Official Title:
Decision Making Support for Parents and Caregivers

NCT#:
NCT05733975

Informed consent document date:
3/10/2023

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Decision Making Support for Parents and Caregivers

Informed Consent: Infant

CONCISE SUMMARY

The purpose of this study is to test the usefulness of a guide to support decision-making for parents of critically ill infants. This guide can be used as a tool to help you understand what is most important to you as you prepare to make decisions for your child. We will study how useful the tool is using surveys and interviews. Information will be collected from your infant's medical record.

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you are the parent of an infant who is critically ill. Research studies are voluntary and include only people who choose to participate. Please read this consent form carefully and take your time making your decision. As your infant's study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Monica Lemmon's and the Neonatal/Perinatal Research Unit's salaries will be paid by this grant.

WHO WILL BE MY INFANT'S DOCTOR ON THIS STUDY?
Dr. Monica Lemmon will conduct this study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to test the usefulness of a parent guide to help assist you while having complex discussions with your infant's medical team regarding your infant's care. This guide could help prepare you for decisions that involve weighing the benefits and harms of a treatment or intervention for your infant. Our goal is to determine whether this guide is helpful to you as you and the health care team make decisions related to your infant's care.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 30 infants, 45 parents and 30 clinicians will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to allow your infant to be in this study, you will be asked to sign and date this consent form. You will be given a guide to review with a member of the team. This tool will be used to help prepare

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you for discussion with your infants' health care team. After you have used the tool, we will ask you to complete a brief interview. The interviews will be audio recorded, transcribed, and de-identified (all personal identifiers will be deleted from the transcript). The recordings will be deleted at completion of the study.

For study purposes only, we will review and record de-identified information about your infant's medical course. For example; age, gender, medical diagnosis, length of stay in the intensive care unit, and technology dependence (presence of feeding tube, tracheostomy, or ventriculoperitoneal shunt). We will also collect information from you.

HOW LONG WILL MY INFANT BE IN THIS STUDY?
Your infant will be in this study until he/she is discharged from the hospital.

We would also like permission to contact you about future research opportunities. If you give permission to be contacted, you will be free to accept or decline at that time. This permission just allows us to contact you. Please initial your choice below.

(_____) Yes, I agree to be contacted in the future.
Initial

(_____) No, I do not agree to be contacted in the future.
Initial

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your infant's information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There are no direct benefits to you. If you take part in this study, you may help others in the future.

WILL MY INFANT'S INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you and your infant is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your infant's personal information may also be given out if required by law.

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The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your infant's research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your infant's research record forever. Any research information in your medical record will also be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your infant's name or other personal information will not be revealed.

Some people or groups who receive your infant's health information might not have to follow the same privacy rules. Once your infant's information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the

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federal law designed to protect your infant's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There are no costs associated with your infant's participation in this study.

WHAT ABOUT COMPENSATION?
You will not be compensated for allowing your infant to participate in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
There are no risks of research related injuries as this study involves your participation as the parent of an infant who is critically ill.

For questions about the study or research-related injury, contact Dr. Monica Lemmon at [redacted] during regular business hours and ([redacted] after hours and on weekends and holidays.

WHAT ABOUT MY INFANT'S RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to allow your infant to be in the study, or, if you agree to allow your infant to be in the study, you may withdraw him/her from the study at any time. If you withdraw your infant from the study, no new data about him/her will be collected for study purposes other than data needed to keep track of your infant's withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to allow your infant to participate or to withdraw him/her from the study will not involve any penalty or loss of benefits to which your infant is entitled. If you do decide to withdraw your infant, we ask that you contact Dr. Monica Lemmon in writing and let her know that you are withdrawing from the study. Her mailing address is [redacted]

A description of this clinical trial will be available on https://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. ClinicalTrials.gov Identifier: NCT05733975

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Monica Lemmon at [redacted] during regular business hours and at [redacted] after hours and on weekends and holidays.

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For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to allow my infant to be in this study, with the understanding that I may withdraw him/her at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____
Printed name of Subject

_____ _____ _____
Signature of Subject Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time