RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Bundle Consent and Expectation Setting in Pediatric Intensive Care Unit (PICU)
VCU INVESTIGATOR: Nikki Miller Ferguson MD 804-828-4080

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will not affect any aspect of your child's medical care.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to find out about how obtaining consent for procedures in the PICU affects parental/caregiver stress. We think that alleviating some of the uncertainly of a PICU stay by discussing types of procedural support we can offer and obtaining informed consent prior to their immediate necessity may help decrease stress experienced by caregivers. This study will allow us to learn more about it.

Having a child admitted to the Pediatric Intensive Care Unit (PICU) is a deeply challenging and stressful experience for parents and caregivers. Despite the high survival when compared to adult ICUs, a PICU admission can have meaningful long-term, negative health consequences for adult caregivers including symptoms of depression, anxiety and PTSD. There is little known in regards to what specific factors impact the mental health of parents/caregivers of PICU patients. However, research into stress and anxiety has suggested that uncertainty is a significant contributor to stress when faced with a new environment.

What will happen if I participate?

Usual informed consent for procedures performed in the PICU is obtained immediately prior to the procedure. You will be randomly assigned (like the flip of a coin) to either usual informed consent prior to each procedure or to a single consent form obtained upon admission to PICU for possible procedures your child may undergo. In this study you will be asked to complete a survey at two separate times during your child's PICU hospitalization- 48-72 hours after admission and again upon transfer or discharge from the PICU. Data will be collected about your child from the medical record including age, diagnosis/reason for PICU admission, length of stay, and any procedures performed in PICU requiring consent.

Your participation in this study will last until your child is well enough to be transferred out of the PICU or discharged home. Approximately 350 individuals will participate in this study.

What alternative treatments or procedures are available?

You have the option to take a paper survey instead of an electronic one. Ask the study staff if you would like a paper survey.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others
• Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. • The study questionnaires ask questions that are personal questions in nature and may make you feel uncomfortable. • There is a small risk, depending upon which consent group you were randomized to, that you will not recall what was consented for or may not like the group randomized to.	There is no guarantee that you will receive any benefits from being in this study. However, possible benefits include reduction in stress and anxiety, better understanding of potential procedures for your child, referral for help in dealing with stress. We hope the information learned from this study will provide more information about how obtaining consent for procedures for a child affects parental/caregiver stress.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your or your child's medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop. Participants who wish to withdraw from the study must do so in writing (either email or letter) to one of the study investigators listed below at any time while the study is collecting data and enrolling patients.

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

In general, we will not give you any individual results from the study. Project findings and reports prepared for dissemination will not contain information that can reasonably be expected to be identifiable

The information and samples collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to permit us to access existing information from your child's healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☐ Complete health record	☒ Diagnosis & treatment codes	☒ Discharge summary
☒ History and physical exam	☐ Consultation reports	☒ Progress notes
☒ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	
☐ Information about mental health	☐ Information about sexually transmitted diseases	
☐ Other physical or mental health information (specify):		

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at 1250 East Marshall St, P.O. Box 980530, Richmond, VA 23298-0530.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Nikki Miller Ferguson MD 804-828-4080
nikki.millerferguso@vcuhealth.org
and/or
Greg Goldstein MD 804-828-4080
Gregory.Goldstein@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT AND PARENT PERMISSION

I have been provided with an opportunity to read this consent/permission form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent/permission form I have not waived any of the legal rights or benefits to which I and my child otherwise would be entitled. My signature indicates that I freely consent to participate and give permission for my child to participate in this research study. I will receive a copy of the consent/permission form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____	

Name of Person Conducting Consent Discussion (Printed)

_____ _____

Signature of Person Conducting Consent Discussion Date

_____ _____

Principal Investigator Signature (if different from above) Date

Signature Block for Enrolling Child Participants - Parent/Guardian Permission

_____

Name of Child/Youth Participant

_____

Name of First Parent/Legal Guardian (Printed)

Study team – verify that this individual is the child's parent or legal guardian.

_____ _____

Required First Parent/Legal Guardian Signature Date

_____ _____

Optional Second Parent /Legal Guardian's Signature Date

_____

Name of Person Conducting Parental Permission Discussion (Printed)

_____ _____

Signature of Person Conducting Parental Permission Discussion Date

_____ _____

Principal Investigator Signature (if different from above) Date