Consent to Participate in Research

Title of Research Study: ***NICU2HOME+: Supporting Illinois Families of Premature Infants with Smartphone Technology***

Principal Investigator: ***Craig Garfield, MD***

Supported By: This research is supported by Health Care Service Corporation.

Key Information about this research study: The following is a short summary of this study to help you decide whether you want to participate in this research as well as whether you want your infant's medical record information to be used as research information for part of this study.
The purpose of this study is to to support diverse Illinois families of premature infants during and after their NICU stays in an effort to address health equity, improve parenting, and reduce costs. Many parents of premature infants report having a baby in the NICU is stressful and disorienting. This research may help health care providers be better informed on how to support and counsel parents of premature infants in the hospital in the future and this research will test the usefulness of the smartphone app experience compared to usual care in the NICU.

TWO RESEARCH GROUPS

Participants will be divided into two research groups based on when their infant was born. The first group, parents of infants born between June 15th and December 31st 2020, will receive the standard care provided in the NICU. The second group of participants, those with infants born between Janaury 1 and July 31 2021, will also receive the NICU standard care and additionally be asked to use a smartphone app related to NICU and at-home care. Participation in the second groups requires ownership of a smartphone and the ability to use a smartphone app.

You have been assigned to the first group. We would like both parents to participate in the study independently and therefore complete individual consent forms. However, we recognize not all families will have two parents that are interested or able to participate and ultimately participation from some families will include only one parent.

As part of the study, you will be asked to complete four surveys. They will be administered at the time of admission, infant's discharge from the NICU, fourteen days after discharge and thirty days after discharge. For those families who have a longer stay in the NICU, we will ask parents to complete two additional surveys; one 30 days after admission and one 60 days after admission.Each survey will take approximately five to ten minutes to complete. The main benefit of participation is that this research that may help improve the NICU experience for other families in the future. The primary risk of participation is the potential loss of confidentiality, but strict measures are in place to minimize the chance of this happening.

In addition, if you agree to the option at the end of this Consent Form, you may or may not be invited to participate in a separate research interview to take place during your NICU stay, around the time of your infant's discharge from the hospital, or within a year of your transition home. These optional, voluntary interviews will be conducted at a time, location and method (phone or in-person) agreed upon by the parent. All interviews will be conducted with our research staff with experience

interviewing parents of NICU graduates. While we encourage both parents to participate in order to hear about differences in experiences, one or both parents can ultimately participate. The purpose of the research interview is to better understand your experience in the NICU and at home as the parent of a premature infant.

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

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

You are being asked to volunteer for this research study because you are the parent of a premature baby who was admitted to the Central DuPage Hospital NICU. This Consent form has important information about the reason for the study, what you will be asked to do, and the way the research information about you and your baby will be used if you choose to be in the study.

How many people will be in this study?

We expect about 600 parents and 350 infants in total will be in this research study; approximately 200 parents and their infants at Central DuPage Hospital, 200 parents and their infants at Northwest Community Hospital, and 200 parents and their infants at Rush University Medical Center.

What should I know about participating in a research study?

You will be introduced to the study and will review this Standard Care Consent form with a member of the research team.

Participants will receive the standard care which includes 1) a welcome packet from the nursing staff, 2) access to their infant's medical team including doctors and nurses, and 3) opportunities to ask any questions and understand the care their baby is receiving through participation in daily work rounds or through setting up family meetings with the medical team.

The study will not conduct any procedures or testing on your infant; however, it will allow our research team to gather protected health information such as your child's medical record number, date of birth, full name, gender, infant due date, length of hospital stay, and clinical information (such as information about your baby's days of life, gestational age, weight, length, and general health). You can agree to take part in the study and later change your mind. This decision will not be held against you. You may ask all the questions you want before you decide. You do not have to answer any questions that you do not want to answer. In the event your child passes away, we will not ask you to complete additional surveys or contact you regarding the optional interview. You will be compensated for your participation to that point.

