

Children's Healthcare of Atlanta Consent to be in a Research Study

Title: The effect of music therapy on psychological signs of anxiety in mechanically ventilated and sedated pediatric patients

Principal Investigator: Hannah Ivey Bush, LPMT, MT-BC

If this form is being read by the parent or legal guardian, the term "you" refers to "your child."

General:

- You are being asked to be in a research study. This form explains what would happen if you join this research study.
- Taking part in this study is voluntary and it is entirely your choice.
- If you take part in this study, you may stop being in the study at any time.
- Your decision to join or not join the study will not affect your current or future medical care at Children's.
- It is important that you read and understand this form in order to decide whether or not you want to be a part of this study. Take as much time as you need.
- It is also important that you ask any questions that you may have and that you understand all the information in this form.

Why is this study being done?

- The purpose of the research is to examine the effect of live music therapy on psychological signs of anxiety (heart rate, respiratory rate, blood pressure) on pediatric patients who are mechanically ventilated and sedated.
- You are being asked to volunteer because your child meets the study criteria and we appreciate your input into the care your child is receiving while admitted to the intensive care unit.
- We are recruiting 24 patients to participate in the study.
- Individuals are asked to participate in the study if they meet study criteria (ages birth to two years, have a caregiver present for consent, and are mechanically ventilated and sedated).

What will happen to you in this study?

- We will ask that you take a quick survey before we begin the music intervention. We will record your child's heart rate, respiratory rate, and blood pressure twice before beginning. These things are automatically recorded in your child's chart. We will also record their heart rate, respiratory rate, and blood pressure immediately following the music intervention as well as every fifteen minutes for an hour following the intervention. You will then be asked to take a quick survey regarding your perception of the pediatric intensive care unit.
- The research will be conducted here in your child's room as the music therapist will be playing music at your child's bedside.
- The study involves random assignment, meaning you and your child will be hearing either recorded music or live music, but you will not know which until the music therapist begins. It is like flipping a coin to determine if your child will receive recorded or live music.
- The survey you will be asked to complete contains 20 questions regarding your child's hospitalization and how the hospitalization affects you and your child.

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- Research supports both recorded and live music in the reduction of anxiety in hospitalized patients. We are trying to determine if one is better than the other.
- As the caregiver, we ask that you are present for the playing of music. However, you may choose to participate or not to participate when the music therapist plays music.
- At the conclusion of the interaction, you will be asked to take a short qualitative survey.

How long will you be in this study?

- The music therapist will play music once for the study for fifteen minutes. It will then take approximately five minutes to complete the study survey.
- You will only be asked to participate in the study once. Following completion, you may continue to receive music therapy services during your child's admission to the intensive care unit if you wish. During the time following the study, you may choose if your child receives recorded or live music.

What are the possible risks to being in this study?

- While music has been shown to decrease signs of anxiety in hospitalized children, there is a possibility the reverse could happen and that your child does not enjoy the music provided. If the researcher sees that your child shows signs of agitation instead, the researcher will immediately stop the music intervention.
- Due to the investigational nature of this study there may be risks, discomforts or side effects that are not yet known and there may be additional costs that result from participation (i.e., extended hospitalization).

What are the possible benefits of being in this study?

- The music could help reduce your child's anxiety surrounding their hospitalization by providing something familiar to them.
- Taking part in this research study may not benefit you personally but we may learn new things that may help others in the future. We know this time period is critical for our patients and families and we are hoping to learn how to best support our patients and their families during this challenging time.

What are the alternatives to being in this study?

You will receive the same medical care whether or not you participate in the study.

What is the cost of being in this study?

The research music is being provided at no cost to you or your insurance company.

What if you have any questions or problems while in this study?

If you have any questions, concerns or complaints about this study call Hannah Ivey at 404-785-2693. If you have any questions, concerns or complaints about your rights as a participant in this study, or would like to obtain information, or offer input, you can call the Children's Healthcare of Atlanta Institutional Review Board (IRB) at (404) 785-7477 or via email at irb@choa.org. The IRB is a committee of people that approves all research in this hospital and follows all the rules and regulations made by government agencies about how research is done.

Who will be able to see your records of study participation?

Your records of participation in this study are not accessible to the general public and every effort will be made to maintain confidentiality. However, all records may be subject to subpoena by a court of law. Information that may be gained from this study will be used only for research and educational purposes. Information may be published in medical journals with permission of the Principal Investigator, but your identity will not be revealed or written in a way that you can be recognized. Additionally, identifying information will be available to people from the Children's Healthcare of Atlanta Human Research Protections Program (i.e., IRB, the Research Compliance Office, Office of Sponsored Programs, Office of Grants Administration, Grants Accounting, etc.), the Office for Human Research Protections, the Sponsor(s), and the Food and Drug Administration (FDA), Contract Research Organization (CRO).

