Informational Meetings for Planning and Coordinating Treatment (IMPACT)

NCT04330833

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

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NIH 1R01CA235632-01A1

ABOUT THIS RESEARCH
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY
You may choose to take part in this study or may choose to leave the study at any time. Please take your time to make your decision. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with your medical team at IU Health Riley Children's Hospital.

WHY IS THIS STUDY BEING DONE?
Physicians and nurses from several hospitals across the country have been asked to participate in this research study, including your child's physician/nurse team. The teams who agreed to participate have been assigned by chance (like a coin toss) into one of two groups: one group has been trained to use a new approach to communication (intervention group), and the other group will continue to provide care as usual (standard care group). You or your physician/nurse team cannot choose your study group. Your physician/nurse team had an equal chance of being assigned to the intervention group or the standard care group. It is possible that your physician/nurse team was not assigned to the intervention group. You will not know which group your team is in, but your physician/nurse team will know. Either way, your physician/nurse team will continue to care for you and your illness as he or she normally would.

You are being asked to participate in this research study because you are a parent (or legal guardian) of a child with a newly diagnosed high-risk, solid-tumor or brain/central nervous system cancer prior to receiving any treatments, or your child has a first-time recurrence of a high-risk solid tumor.

During our study, we want to know about parental information needs, emotions, support resources, and parents' appraisal of their child's symptom management. We also want to know about your child's emotions and their symptom management.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of about 166 families taking part in this study in children's hospitals with cancer centers across the United States. We plan on enrolling about 13 families at IU Health Riley Children's Hospital.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will be asked to complete the first set of study questionnaires soon after consenting to participate in this study. These questions will help us understand more about you and your child and will help us to determine the impact of our intervention on you and your child's health care-related experience. We ask that you not share details about the study with other families as they may be participating in another part of the study and this could compromise the results.

After your child's treatments are started, a nurse will schedule the first of 3 meetings with you (child's parent). The second two sessions will generally coincide with your child's scheduled clinic appointments (usually after your child's scans). After 3 scheduled meetings, you will complete the study questionnaires again and then about every 1- 4 months until 10 time points are completed or the study closes (whichever comes first). Your completion of the study questionnaires each time should take about 25 to 40 minutes. If your child is 5 years of age or older, he or she may complete some of the questionnaires. In addition, the study team will review your child's treatment plan through review of their medical records. Your sessions with the research study team will be audio recorded for quality assurance purposes (monitoring of the doctors/nurses rather than the patient/parent).

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

There are no physical risks as a result of taking part in this study, although you or your child may experience fatigue during sessions with the research team. If this occurs, you will be encouraged to take a break or stop the session. Some of the items on the questionnaires may make you feel uncomfortable, but you do not have to answer any questions you do not want to answer. If you become distressed after the intervention or after completing the questionnaires, you can request to be referred to a healthcare provider for additional support.

There is also a risk of a possible loss of confidentiality. The greatest risk is the release of information from your child's health records. Our team members will protect your records so that you and your child's name, address, and phone number will be kept private. The chance that this information would be given to someone else is very small. All team members listed in our study have completed education on protection of research information, which will help us protect the privacy of our research subjects.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

The benefit to participation in the study is that you will be given extra parent education information regarding your child's diagnosis and treatments by your physician/nurse team and extra time with them to discuss these options. Your physician/nurse team has received special training in how to provide you with this information.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your and your child's personal information confidential. We cannot guarantee absolute confidentiality. Your or your child's personal information may be disclosed if required by law. The audio recordings of your sessions with the study team will not be shared with anyone outside of the research team except as required by law. Any mobile devices used for audio recording will be encrypted. No information which could identify you or your child will be shared in publications about this study.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, Office for Human Research Protections (OHRP), National Cancer Institute (NCI) and/or National Institutes of Health (NIH), and state or federal agencies who may need to access the research records (as allowed by law).

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your child. If you want 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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information collected from you and your child for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you and your child will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION? You will receive a token of appreciation (one $20.00 gift card per family) for your completion of each set of study questionnaires.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There are no additional costs for participating in this study. There may be additional costs if you need to see a psychologist or mental health professional.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study or in the event of an emergency, you may contact the lead researcher at Indiana University, Dr. Amanda Saraf at 317-944-8784 or your doctor.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

We would like to communicate with you about this study by text message and/or email. We might use text or email to send you secure data collection survey links, links to invite you to meetings on HIPAA compliant telemedicine platforms or send you reminders about upcoming study visits or other scheduling communications.
Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, could be accessed or read by someone other than you. If you would like us to communicate with you via text or email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

_____ I authorize the researchers to send me emails related to this research study

Email address for this communication: _____

_____ I authorize the researchers to send me text messages related to this research study.

Phone number for this communication:_____

CAN I WITHDRAW FROM THE STUDY?
If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. You will be told about new information that may affect your child's health, welfare, or willingness to stay in the study.

PARTICIPANT'S CONSENT
In consideration of the above, I give my consent for myself and my child to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Printed Name of Parent:_____

Signature of Parent : _____

Date:_____

If two parents are participating in study:

Printed Name of Parent:_____

Signature of Parent:_____

Date:_____

This section should only be completed by participants who reach age of majority during the study:

Printed Name of Participant (≥ 18 years old):_____

Signature of Participant (≥ 18 years old):_____

Date:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____