



ADOLESCENT ASSENT FORM FOR YOUTH AGES 12-17

Nemours Template December 2024

Your parent has given permission for you to be in a project called a research study. But first, we want to tell you about it so you can decide if you want to be in it. If you don't understand, please ask questions. You can choose to be in the study, not be in the study or take more time to decide.

1. What is the name of the study?

The Utilization of Ultrasound to Diagnose Pediatric Elbow Fractures: Evaluation of Cost Savings, Radiation Exposure, and Patient Satisfaction

2. Who is in charge of the study?

The doctor in charge of the study is Dr. Jason Malone, DO.

3. What is the study about?

The study team would like to find out if using point of care elbow ultrasounds for diagnosing fractures in patient's elbows could be easier and less painful than x-rays. There are different types of pictures that the doctor can take to see the inside of your elbow, and they can help tell the doctor if your elbow is broken or fractured. There are differences between the two types of pictures that this study is using, x-rays and ultrasounds. This study is going to compare patient's experiences with those two kinds of pictures. In this study, there are two groups you might be assigned to. The group you're assigned to is decided randomly. In one group, you will get a normal x-ray taken. In the other group, you will have an ultrasound first, and might have an x-ray too if you're still in pain a week later.

4. Why are you asking me to be in this study?

You are being asked to be in the study because you have hurt your elbow, and it might be broken. Because the type of injury that you have is one that would normally get x-rays, you are being offered to be in this study.

5. What will happen to me in the study?

First, the study team will talk to you to make sure you want to be part of this study. The study team will then randomly put you in one of two groups of patients. Group A will only have an x-ray taken of their elbow while they are in the Nemours Emergency Department. Group B will have an ultrasound of their elbow taken while in the Nemours Emergency Department. If you are in Group A, the study doctor will talk to you about how an x-ray will be taken of your elbow. If you are in Group B, the study team will put a wand on the skin of your elbow to take an ultrasound picture, which only touches your skin with slight or no pressure.

The study team will also want to talk to you afterwards to find out how you felt about the process. If any of the questions that the study team asks you make you uncomfortable or embarrassed, you do not need to answer them. Please talk to the study team if anything about this study makes you uncomfortable. You might not directly benefit from this study, but it will help us to find out if ultrasounds are an easier way to take pictures of your elbow fracture, and how you felt throughout the process. This study might help the study team to replace elbow x-rays with ultrasounds. Also, the study team will want to talk to you one week after your first scan (x-ray or ultrasound). This is to make sure that your elbow is healing well. You might need to come back for a clinic visit if your elbow is still hurting. If your elbow is still hurting after one week

and you come back to the Nemours clinic you will get an x-ray of your elbow taken, no matter which group you were put in.

When you get an x-ray, it exposes you to a tiny amount of radiation. The amount of radiation from one x-ray is not enough to hurt you. There is a small risk of your private information being shared if you choose to be in this study. The study team will be doing everything they can to make sure that your study will stay private and will only be seen by people who work on the study.

6. Will I be paid to be in this study?

You will not be paid for being in this study.

8. Do I have to be in the study?

You don't have to do the study if you don't want to. If you are in the study, you can stop being in it at any time. Nobody will be upset with you if you don't want to be in the study or if you want to stop being in the study. The doctors and nurses will take care of you as they have in the past. If you have any questions or don't like what is happening, please tell the doctor or nurse.

You have had the study explained to you. You have been given a chance to ask questions. By writing your name below, you are saying that you want to be in the study.

Name of Adolescent (**Print**)

Signature of Adolescent

Date

Name of Person Obtaining Assent (**Print**)

Signature of Person Obtaining Assent

Date