- A copy of this consent form will be placed in your medical record. Medical information collected during this study will become part of your hospital record, if the information is determined to be pertinent to your care. Medical records are considered permanent records; therefore, materials cannot be deleted from the record. Medical records are available to healthcare professionals at Children's and may be reviewed by Children's staff in their course of carrying out their responsibilities. Children's staff are required to maintain confidentiality in accordance with applicable laws and Children's policies. Information contained in your medical record may not be given to anyone unaffiliated with Children's in a way that could identify you without written consent, except as required or permitted by law.

Can I leave the study?

Taking part in this study is completely voluntary. You may choose not to take part in this study. If you take part in this study, you may stop being in the study at any time. Your decision to join or not to join the study will not affect your current or future medical care at Children's.

The study doctor may stop you from taking part in this study for any of the following reasons: you need treatment or medication that may not be taken while on the study or the PI feels it is in your best interest to be taken off this study; you do not follow study procedures or are not able to attend required study visits; withdraw of parent/guardian permission or the study sponsor decides to end the study.

Authorization to Release Protected Health Information for Research Purposes

Your health information is protected by a law called the Health Insurance Portability and Accountability Act (HIPAA) is a federal law passed to protect the privacy of your Protected Health Information (PHI). PHI is any information about you that could tell someone who you are. The following information will explain how we will use and disclose your PHI for this study.

What PHI will be collected for this study:

The PHI that we will use or share for the research study includes:

- Medical information about your child's reason for admission (respiratory diagnosis) and their age.
- Vital signs collected pre and post intervention.

Who will collect the information:



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The research staff conducting the study will collect and copy your PHI. Your PHI will be used and shared for the conduct and oversight of this study, study related treatment and payment for such treatment. Your PHI will also be used to conduct normal business operations.

Who else will see the information:

- Research staff involved in this study;
- Other staff directly involved in your care that is related to the research or arises from it;
- Other researchers and centers that are part of this study, including people who oversee research at those institutions;
- People at Children's who oversee, advise and evaluate research and care or are involved in the study administration and billing. This includes offices within the Human Research Protections Program (i.e., Institutional Review Board, Research Compliance Office);
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information such as data safety and monitoring boards, clinical research organizations, data coordinating centers and others;
- Sponsors or others who fund the research;
- Government agencies that regulate research including the Food and Drug Administration, The Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups hired to provide services related to this research (i.e., service providers, laboratories, etc.);

The Privacy Rule applies to doctors, hospitals, and other healthcare providers. Some of the groups listed above are not required to follow the Privacy Rule and may share your information with others, if other laws allow. However, other privacy protections may still apply. If you have a question about this, you may contact the Children's Privacy Office at 404-785-1516 and they can help you understand privacy and confidentiality.

How long does the permission last:

Because research is ongoing, this permission will not expire. However, you may cancel this permission at any time.

If you change your mind and want to cancel your permission, you must contact the study team at: (insert study team contact information, including name and address). At that point, researchers would not collect any more PHI, but may use or disclose information already collected for safety reasons, to verify research data or if required by law. If you cancel your permission, you will not be able to stay in the study.

Contact Information

You may use the following contact information to reach the appropriate person/office to address any questions or concerns you may have about this study:

For questions about the study, research-related injuries, emergencies or concerns, contact (Insert PI name and contact number or Insert additional study contact name and number)

For questions about your rights as a research participant or if you have questions, concerns or complaints about the research, contact the IRB at 404-785-7477 or irb@choa.org.

Informed Consent and Authorization:



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Your signature below indicates that:

- You have read this informed consent form and have been given enough time to consider the decision to participate in the study;
- The research study has been satisfactorily explained to you;
- You have been given the chance to ask questions and have had those questions answered to your satisfaction;
- You understand this study is voluntary and you can withdraw at any time;
- You are signing this consent form prior to participation in any research activities; AND
- You agree to participate in this research study and allow the use of associated protected health information (PHI) as described above.

You will receive a copy of this form.



Documentation of Informed Consent and HIPAA Authorization

Child Research Participant:

Printed Name of Research Subject

Date of Birth

(If the child to be involved in this research study is a foster child or a ward of the state, please notify the researcher or person obtaining your consent)

Printed Name of Parent/Legal Guardian:

Signature of Parent/Legal Guardian

Date

Time

(Required for research subjects under the age of 18 years)

Relationship to child: Parent Legal Guardian (state relationship): _____

Parent/Legal Guardian Participant:

Printed Name of Parent/Legal Guardian:

Signature of Parent/Legal Guardian Participant

Date

Time

Researcher:

I have fully explained the research study described in this form, including the risks and benefits. I have answered participant and/or parent questions and will continue to answer future questions to the best of my ability. I will tell the participant and/or family if there are changes to the research procedures or risks and benefits that may impact their health or willingness to stay in the study.

Printed Name of Person Obtaining Consent:

Signature of Person Obtaining Assent/Consent/Permission

Date

Time

Assent Determination:

- The child is 5 years of age or younger and assent is not required for participation in this research study.
- The child is between the ages of 6-10 years old and has been verbally assented to participate in this research study.
- In my opinion, the child is not able to assent to participate in this research study for the following reason:

Interpreter:



Signature of Interpreter (if applicable)	Date	Time
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