Ann & Robert H. Lurie Children's Hospital of Chicago

R S C H

Affix Patient Label Here
Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Parent Permission for an Infant to Participate in a Research Study

Study Name: *Evaluating the Effects of Kangaroo Care in the NICU*

Sponsored by: Stanley Manne Children's Research Institute
Name of Researcher (referred to as the study doctor): Dr. Craig Garfield

This consent form describes a research study for which your infant might qualify at Northwestern Medicine Prentice Women's Hospital. Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to allow your infant to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family or healthcare providers before you decide to allow your infant to take part in this study. The study staff will also explain the study to you and answer any questions that you may have. Your decision will not affect your infant's regular care. Please note that this consent focuses on your infant's participation in the study. Another consent ("Adult Consent to Take Part in a Research Study") focuses on your participation as the parent and will also be needed for participation in this study.

What are the purpose and goals of this study?
Skin-to-skin contact between a preterm infant and a parent is a practice that is commonly referred to as Kangaroo Care (KC). KC is sometimes used in the neonatal intensive care unit (NICU) as a tool to support infant development and encourage parent-infant bonding. During KC, a parent holds an infant against their bare chest, skin-to-skin. KC in the NICU has shown many positive effects in both infants and parents, such as improved infant development, decreased infant illness, and improved parent-infant bonding.

In this study, we hope to learn more about how KC impacts infants and their parents while in the NICU and beyond. We will do this by looking at how participating in KC affects vital signs (such as heart rate and respiration) and hormone levels in both parents and infants, as well as how it affects parental feelings and opinions. Understanding how KC affects all three of these things - vital signs, hormone levels, and feelings about parenting - will help us encourage and support the implementation of KC as a standard of care practice in the future.

You are being asked to allow your infant to participate in this study because your infant is currently in the NICU at Prentice Women's Hospital. Up to 50 infants and 100 adult parents will be enrolled in this study at Prentice in order to sufficiently evaluate the effect of KC on infants and their parents.

If I agree to have my infant take part in this study, what would my infant need to do?
Participation in this study will occur during your infant's time in the NICU at Prentice Women's Hospital. The maximum amount of time that your infant will participate in this study is 48 hours. The three main parts of this study are described below.

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Kangaroo Care Sessions: If you agree to participate, a member of the study team will schedule your family for two Kangaroo Care (KC) Sessions, one Kangaroo Father Care (KFC) Session and one Kangaroo Mother Care (KMC) Session, ideally on two consecutive days in the NICU. Each session will be two hours in length. If you would like to participate in additional KC sessions, not associated with this study, you can talk to your infant's clinical care team about performing KC as part of your child's standard NICU care.

Wireless Sensor Vital Sign Monitoring: Before the first scheduled KC session, two wearable sensors will be placed on your infant's skin. One sensor will be placed on your infant's chest and one sensor will be placed on your infant's foot, hand, leg, or arm. The sensors will remain attached to your infant for up to 48 hours to continuously record their heart rate (HR), body temperature, movement, and other vital sign measures for the duration of the study. This information will be transferred wirelessly to a nearby computer or stored in the sensor's memory. The information recorded by the sensors will be recorded for research purposes only. These sensors will not affect the standard monitoring done in the NICU.
Before and after the sensor is placed on your infant, the study team will take pictures of your infant's skin at the site of sensor placement to help monitor their skin. These pictures are taken for research purposes only and will not contain your child's face or any other information to identify your child.

Saliva sample collection: Right before each of the scheduled KC sessions, a member of the study team will collect a small sample of saliva from your infant's mouth. The same samples will be collected ~30 minutes after the start of the 2-hour KC session and ~30 minutes after the end of the session. These saliva samples will be tested to determine how KC affects the hormones in your infant's body that are associated with stress and parent-infant bonding.

What are the risks, side effects, or discomforts related to the study?
Your infant may have some side effects and discomfort while in this research. If your infant has any side effects, you should tell the study doctor or staff as soon as possible. They will monitor your infant closely. This research may also have risks or side effects that are not well known or understood at this time. Two known risks are outlined below.

Sensor Risk: The sensors use adhesives that are commonly used on NICU infants. While the adhesive is usually well tolerated in the NICU and we do not expect any side effects, we cannot predict how your infant's skin will react. In order to minimize the risk of skin irritation, the study team will closely monitor your infant's skin at the sites of sensor placement before, during, and after sensor placement. If your infant exhibits any side effects, such as discomfort or skin irritation, the sensors will be removed, and the bedside care team and a physician from the study team will be consulted.

Data Risk: The data risk involved with this study includes potential loss of privacy or confidentiality. There are a number of safeguards in place to de-identify and store data in a way that should minimize this risk. Access to this research data is restricted to the PI of the study and key personnel on the research team. Data will be coded, meaning that we will remove identifying

information from the data and store it with only a study number. Data will remain on the secure hospital network and under the same safeguards that are in place for clinical data. Any data stored for future studies will be further de-identified, after study conclusion. Any data that is transferred off of the hospital network for statistical/data analysis will be fully de-identified before it is transferred.

What are the benefits from this study?
Your infant will not benefit from taking part in this study. The information learned from this study may help other children in the future.

What other options does my infant have?
The alternative to participating in this study is not participating. Your decision regarding participation will not affect the treatment that your infant receives from the NICU clinical team.