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

All recruitment and explanation of the study will take place through the CDH postpartum room and NICU. You will be asked to complete a brief form and a survey that helps us understand the transition to parenting for families with a baby in the NICU. The same survey will again be administered to you three more times; around the time of the infant's discharge from the hospital, two weeks after the infant's discharge, and 30 days after the infant's discharge. For those infants who remain in the NICU

for more than 30 days, you will be surveyed at both 30 days and 60 days after NICU admission. The surveys will be online and available via an email link that will be provided to you.

Optional Interview

At the end of this NICU2HOME+ App Consent Form you will be asked if you agree or do not agree to participate in a research interview lasting about 30-45 minutes. The interview may take place in-person in the NICU or over the phone. The purpose of the interview will be to 1) address concerns and challenges faced by a parent such as you in the NICU and at home regarding the ongoing medical care of your infant and their own personal health throughout their NICU stay and transition to home; 2) identify other potential sources of support, information, and communication that would help you better manage the care of your infant and yourself; and 3) address issues related to the the smartphone app.

Up to 15 people in the study who have indicated in this Consent Form that they are willing to participate in a research interview, will be invited to attend an interview in person in the NICU or over the phone.

You do not have to agree to participate in the research interview in order to participate in the main study. The interview will be audio-recorded to aid the researcher in collecting all of the discussion as part of the research findings, and will take place during the time your baby is in the NICU, around the time of discharge from the hospital, or within [disclose a more specific window of time] after your baby's transition to home.

Will being in this study help me in any way?

The main benefit of your participation in this study is that your feedback regarding challenges and concerns about your baby being in the NICU may help other families in the future that are faced with having a baby in the NICU and faced with caring for a premature infant at home. You may also become more aware of your own personal concerns about the care of your infant.

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

There are no physical risks to your participation in this study. Participation in this study does not involve any physical risk to you or your infant. The study will not involve any procedures or testing of your infant.

Given the emotionally charged nature of infant NICU hospitalization, participants may experience discomfort in answering some of the survey questions. You can choose to skip any question that may cause discomfort or emotional upset. Participants are able to stop completing the surveys at any time or to not answer questions. Participants may stay in the study even if they skip some of the questions.

A possible risk for this research is that there may be a loss of confidentiality – that is, that people outside the study might obtain your confidential study information. We will take measures to minimize this risk as described in more detail later in this Consent form.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship with Northwestern University/Northwestern Memorial Healthcare.

You can stop your participation in this research at any time and leave the research at any time and it will not be held against you. We can also end your participation in this research at any time. If you request to stop participation in this research, we will no longer provide e-mails to you about the online surveys. If this happens, I will ask you if any data collected from you or your child up until that point may be used in the research.

How will the researchers protect my information?

To help maintain some confidentiality, all subjects will be given a unique study code (PIN) and all of your and your infant's research information collected for the study will be linked to that number, and will not include any of your and your child's identifying information. All documents that include your and your infant's identifying information will be stored separatelyin a locked, secure location that only authorized study personnel will have access to.

If you choose to participate in the audio recorded interview, the recordings will be given an ID number and kept on secure computers. The audio recordings will be transcribed and kept on password protected computers. (There will be no personal identifiers (such as names) in the transcribed documents.) After the recordings are transcribed, the audio files will be erased. Only the people listed on the Authorized Research Personnel list will have access to identifiers and the collected research data. All paper data will be kept in locked files and rooms in Dr. Garfield's Northwestern University office. Electronic data will be kept on password- encrypted computers on Northwestern University's secure network and files with your identifying information will be individually password protected.

Your and your infant's names and contact information will be stored only for the purpose of contacting you and for linking to your study data. This information will be stored separately from study data and the two will only be linked by a study ID, kept in a password protected file on Northwestern University's network. Upon completion of study data collection identifying records with your and your infant's name and contact information will be deleted.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include university officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research study for study recordkeeping and for potential use in future research projects. Your name and other information that can directly identify you will be stored securely and separately from the study data we collect from you.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove or code any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee anonymity of your personal data.

