

Cover Page for Assent Form

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| NCT Number | NCT03980067 |
| Official title of study: | Pediatric Procedural Sedation and the Relationship with Post-Discharge Negative Behavioral Changes in the Emergency Department |
| Document Date: | April 21, 2020 |



CHILD'S ASSENT FOR RESEARCH STUDY

Study Title: Pediatric Procedural Sedation and the Relationship with Post-Discharge Negative Behavioral Changes in the Emergency Department

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Name:

Medical Record Number:

- **We are asking you to be in a research study.**
- **It is your choice. You do not have to be in the study.**
- **Feel free to ask questions.**

A. Why are we asking you to be in this research study?

You are being asked to take part in this study because you have an injury that needs to be treated. Before your injury can be treated, your doctor needs to give you some medicine to make you sleepy. This is called "procedural sedation."



B. Why are we doing this study and what do we hope to learn from it?

The reason we're doing this study is to see if we can help improve behavior changes that sometimes occur in children at home after they have had procedural sedation. This can be related to being anxious or nervous before the procedure. We hope to provide a relaxing environment in the Emergency Department for kids like you who are undergoing a sedation to fix an injury. If we know what strategies may work better than others to keep our patients comfortable, we can do a better job caring for patients when they come in with broken bones and help them feel well at home too.

C. What will you have to do?

If you are going to be in this study, your parent(s)/guardian(s) will:

- Answer questions.
 - Your parent(s) or guardian(s) will answer questions about you. These questions are about your behavior one week before your injury happened. This will take about 10 minutes to finish.
- You may be selected to be in the “Standard of Care” group for the study. This group of children will have access to in room activity including TV distraction if desired, parent support and distraction at bedside, and quiet time like a typical emergency department visit for this type of injury. There will be no active intervention or virtual reality game initiated by the Children’s Hospital of Wisconsin staff/Research team in the “Standard of Care” group. This is the routine care that you would receive even if you were not enrolled in the study.
- Alternatively, you may be selected to be in the “Standard of Care” AND Virtual Reality group. In this group, you will be asked to participate in a virtual reality interactive game before your procedural sedation. If asked, the virtual reality game would involve wearing a headset device, watching a small screen on the device where the game is displayed, and moving your head to control the characters on the screen to collect points toward a score. You would be allowed to choose 1 of the game options available (Pebbles the Penguin, Asteroid Miner, or Space Pups) to play. For example, you could control a penguin sliding down a mountain to collect gems for points, mine asteroids of different colors in outer space to collect points, or roam in outer space as a dog to collect treats for points. The virtual reality game only requires you to lay in your bed and you will not have to move your arms or legs. Our research team will talk to you more about it and help you get started. You can stop this activity at any time by letting your parent and/or research team know you are finished.
- A computer software will decide whether you will be in the virtual reality or standard of care AND virtual reality group. This selection is random.



- If you do not wish to participate in the study (which is completely voluntary), you will receive “Standard of Care” and continue your Emergency Department course with your medical provider team without any change in your healthcare plan.
- If you choose to stop participation in the study after it has started, you will receive “Standard of Care” and continue your Emergency Department course with your medical provider team without any change in your healthcare plan.
- Your doctor will check your level of anxiety or nervousness before the procedural sedation happens.
- The research assistant will contact your parent(s)/guardian(s) by phone, text, email, or mail at home in 1 week. The research assistant will ask your parent(s)/guardian(s) to answer the same questions about your behavior over the past week. This will take about 10 minutes to finish

D. Can anything bad happen to you because of this study?

It is possible that you may develop nausea or dizziness while playing a virtual reality game (if you are asked to do so). You should let the team know if you are feeling sick. This does not occur in most patients, but can happen in some participants. The research team will help you remove the device at any time if you are not feeling well. Your medical team will quickly come to your bedside and check on you and determine next best steps to help you feel better, should this occur. Typically, removing the virtual reality device makes your symptoms go away if you do develop side effects. However, in some cases, a nausea medication may be required to help you feel better. The research study does not cover the cost of this medication.

The procedural sedation will be done the same for children who are in the study and children who are not in the study.

E. Are there any good things that could happen to you while you or others take part in this study?

Being in this study will not help you, but may help children who are getting procedural sedation in the Emergency Department in the future

F. Will you be paid for taking part in the study?

You (the child) will receive a gift card in the amount of 25.00 if your parent/guardian completes the 1-week follow up survey. The gift card will be provided within 1 week of receiving the survey results either via email or mail with the contact information provided when you enrolled in the study. If your parent/guardian does not complete the 1-week follow up survey, you will not receive a gift card.



G. Do you have to take part in this study? Can you quit the study any time you want to?

You do not have to be in this study, and if you are in it you can stop at any time. If you have any questions please ask one of the people who are doing the study.

I. PERMISSION TO PROCEED

Writing my name on this form means that the form was read (*by me/to me*) and that I agree to be in the study. I know what will happen to me. If I decide to quit the study, all I have to do is tell one of the people who are doing the study.

Your parent(s) / guardian(s) will receive a copy of this form. A copy of this form will also be kept in your medical record.

Child's Name

Child's Signature

Date

Assent Form administered and explained in person by:

Study Leader or Study Team Designee

Date & Time

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