**Study Title:** Support Tool for Families of High-Risk Children with Heart Disease During Hospital Admission and After Discharge

**NCT number:** NCT05926661

**Date:** 10/25/2023

Approved by the Nemours IRB
Valid From: October 25, 2023
to
[1902609]

# Nemours
# Informed Consent for Participation in an Observational / Non-Interventional Research Study

*Nemours IC Non-interventional Template July 2020*

---

You have been asked to be in a research study. This form explains the research, your rights as a research participant, and any responsibilities that you may have as a result of your participation. You should understand the research study before you agree to be in it. ***You will receive a copy of this form. Read this permission form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.***

## 1. WHAT IS THE TITLE OF THE STUDY?

Support tool for families of high-risk children with heart disease during hospital admission and after discharge.
AIM 3

## 2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?

If you have a question, complaint, or problem related to the study, you can call the investigator anytime at the numbers listed below.

| | **Nemours - WIL** |
|---|---|
| **Principal Investigator** | Deepika Thacker, MD |
| **Co-Investigator(s)** | Erica Sood, PhD<br>Jennie Ryan, APRN |
| **Study Coordinator(s)** | Varsha Zadokar, MBBS<br>Carol Prospero, BS |
| **Address** | Nemours Children's Hospital<br>1600 Rockland Road<br>Wilmington DE 19803 |
| **Daytime Phone**<br>**After Hours Phone** | 302-651-6600<br>302-651-4000 |
| **Long Distance** | 1-800-SOS-KIDS *or* 1-800-767-5437 |

## 3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?

If you have questions about your rights as a research participant, what to do if you are injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed below.

Chairperson, Nemours IRB 1 at 302-298-7613
Director, Nemours Office of Human Subjects Protection at 302-298-7613
Email address: NOHSP@nemours.org

**4. WHAT IS THE PURPOSE OF THE STUDY?**

Based on the qualitative interviews conducted during Phase 1 of the study, we have developed the "support tool" for high-risk families to improve post-discharge outcomes. Our goal is to assess the acceptability and feasibility of the tool through questionnaires administered to parents/caregivers and healthcare personnel.

**5. WHO IS SPONSORING OR PAYING FOR THE STUDY?**

The National Institute of General Medical Sciences is providing funding for this study through the Delaware Center for Translational Research (DE CTR ACCEL program).

**6. WHO CAN BE IN THE STUDY?**

You are being asked to be in this study because you are a member of healthcare team involved in discharge planning.

**7. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?**

The research team plans to include up to 5 healthcare providers in this phase of the study at Nemours.

**8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?**

The participation includes completing a survey questionnaire and some open-ended questions to get feedback on acceptability and feasibility of the tool. This will be done via phone, Microsoft Teams or in-person and will take approximately 15-20 minutes.

**9. WHAT ARE THE RESEARCH PROCEDURES?**

If you agree to participate, you will be asked to complete a qualitative interview and a ratings questionnaire via phone or in-person, or Microsoft Teams to assess the acceptability and feasibility of the support tool either in-person or via phone call. The interview will take approximately 30 min. During the interview, you will be asked questions about discharge process and any feedback or suggestions. You will also be asked a few demographic questions. The interviews will be recorded and transcribed (typed out word for word) within Microsoft Teams.

**10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?**

The risks involved in this study are the same as the risks you would ordinarily encounter in daily life. This research is observational and minimal risk. The possible risks are described below.

The main risk of participating in this study is loss of confidentiality due to work relationships. We will protect your identity as much as possible by storing records in files or computers that can only be used by authorized Nemours staff.

**11. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?**

You are unlikely to experience any direct benefits from being in this study. You may feel good about helping the researchers learn more about opportunities to support families of high-risk children with heart disease.

**12. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?**

If you think that you have been injured while in this study or has a problem related to the study, you should tell one of the study doctors as soon as possible. The study doctor or research staff will tell you what you should do. The study doctor(s)' names and phone numbers are on the first page of this form.

**13. IS BEING IN THE STUDY VOLUNTARY?**

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. No one will be upset with you or treat any differently than before you were asked to be in the study.