The results of this study could be shared in articles and presentations, but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations.

Will I be paid or given anything for taking part in this study? Each family as a whole, whether one or two parents participate,will receive up to $50 as financial compensation, via a pre-paid PNC Bank cash card, for completing the entire study. One parent in the family will receive $10 on one card within a week of enrollment, $15 at discharge from the hospital, and $25 at 30 days after discharge if you have completed all of the surveys; four, five, or six surveys depending on the length of stay of their infant in the NICU. You can withdraw from the study at any point in time; no further payments will be made for surveys not completed. For those participants who are invited to participate in the optional research interview, an additional $25 will be paid to to the PNC card upon completion of the optional research interview.

You will be asked to activiate an account via the Northwestern University Prepaid Card Portal in order to activate and use the PNC Bank card. Funds will be transferred to the PNC card account provided surveys are completed 1) at the time of enrollment, 2) upon the infant's discharge, and 3) upon completion of the study 30 days after discharge) and instructions provided via email regarding account access, activation, and non-use penalties. There is no fee for activation of the card and no fees for use of the card. A $3.00 fee will be incurred if your account is not activated within 180 days. An additional $3.00 fee will be charged for each 30 day period that the card is not used.

HIPAA Authorization -- Permission to Use Personal Health Information For Research

In order to participate in this study, we need to obtain your infant's health information from their medical providers. Your signature on this consent with HIPAA Authorization is the means for getting access to that information. We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your infant's personal health information that includes health information in your infant's medical records and information that can identify you or your infant. For example, your personal information may include your name, address, phone number or social security number. We will not access your medical record. Your infant's health information we may collect and use for this research includes:

- Specific points of data (i.e. days of life, adjusted gestational age, weight, length, and general health) and results of physical examinations
- Medical history

- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

This consent expires on 12/31/2022. After this date, Northwestern University may not gather new information about you or your infant, use or disclose your or your infant's personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

During this study, you or your infant will be at a Northwestern Memorial Healthcare Corporation entity (for example, Central DuPage Hospital) for clinical care. When that happens, you will be scheduled for tests or services through the NMHC computer system.

The following clinical providers may give the researchers information about your infant: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Central DuPage Hospital, Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University 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 University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern 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.
- Clinical affiliates, including but not limited to the Northwestern Medicine Central Dupage Hospitial (NM CDH), Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.

- Clinical affiliates, including but not limited to Northwestern Medicine Central Dupage Hospital (NM CDH), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- 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.

Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

Unless you revoke your consent, it will expire 12/31/2022.

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:

PI's Name: Craig Garfield, MD
Institution: Northwestern University, Feinberg School of Medicine
Department: Department of Pediatrics
Address: 625 N. Michigan Ave, Floor 21, Chicago, IL 60611

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.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Who can I talk to?

If you have questions, concerns, or complaints, you can contact the the Principal Investigator, Craig Garfield at (312) 503-5463 or c-garfield@northwestern.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-9338 or by email at 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.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to your choice for each activity.

I agree	I disagree	
_____	_____	I am willing, if I am selected, to participate in a research interview about my experiences in the NICU and at home with a premature infant. It will last approximately 30-45 minutes with a time, location and method (phone, in-person, online) agreed upon by the parent. Participants will be selected based on the age of their infant at time of birth and length of stay in the NICU.
_____	_____	The researcher may use your audio recording in scholarly presentations or publications when hearing your voice might serve to help others understand the research. Audio recording will not be used for promotional purposes of the app. Althgough your names will NOT be in the recording, you may be identifiable by your voice in the audio recording.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.

Signature for Adult 18 or older

Your signature documents your permission to take part in this research and for disclosure and use of personal health information from your medical record for purposes of this study.

_____ _____

Signature of participant Date

_____

Printed name of participant

_____ _____

Signature of person obtaining consent Date

_____

Printed name of person obtaining consent

Signature for Parent Permission:

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

_____

Printed Name of Child

Consent to Participate in Research

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