Cover Page for Consent

NCT Number:	NCT03980067
Official title of study:	Pediatric Procedural Sedation and the Relationship with Post-Discharge Negative Behavioral Changes in the Emergency Department
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Statement of Volunteer Consent and Health Insurance Portability and Accountability Act (HIPAA) Authorization for Research Study

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

Principal Investigator(s) / Study Leader(s):

Amy Drendel, DO, MS. The Principal Investigator is the Study Leader for this research.

Phone Number(s): (414) 266-2625

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Co-Investigator(s)

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Sponsor: N/A

Name: **Medical Record Number:**

Date of Consent Discussion:

"You" refers to you or your child throughout the consent form.

- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can stop the study at any time.**
- **Your health care will not change in any way if you say no.**
- **Feel free to ask questions.**
- **Take as much time as you need to make your choice.**
- **Only sign this form if you want to be in the study.**

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

We invite you to take part in this research study to learn more about children like you who have a broken bone that needs to be repaired. Your injury requires that your doctor give you some medication called "procedural sedation" in order to complete the procedure in a safe and comfortable way. Sedation is a relaxed, calm, or sleepy feeling that results from taking a drug called a sedative.

This study will help us learn more about how 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.

We hope to find out if we can do a better job in looking for anxiety in the Emergency Department and/or at home. We can then start taking better care of children's anxiety.

243 children ages 6 years to 17.5 years will be asked to participate in this study. All the children will be from Children's Hospital Emergency Department.
Monetary support through the Jon Vice Innovation award will be used to fund the study.

B. What happens if you say yes, you want to be in this study?

If you say yes, we will:

- Ask you to fill out several surveys. These surveys are part of the research project and are not filled out by children and parent(s)/guardian(s) who are not in the study.
    - Children:
        - You do not have to complete any surveys as part of this study.
        - 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 standard of care or standard of care AND virtual reality group. This selection is random. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. Neither you nor the research doctor can choose what group you will be in.

- 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.

- Parent(s)/Guardian(s):
  - You will be asked to answer some general demographic questions including your child's age, weight, gender, race, ethnicity, weight, zip code, phone number/best time to contact, cell phone number to text, email address, mailing address, your child's medical conditions, and history of any sedation difficulty. You do not have to answer any question you don't want to answer.
  - You will be asked to fill out 1 survey on paper while in the Emergency Department. The survey will ask questions about <u>your child's behaviors</u> one week before the injury happened. There are 27 questions and it should take about 10 minutes to finish. This survey is completely voluntary, and your participation is strictly your choice. There are no right or wrong answers to these questions. You can skip over any questions you do not want to answer. Your answers will be kept confidential. You can choose to stop participation in the study at any time.
  - One (Parent/Guardian) will be asked to remain at the bedside with your child throughout the activity and keep the rails of the bed up at all times if selected for the virtual reality game group.
  - The research assistant will contact you at home in 1 week via phone, text, email, and/or mail with a pre-addressed stamped envelope provided. The research assistant will ask you to answer the same questions as before (from the survey) but about your <u>child's behavior over the past week</u> <u>after the procedural sedation</u>. There are 27 questions and it should take about 5-10 minutes to finish. We ask that you complete <u>ONE</u> copy of the follow up survey and pain questions (whether it is phone, text, email, or mail to help us learn how to best care for children with similar injuries).

- The research assistant can read the questions out loud and fill out the form with you, if you would like him/her to.

How long will the study take?
The study will take about 40 minutes of your time. You should be able to complete all the study while you are waiting to receive your Emergency Department care. We will not interrupt any of the care that you will be receiving to have you take part in the study. The study should not make your Emergency Department visit any longer. You will receive a phone call from one of our research assistants 7-14 days after your emergency department visit to complete a follow-up phone survey. Or, if you cannot be reached by phone the survey will be mailed to you. This survey will take approximately 5-10 minutes of your time and will conclude the study.

C. 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 your medical 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 patients who are in the study and patients who are not in the study.

The activities you may be asked to take part in may help you to feel better, or they may not change how you feel, or they may make you feel worse. If you are not happy with how you are feeling you can stop taking part in this study at any time.

All the questions you answer for us will be kept confidential. We will do our best to protect your privacy.

D. Will this study help you in any way?
Being in this study will not help you but may help other children in the future who get procedural sedation in the Emergency Department.

E. Will you be paid for being in this 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.

F. Will it cost you anything to be in this study?
It will not cost you anything to be in this study. However, if treatment is required due to a side effect of being in the study, for instance nausea, that cost will be billed to your insurance company or the legal guardian of the study participant and not covered by the study. Some insurance companies do not cover costs associated with medical studies

G. Do you have to participate in this study?

No, you do not have to be in this study**.** You can stop being in the study at any time. Just let your doctor know that you don't want to participate anymore.

