INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Music-Play and Stories for Kids/Parents during Cancer Treatment
Sheri Robb, PhD IUSCC-0578

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 not to take part in the study or may choose to leave the study at any time. 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 Riley Hospital for Children at Indiana University Health.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to find out if play activities, like stories and music, can be used to help decrease parent/caregiver and young child distress and improve quality of life during cancer treatment. We also want to know if these programs can help parents/caregivers and young children cope better with treatment.

You were selected as a possible participant because you are the parent/guardian or caregiver of a young child who is being treated for cancer.

The study is being conducted by Sheri Robb, PhD, Joan Haase, PhD, Indiana University School of Nursing; Susan Perkins, PhD, Indiana University School of Medicine; Seethal Jacob, MD, MS, FAAP, and Paul Haut, MD, Riley Hospital for Children. It is funded by the National Institutes of Health.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 184 parents/caregivers and 184 child participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will do the following things:
Parent Questionnaire and Random Assignment. You will be asked to complete the first set of study questionnaires during a routine clinic visit. The first set of questionnaires will take about 25 minutes to complete. These questions will help us judge the quality of the study activities and how things have

gone for you. If you need help, a study team member will be on hand. A study team member will also review your child's medical record to complete treatment-related information. Each evaluation session will be audio-recorded to make sure the study team member followed the protocol.

Once you have completed the questionnaires, you and your child will be randomly assigned to receive one of two different study programs. Random assignment means that the program is assigned based on chance. It is a lot like flipping a coin, except that it is done by a computer to make sure that there are about the same number of people in each program.

Program A. If you are assigned to Program A, you will receive three visits from a board-certified music therapist over 3 days. Visits will take place in your child's hospital room or the outpatient clinic and each visit will last about 45 minutes to one hour. During the first visit, you will receive information on common responses of young children to cancer treatment and how you can use music play activities to support your child during treatment. The music therapist will lead you and your child in a variety of music play activities. You and your child will receive a music kit that includes items such as hand-held rhythm instruments, puppets, and a music CD so that you can use these activities when the therapist is not around. During the second and third visit the music therapist will lead you and your child through the music play activities, answer questions, and make suggestions for using these activities in the hospital and at home.

Each music session will be video recorded to make sure the music therapist delivers sessions according to the protocol. Video recordings are also used to determine whether the activities are helpful for improving your child's mood, participation in play, and reducing any distress. We rely on video recordings because young children are not able to answer paper-pencil questionnaires. At the end of the three visits, you will be asked to complete a second set of study questionnaires that will take about 20 - 30 minutes to complete. If you need help, a study team member will be on hand. This evaluation session will be audio-recorded to make sure the study team member follows the protocol. You and your child will be given the music kit to take home with you.

Program B. If you are assigned to Program B, you will receive three visits from a board-certified music therapist over 3 days. Visits will take place in your child's hospital room or the outpatient clinic and each visit will last about 45 minutes to one hour. During each visit, you and your child will have an opportunity to choose an illustrated storybook with audio-recorded narration. You will then have time to listen to and view the storybook together. The music therapist will remain in the room to answer any questions.

Each storybook session will be video recorded to make sure the music therapist delivers sessions according to the protocol. Video recordings are also used to determine whether the activities are helpful for improving your child's mood, participation in play, and reducing any distress. We rely on video recordings because young children are not able to answer paper-pencil questionnaires. At the

end of the three visits, you will be asked to complete a second set of study questionnaires. If you need help, a study team member will be on hand. This evaluation session will be audio-recorded to make sure the study team member follows the protocol. You and your child can keep the illustrated audio storybooks to take home with you.

Final Questionnaire and Parent Interview. About 30 days after your child is discharged from the hospital, a member of our study team will contact you to complete the third set of questionnaires. The questionnaire will take about 20 - 30 minutes to complete. The questionnaire can be completed by telephone or during a subsequent clinic visit, at a time convenient for you. The evaluation session will be audio-recorded to make sure the study team member followed protocol.

You may be asked to participate in an interview to share your thoughts and feelings about the program. The interview will be done in a private space that is most comfortable for you, and can be done in person or by telephone. The interview will happen after all other parts of the study have finished and at a time that fits into your schedule. This interview session will be audio-recorded and then transcribed for study purposes. Names and other information that could identify you or your child will not appear in the interview transcription.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

There are no physical risks to you or your child as a result of taking part in this study. Some of the questions may make you feel uncomfortable, but you do not have to answer any questions you do not want to answer and you may withdraw from the study at any time.

There is the possibility that your child may be experiencing fatigue, nauseousness, or other symptoms that make him/her not want to participate in the session. Should your child experience any of these you/your child can ask for a break or ask to end the session. You/your child may also withdraw from the study at any time.

There is a risk of a possible loss of confidentiality. The greatest risk to you and your child will be release of information from your health records. Our team members and Riley Children's Hospital will protect your health 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 human subject's health information, which will help us protect the privacy of our research participants.

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

The benefits to participation in the study that are reasonable to expect are being able to talk with someone about having your child undergoing cancer treatment. We expect that information learned from this study will benefit other parents/caregivers and young children with cancer in the future. However, you may not benefit from participating in this study.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. The information you share with us will be kept private. Only study team members will be able to see the information, unless you specifically give permission in writing to do differently. We will give your information a special ID number. All the information we collect will be linked to this number so there is no direct connection of information with your name. We will keep a master list of names in a password protected file, which along with digital video files and audio taped evaluation and interview sessions, will be stored in a HIPAA compliant data storage website. Paper copies of any information will be protected in locked file cabinets in a locked office. If the results are published or presented orally, you will not be identified.

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, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH), etc., who may need to access the research records.

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. If you want your 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 will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study. However, you will receive a token of appreciation for your completion of the study program. If you complete Program A, you and your child can keep the music kit. If you complete Program B, you and your child can keep the illustrated audio storybooks.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher Sheri Robb at (317) 274-3152. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (317) 274-8289.

In the event of an emergency, you may contact the IU Human Subjects Office (317) 278-3458 or (800) 696-2949.

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.

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. The study team will help you withdraw from the study safely. If you decide to withdraw, a study team member can help you do so.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give consent for my child's participation in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to my child's participation in this study.

Child Participant's Printed Name:_____

Printed Name of Parent/Guardian:_____

Signature of Parent/Guardian:_____**Date**:_____

In consideration of all of the above, I give my consent 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/Caregiver:_____

Signature of Parent/Caregiver:_____**Date**:_____

Printed Name of Person Obtaining Consent:_____

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