**14. WHAT ARE THE COSTS OF BEING IN THIS STUDY?**

There is no cost for being in the study.

**15. WILL I BE PAID FOR BEING IN THIS STUDY?**

You will not be compensated for this study. No arrangement exists that would allow participants to share in any profit generated from this study or future research.

**16. WHAT INFORMATION ABOUT ME WILL BE USED OR DISCLOSED? (AUTHORIZATION TO USE AND / OR DISCLOSE PROTECTED HEALTH INFORMATION)**

Identifiable health information about you will be used by Nemours researchers and may be given to people outside of Nemours for this research. This is done to conduct the research study, to monitor the safety of research participants and for auditing. Federal law requires us to tell you about, and get your approval for research use and disclosure of health information that includes "identifiers" that can connect the health information to you. (Names, initials, date of birth, addresses, phone numbers, and social security numbers are examples of identifiers.) This Identifiable health information is called Protected Health Information (PHI).

**17. SIGNATURES:**

I am making a decision whether or not to participate in this study. I have read this form or have had it read to me in a language I understand. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly consent to participate in this study. By choosing to participate in this study, I am not giving up any rights to which I am entitled under law.

I understand that:

- I can withdraw consent for participation in this study and for the use and / or disclosure of my PHI by contacting the person in charge of the study listed on the first page of this form.
- The use and / or disclosure of my PHI will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- Unless I withdraw consent, the use and / or disclosure of my PHI described in this form will expire when the research study is complete, and analysis and publication have ended.
- My PHI may be disclosed again by the person or organization (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this permission form.
- If I refuse to sign this consent form, I will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my protected health information.
- I have the right to revoke my permission for the use and disclosure of my health information at any time, which would end my participation in this study.
- I will receive a signed and dated copy of this form.

My signature indicates that:

- I give my consent to participate in the research study described in this form.
- I give the researchers and Nemours permission to use and / or disclose my individually identifiable health information for this research study as described in the section on use and disclosure of PHI.

| | |
|---|---|
| Name of Participant (**Print**) | Participant Date of Birth |
| **Signature** of Participant | Date |

I, the undersigned, certify that to the best of my knowledge the participant signing this consent had the study fully and carefully explained and that she / he understands the nature, risks and benefits of his / her participation in this research study.

I, the undersigned, certify that the participant completed no research procedures for this study prior to signing this consent.

Name of Person Obtaining Consent (**Print**)
(Investigator or Designee)

**Signature** of Person Obtaining Consent
(Investigator or Designee)

Date

A copy of the signed form was provided to Participant ☐

| Patient's Name | |
|---|---|
| MRN | |

Approved by the Nemours IRB
Valid From: October 25, 2023
to
[1902609]

# Nemours
# Informed Consent for Participation in an Observational / Non-Interventional Research Study

*Nemours IC Non-interventional Template July 2020*

You have been asked to be in a research study. This form explains the research, your rights as a research participant, and any responsibilities that you may have as a result of your participation. You should understand the research study before you agree to be in it. ***You will receive a copy of this form. Read this permission form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.***

## 1. WHAT IS THE TITLE OF THE STUDY?

Support tool for families of high-risk children with heart disease during hospital admission and after discharge.
AIM 3

## 2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?

If you have a question, complaint, or problem related to the study, you can call the investigator anytime at the numbers listed below.

| | **Nemours - WIL** |
|---|---|
| **Principal Investigator** | Deepika Thacker, MD |
| **Co-Investigator(s)** | Erica Sood, PhD<br>Jennie Ryan, APRN |
| **Study Coordinator(s)** | Varsha Zadokar, MBBS<br>Carol Prospero, BS |
| **Team members** | Dana Zingo, BSN, RN, CPN |
| **Address** | Nemours Children's Hospital<br>1600 Rockland Road<br>Wilmington DE 19803 |
| **Daytime Phone**<br>**After Hours Phone** | 302-651-6600<br>302-651-4000 |
| **Long Distance** | 1-800-SOS-KIDS *or* 1-800-767-5437 |

## 3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?

If you have questions about your rights as a research participant, what to do if you are injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed below.