If you say no, your health care will not change in anyway.

If you stop being in this study, we may still use the study information we have already collected as long as it cannot be linked back to you.

H. What if you have questions?

If you have questions or there is something you do not understand, please call Dr. Amy Drendel at (414) 266-2625

Please call if you have:

- Any questions about the study
- Concerns that you have been injured in any way by being in this study
- Questions about how we will use your information

You can also call the Institutional Review Board (IRB) if you have any questions about your rights as a research subject. The IRB is the committee that has reviewed this study. A member of this committee can talk to you if you have any questions or complaints at 414-337-7133.

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 you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The FDA has access to review and copy all relevant records.

I. Will your information be kept private?

The only people allowed to see your information will be the people who work on the study and people who make sure the study is done the right way and hospital rules are followed. Groups or people that might look at and/or copy your research records are:

- The IRB at Children's Hospital of Wisconsin.

Your health information and a copy of this form will be locked in our files.

When we share the results of the study in medical journals, we will not include any information that identifies you. We will do our best to make sure no one outside of the study will know you are a part of the study.

J. Permission to collect, use and share your health information.

The health information we are asking for is called "Protected Health Information" (PHI). It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA).

We cannot use your health information for research without your permission. If you do not give permission, you cannot be in this study. We will only use your information needed for this study.

If you decide to stop being in the study and would like to cancel your permission to share your health information, please let Dr. Amy Drendel know at (414) 266-2625.

What and how will your health information will be used for this study?

Example (what)s:

- Past and present treatment as an inpatient or an outpatient, clinic or physician office setting.
- History and identification of the problem / disease.
- Other medical conditions that may affect treatment.

Examples (how):

- To decide whether you are able to take part in this study.
- To determine the results of the study procedures.

A copy of this consent/HIPAA authorizationform will be stored in your medical record. We may also record your research information in your medical record, including:

- Clearly defined information in the patient locator or other important portions of the record that the patient is enrolled in a clinical trial, the PI's contact information to notify in case of an emergency or question concerning care.
- Processes to ensure confidentiality (especially if a Certificate of Confidentiality has been granted).

The information put in your medical record by the study team may be seen by people allowed to see your medical records for healthcare, people that run the hospital, those you give written permission to see your medical records, and by others when required by law.

We will not use your health information for a different study without again asking you for permission, or asking the IRB to use your information as long as everything that may identify you is removed (such as name, birth date, visit date, etc.).

Once all information that can identify you is removed the information might be used or released for other purposes without asking you. Results of the study may be discussed in public talks or written articles, as long as we will not be able to tell that the information belongs to you.

You have the right to see/or copy your health information that's in your medical records related to this study. It may not be possible to give you that information right away. You do not have the right to see or copy other records kept by the study team.

How long will your information be kept for this study?
If you sign this form, we plan to keep your information for 10 years after the end of the study in case we need to check it again for this study.

Can you cancel your permission to share your health information?
Yes. If you change your mind later and do not want us to collect or share your health information, you

need to write a letter to: Dr. Amy Drendel
Children's Corporate Center
999 North 92nd Street, Suite C550
Milwaukee, WI 53226

You must say that you have changed your mind and do not want the study team to collect and share your health information. We may still use the information we have already collected, as long as we can't tell that it belongs to you. If you decide not to share your health information, we may need to take you off the study.

K. Permission for you to participate in this study

This study, consent form and HIPAA Authorization has been explained to you by:

Name of Study Leader or Study Team Designee	**Signature of Study Leader or Study Team Designee**
Date	**Time**

Sign this document if:

- **You have read (or had it read to you) this entire consent form.**
- **We have talked with you about the information in this form and have answered your questions.**
- **You agree to let the study team use and share your health information for this study.**
- **You agree to let your primary care doctor share your health information with us.**
- **You agree to be in this study.**

After you sign this document, we will give you a copy of this form.

Printed Name of Study Participant or Authorized Representative	
Signature of Study Participant or Authorized Representative	**Date**

CHILD ASSENT TO TAKE PART IN A RESEARCH STUDY

I have explained this study and the procedures involved to _____ in terms he/she could understand and he/she freely assented to take part in this study.

_____ _____

Signature of Minor **Date**

If child's assent is not obtained above, please indicate reason below (check one):

☐ **Assent is documented on a separate IRB-approved assent form**

☐ **Child is under the required age range for assent**

☐ **The IRB granted a waiver of assent, please specify: _____**

_____ _____

Printed name of Principal Investigator **Date**
or Research Team Designee

_____ _____

Signature of Study Team Leader **Date**
Or Study Team Designee

If appropriate:

_____ _____

Signature of Interpreter **Date**

_____

Printed Name of Interpreter