because the sponsor has decided to stop the research, etc..

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Lisa Segre, PhD 319-335-7079 If you or your baby/babies experience/s a research-related injury, please contact: Lisa Segre, PhD 319-335-7079.

If you have questions, concerns, or complaints about your and your baby's/babies' rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your and your baby's/babies' experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide for you and your baby/babies to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Baby/Subject's Name (printed): _____

Baby/Subject Name (printed)_____

Baby/Subject Name (printed)_____

Baby/Subject Name (printed)_____

Mother/Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 04/14/21.

_____ _____

(Signature of Mother/Subject) **(Date)**
for mother's participation

FOR IRB USE ONLY
APPROVED BY: IRB-01
IRB ID #: 201805961
APPROVAL DATE: 04/14/20
EXPIRATION DATE: 04/14/21

Parent/Guardian's Name and Relationship to Subject:

_____ _____
(Name - printed) (Relationship to Subject - printed)

Do not sign this form if today's date is on or after **EXPIRATION DATE: 04/14/21.**

_____ _____
(Signature of Parent/Guardian) (Date)
for baby's/babies' participation

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) **(Date)**