Chairperson, Nemours IRB 1 at 302-298-7613
Director, Nemours Office of Human Subjects Protection at 302-298-7613
Email address: NOHSP@nemours.org

**4. WHAT IS THE PURPOSE OF THE STUDY?**

Based on the qualitative interviews conducted during Phase 1 of the study, we have developed the "support tool" for high-risk families to improve post-discharge outcomes. Our goal is to assess the acceptability and feasibility of the tool through questionnaires administered to parents/caregivers and healthcare personnel.

**5. WHO IS SPONSORING OR PAYING FOR THE STUDY?**

The National Institute of General Medical Sciences is providing funding for this study through the Delaware Center for Translational Research (DE CTR ACCEL program).

**6. WHO CAN BE IN THE STUDY?**

You are being asked to be in this study because you are the parent or guardian of a child who was diagnosed with heart disease and admitted to the Nemours Cardiac Center for care.

**7. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?**

The research team plans to include up to 5 parents/caregivers in this phase of the study at Nemours.

**8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?**

The participation includes completing the activities under applicable subtools while in-patient and/or during immediate post-discharge period.

**9. WHAT ARE THE RESEARCH PROCEDURES?**

If you agree to participate, you will be provided training on how to use Nemours App and use it for your child's care. This will be done either on your mobile phone device or we will provide a loaner iPad with Nemours App. You will also be provided with meal cards and gift cards for gas to facilitate any transportation barriers and to allow you to be present at bedside. In addition, you will be offered other subtools if applicable such as option for language line, roadmap for feeding tube, psychological support and verification of medications prior to discharge.

At the end of the study, you will be asked to complete a qualitative interview and a ratings questionnaire via phone or in-person, or Microsoft Teams to assess the acceptability and feasibility of the support tool either in-person or via phone call. The interview will take approximately 30 min. During the interview, you will be asked questions about your child's admission and your experience about discharge process. You will also be asked a few demographic questions about your family. The interviews will be recorded and transcribed (typed out word for word) within Microsoft Teams. The recording will be audio (sound) only and will not include video.

**10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?**

The risks involved in this study are the same as the risks you would ordinarily encounter in daily life. This research is observational which means that there is no change to any treatment that your child may be receiving. The possible risks are described below.

The main risk of participating in this study is loss of confidentiality. We will collect information from you and from your child's medical record in order to conduct the study. We will protect your identity as much as possible by storing records in files or computers that can only be used by authorized Nemours staff. The information will not be given outside of Nemours.

**11. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?**

You are unlikely to experience any direct benefits from being in this study. You may feel good about helping the researchers learn more about opportunities to support families of high-risk children with heart disease.

**12. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?**

If you think that you have been injured while in this study or has a problem related to the study, you should tell one of the study doctors as soon as possible. The study doctor or research staff will tell you what you should do. The study doctor(s)' names and phone numbers are on the first page of this form.

**13. IS BEING IN THE STUDY VOLUNTARY?**

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your child's usual medical care if you decide not to participate the study or decide to stop your participation in the study. No one will be angry with you or your child, or treat your child any differently than before you were asked to be in the study.

**14. WHAT ARE THE COSTS OF BEING IN THIS STUDY?**

There is no cost for being in the study.

**15. WILL I BE PAID FOR BEING IN THIS STUDY?**

You will be given a $50 gift card after completing a survey questionnaire at the end of the study.

No arrangement exists that would allow participants to share in any profit generated from this study or future research.

**16. WHAT INFORMATION ABOUT ME WILL BE USED OR DISCLOSED? (AUTHORIZATION TO USE AND / OR DISCLOSE PROTECTED HEALTH INFORMATION)**

Identifiable health information about your child will be used by Nemours researchers and may be given to people outside of Nemours for this research. This is done to conduct the research study, to monitor the safety of research participants and for auditing. Federal law requires us to tell you about, and get your approval for research use and disclosure of health information that includes "identifiers" that can connect the health information to your child. (Names, initials, date of birth, addresses, phone numbers, and social security numbers are examples of identifiers.) This Identifiable health information is called Protected Health Information (PHI).