What if my infant's study doctor or I do not think my infant should stay in the study?
If you, the study team, or your infant's clinical care team determines that your infant should not be in the study, we will immediately end your infant's participation. You can stop your infant from taking part in this study at any time. Your choice will not affect the standard NICU care that your infant receives.

Returning Study Results:
The study team will not return study results to you and your child. You can ask the study team any questions you have about study results.

Important New Information:
We will tell you if we learn new information that may make you change your mind about your infant being in this study.

Planned Sharing of your Infant's Information:
If you agree to let your infant take part in this study, you also give permission to the use and sharing of your infant's information. This permission lasts until the study is completed.

This information that may be collected and shared will include your infant's:

- Personal and health information
- Past and present medical records
- Records from study visits and phone calls

The study staff, including employees and Medical Staff at Lurie Children's Hospital, Prentice Women's Hospital, Northwestern Memorial Hospital (NMH), and Northwestern University (NU), may use your infant's information and share it with:

- The study sponsor, Stanley Manne Children's Research Institute, and those working with the sponsor.

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- The Lurie Children's Institutional Review Board (IRB; the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
- Your infant's other providers and their staff directly involved in your infant's care, if your infant's provider is a part of the Lurie Children's electronic health information exchange.
- Authorized members of NU workforce, who may need to see your infant's information, such as administrative staff members from the Office for Research, Office for Research Integrity, and the NU IRB.
- Clinical affiliates, including but not limited to the Shirley Ryan Ability Lab, Northwestern Medical Group, NMH, Northwestern Lake Forest Hospital, and Lurie Children's. Your participation in this study may be tracked in an electronic database and may be seen by investigators running other studies that you are enrolled in and by your healthcare providers.
- The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.

These are the only people to which we will give your infant's information. We cannot guarantee that those listed above will not share it with others without your permission.

Your infant's name will not be included in any written or verbal reports of study results.

What if I decide not to give permission to use and give out my infant's information?
If you decide not to allow the release your infant's information, your infant will not be able to take part in this study. If you give permission to the use of your infant's information, you can withdraw it at any time. Your request should be in writing and sent to the study doctor. The study team can still use any information collected before you tell them to stop.

Can I review or copy my infant's information?
You cannot see your infant's study records. However, any testing that relates to your infant's medical care will be put in your infant's medical record. You still have a right to request a copy of your infant's medical record.

Will my infant's information or samples be used in future research studies?
Data collected by the wearable sensors and standard of care monitoring devices will be collected during the 48-hour study duration and stored for future research. This research may include validation of sensor signals and/or analysis of these measures for use as predictors of health outcomes. These data will be coded and stored without identifiers. A sheet linking this coded information to your infant's identifiers will be stored separately, on an encrypted hospital computer to which only members of the study team will have access.
The study team may share your infant's information for future research. They will only share the de-identified information for such research. The study team and other researchers may use this for other studies without getting consent from you or your child.

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Costs Related to this Study:
There are no study related costs to you or your insurance company. However, you and/or your insurance company are responsible for the costs of normal care, including any skin treatment that may be associated with reactions to standard NICU adhesives used in the wearable sensors, or as standard of care. Lurie Children's may be able to provide some financial help to patients. Ask your infant's health team for more information about this program.

Payment for Taking Part in this Study:
Your infant will not receive any payment for taking part in this study.

Your Infant's Rights When Taking Part in this Study:
If you agree to have your infant take part in this study, you are not giving up any of your or your infant's legal rights. You can stop your infant's participation in this study at any time. Your choice will not affect your infant's regular care.

Who can answer my questions about this study?
If you or your infant has any questions, contact the study doctor, Craig Garfield, MD, at 312-503-5463, or the study manager, Casey Rand, at 312-227-3300 during a workday, at night, or on weekends.

If you have questions about your child's rights or if you have a complaint, you can call the IRB Office at (312) 503-7110; or via email at IRB@luriechildrens.org.

You will be given a copy of this consent form. A copy will also be placed in your infant's medical record.

Please be advised that John Rogers, Steve Xu, and Ha Uk Chung, Investigators on this study, are inventors of the technology being tested in this study and are a part of a company, Sibel, that could benefit from the results of this study. In addition, Northwestern University owns the invention being tested in this study and may benefit financially from it in the future. You may request additional information about this relationship from the study doctor at any time.

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Printed Name of Child:

Parent/LAR Signature:

By signing this form, I affirm: 1) I have read this form. 2) The research has been explained to me. 3) All of my questions have been answered. I give my consent for my infant to take part in this research study.	
Signature of Parent or Legally Authorized Representative (LAR):	Date:
Printed Name:	
Relationship to Child:	

Signature of Authorized Person Obtaining Consent:

I certify that I have explained the above to the parent(s)/LAR and the signature(s) was obtained voluntarily.	
Signature:	Date:
Printed Name:	

Signature of Interpreter/Witness*:

☐ Not applicable, no interpreter used.
I attest that the study information has been presented to the parent/legally authorized representative (LAR) in his/her native language. He/she was given the opportunity to have all questions answered.
Signature of Interpreter/Witness:
Printed Name or Unique Phone ID/Company Name:

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Note to Investigators: When obtaining consent from a non-English speaking parent/LAR

When a study-specific translated consent document is not available, a translated "short form" (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

a. *The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*

b. *The parent/LAR should sign the short form (in the language they understand).*

c. *The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*

d. *A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the parent/LAR.*