

COMPOUND AUTHORIZATION AND PARENTAL PERMISSION FOR PARTICIPATION IN A RESEARCH STUDY**YALE-NEW HAVEN HOSPITAL**

Study Title: Audiovisual interactive games to improve pediatric patient cooperation with induction of anesthesia and alleviate perioperative anxiety

Principal Investigator (the person who is responsible for this research): *Dr. Anthony Longhini, 333 Cedar St, TMP-3, New Haven, CT 06510*

Phone Number: 203-785-2802

Research Study Summary:

- We are asking your child to join a research study.
- The purpose of this research study is to test different strategies for calming down children prior to their surgery and to evaluate newly developed strategies using technology to help children remain calm and comfortable prior to undergoing anesthesia.
- Study procedures will include: completing a short demographic form and a study team member observing and documenting your child's reaction to arriving to the operating room and receiving anesthesia.
- Your child may be engaged in a game prior to and while going completely asleep with anesthesia.
- Your child will be videotaped in order for an independent observer to assess your child's reaction to the anesthesia.
- No additional visits are required.
- There are minimal risks from participating in this study. Though most children enjoy the games we are employing, your child may not enjoy the game and may react poorly to it. There is also a risk that information obtained in the study be involuntarily seen by others though we do everything possible to ensure this does not occur by protecting all information.
- The study may help your child in the process of being put under anesthesia with use of a face mask. It may decrease their agitation and discomfort in the process. It may also not benefit them.
- There are other choices available to your child outside of this research. You can proceed with surgery without use of the technology being tested in this study.
- Giving permission for your child to take part in this study is your choice. You can choose to give permission, or you can choose not to. You can also change your mind at any time. Whatever choice you make, your child will not lose access to his or her medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to give permission for your child to participate; if so, you will have to sign this form.

Why is this study being offered to my child?

We are asking your child to take part in a research study because your child was identified as someone who might benefit and fits the assigned parameters of the study (aged 4-14 years and undergoing non-emergent surgery with use of inhalational anesthesia). We are looking for 80 children to be part of this research study.

Who is paying for the study?

Yale University, Yale New Haven Hospital, and Yale New Haven Children's Hospital.

Who is providing other support for the study?

No additional parties

What is the study about?

The purpose of this study is to test a new interactive gaming system developed to playfully allow a child to go under anesthesia using a face mask with as little discomfort and anxiety as possible. We are assessing how well the gaming system works for this purpose and other benefits it may offer.

What are you asking my child to do and how long will it take?

If you give permission for your child to take part in this study, this is what will happen:

- You will be asked to provide basic demographic information of your child prior to the procedure
- Your child will be "randomized" into one of two study groups: one that interacts with the new gaming system and one that interacts with our standard of care approaches. Randomization means that your child is put into a group by chance. It is like flipping a coin. Neither you nor your doctors will choose the group. Your child will have an equal chance of being placed in any group.
- If your child is assigned to the gaming system, they will interact with the game upon entering the operating room. A projection screen will be placed at the end of the operating table and a projector will project the interactive game.
- Your child will be observed prior to the surgery, upon entering the operating room, and while being put under anesthesia. This will be for assessment of anxiety and your child's care will not be changed due to this.
- Upon completion of your child's surgery, we will look at their electronic medical record and record the times of different parts of the procedure and medications administered. We are obtaining this information to see if the game changes the time spent in the operating room and hospital, and to see if it changes the amount of pain medication needed.

What are the risks and discomforts of participating?

There are minimal risks and discomforts to enrolling in this study. It is possible that your child does not like the game provided, and it may cause them distress. Your child's information will be maintained in a secure location, however the chance of breaching confidentiality is also possible.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about your child taking part in this study.

How can the study possibly benefit my child?

This study may benefit your child by improving their anxiety and distress. It may also benefit your child by decreasing their time in the hospital and operating room.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of strategies that can be used to improve pediatric patient perioperative anxiety.

Are there any costs to participation?

You will not have to pay for your child taking part in this study. There will be no additional study visits.

Will my child be paid for participation?

Your child will not be paid for taking part in this study.

What are our choices if I decide not to give permission for my child to take part in this study?

Instead of participating in this study, you have some other choices.

Your child could:

- Get treatment without being in a study by normal standard of care.
- Take part in another study.

How will you keep my child's data safe and private?

We will keep information we collect about your child confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that someone is hurting a child or an older person.

The records that we keep will be coded so that no identifiable information of your child is on the papers. The code will be linked to your child's medical record number on a separate document. All of the study data will be stored in a locked area or on password-protected computer files.

When we publish the results of the research or talk about it in conferences, we will not use your child's name. If we want to use their name, we would ask you both for your permission.

We will also share information about your child with other researchers for future research, but we will not use his or her name or other identifiers. We will not ask you for any additional permission.

Your child's identifiers might be removed from the identifiable private information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Your child's information may be shared with the U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about a device (Bedside Entertainment and Relaxation Theater) that is involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.

What information will you collect about my child in this study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and

Accountability Act (HIPAA). In general, we cannot use or share your child's health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about your child and their health that we will collect, use, and share includes:

- Indicators of your child's anxiety level and cooperation with the procedures of undergoing surgery and anesthesia.
- Timing of your child's surgery, including the time anesthesia starts/ends, and the time your child is discharged from the post anesthesia care unit. This information will come from your child's medical record from YNHCH.
- The medications used during your child's surgery. This information will come from your child's medical record from YNHCH.

How will you use and share my child's information?

We will use your child's information to conduct the study described in this consent form.

We may share your child's information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The study's Principal Investigator
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your child's information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your child's information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your child's health information, agreements are in place with these individuals and/or companies that require that they keep your child's information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your child's information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your child's health information in their medical record.

What if I change my mind?

The authorization to use and disclose your child's health information collected during their participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to **Dr. Anthony Longhini at 333 Cedar Street, TMP-3, Department of Anesthesiology** at the Yale University, New Haven, CT 06520.

If you withdraw your permission, your child will not be able to stay in this study but the care they get from their doctor outside this study will not change. No new health information identifying your

child will be gathered after the date you withdraw your permission. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

What if I want to refuse or end my child's participation before the study is over?

Allowing your child to take part in this study is your choice. You can choose to give permission, or you can choose not to give permission. You also can change your mind at any time. Whatever choice you make, your child will not lose access to his or her medical care or give up any legal rights or benefits.

If your child is older than 10 years old, they will be asked to give their assent to be in the study. If they decide they do not want to be in the study, they will not be enrolled in the study even if you have given permission. You will not be told the reason why your child didn't want to participate.

We would still treat your child with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your child's relationship with their own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want your child to take part.

The researchers may withdraw your child from participating in the research if necessary, such as if the game is distressing to them.

What will happen with my child's data if they stop participating?

All identifiable data will be destroyed if able. If the data has already been de-identified by the time they stop participating, it will not be possible to remove their data from the study.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-785-2802**

If you have questions about your child's rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you give permission for your child to be in this study.

We will give you a copy of this form.

Participant Printed Name

Parent Signature

Relationship to Participant

Date

Person Obtaining Consent Printed
Name

Person Obtaining Consent
Signature

Date

Study Team Initial Here if Assent Obtained from Patient