**Use of Health Information by Nemours Staff**

The health information that will be used within Nemours includes all data collected for this study, as described in Section called "What Are the Research Procedures?"

Your child's identity will be protected as much as possible. Nemours protects you and your child's health information by storing records in files or computers that can only be used by authorized Nemours staff. The people within Nemours that may use this health information include:

- The investigators listed on the first page of this permission form and their staff,
- The Nemours Institutional Review Board (IRB) (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of research participants), and; □ Nemours internal audit staff.

**Disclosure of Health Information to Others**

Identifiable health information will not be disclosed outside of Nemours.
The research results may be presented at scientific meetings or in print. Participants' identities will not be disclosed in those presentations.

Your/your child's name, address, subject ID number, date of birth, email address, and cell phone number will be collected and given to Greenphire to manage stipend payments to your ClinCard. Your/your child's personal information will be stored on Greenphire's confidential computerized processing system. Greenphire has committed to not sharing your/your child's information with any third parties. Your/your child's personal information will be kept completely confidential to the extent possible.

Payment for taking part in a research study may be considered taxable income. Please be aware that all expenses such as parking, meal vouchers, hotel, transportation, etc. do not count towards the $600 limit and will not be taxed as income. If payment exceeds $600 in any one calendar year, Greenphire will file a 1099 (Miscellaneous Income) form on behalf of Nemours. If a 1099 is needed, Greenphire will need your/your child's name, address, and social security number.

**17. SIGNATURES:**

I am making a decision whether or not to participate in this study. I have read this form or have had it read to me in a language I understand. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly consent to participate in this study. By choosing to participate in this study, I am not giving up any rights to which I am entitled under law.

I understand that:

- I can withdraw consent for participation in this study and for the use and / or disclosure of my PHI by contacting the person in charge of the study listed on the first page of this form.
- The use and / or disclosure of my PHI will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- Unless I withdraw consent, the use and / or disclosure of my PHI described in this form will expire when the research study is complete, and analysis and publication have ended.
- My PHI may be disclosed again by the person or organization (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this permission form.
- If I refuse to sign this consent form, I will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my protected health information.
- I have the right to revoke my permission for the use and disclosure of my health information at any time, which would end my participation in this study.
- I will receive a signed and dated copy of this form.

My signature indicates that:

- I give my consent to participate in the research study described in this form.
- I give the researchers and Nemours permission to use and / or disclose my individually identifiable health information for this research study as described in the section on use and disclosure of PHI.

| | |
|---|---|
| Name of Participant (**Print**) | Participant Date of Birth |
| **Signature** of Participant | Date |

I, the undersigned, certify that to the best of my knowledge the participant signing this consent had the study fully and carefully explained and that she / he understands the nature, risks and benefits of his / her participation in this research study.

I, the undersigned, certify that the participant completed no research procedures for this study prior to signing this consent.

Name of Person Obtaining Consent (**Print**)
(Investigator or Designee)

**Signature** of Person Obtaining Consent
(Investigator or Designee)

Date

A copy of the signed form was provided to Participant ☐

| | |
|---|---|
| Patient's Name | |
| MRN | |

Approved by the Nemours IRB
Valid From: October 25, 2023
to
[1902609]

**Nemours**

**Addendum for iPad Use and Return to Nemours Cardiac Research Team**
*Version March 2018*

As a part of this research study, I agree to receive a loaner iPad from Nemours Cardiac Center to assist with the care of my child, and I understand that this device must be returned to Nemours Cardiac Center Research Team at my child's first cardiac outpatient clinic visit after hospital discharge.

By signing below, I acknowledge the receipt of the iPad and a charging cord, and I agree to return these items at the expected time. I understand that Nemours Cardiac Center staff will contact me to coordinate the return process if it is not returned at the expected time. I also understand that I must take all the precautions to protect the iPad against any damage, loss or misuse while in my care.

Items to be returned to the Nemours Cardiac Center: Apple iPad (9th generation10.2") and charging cord.

| | |
|---|---|
| Name of Participant (**Print**) | Participant Date of Birth |
| **Signature** of Participant | Date |