Nemours Children's Health: Informed Consent for Participation in a Research Study and HIPPA Authorization

We are asking you to be in a research study. This form explains the research, your rights as a research participant, and any responsibilities that you may have as a result of your participation. You should understand the research study before you agree to be in it. ***You will receive a copy of this form. Read this form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.***

1. **TITLE OF THE STUDY: The Utilization of Ultrasound to Diagnose Pediatric Elbow Fractures: Evaluation of Cost Savings, Radiation Exposure, and Patient Satisfaction**

Key Information for You to Think About

The first section of this document lists important points about the study that the research team thought you would find helpful. The study is described in more detail after this section. If you do not understand something, please ask someone to explain further.

- **Voluntary Consent**. We are asking you **to volunteer for a research study.** It is up to you whether you choose to participate or not. If you choose not to participate or to discontinue participation, there will be no penalty or loss of benefits to which you are otherwise entitled.
- **Purpose**. The purpose of this research is to see how using point of care ultrasounds instead of x-rays to diagnose elbow fractures in children could be easier and less painful for patients.
- **Duration.** It is expected that your participation will last about one week.
- **Procedures and Activities.** In this study, you will get randomly grouped into one of the two study groups. Group A will only get an x-ray to help see if your elbow is fractured, which is the standard Emergency Department treatment. If you are sorted into Group B, you will get an ultrasound, and maybe an x-ray if necessary. You will be asked to fill out a questionnaire.

The study team will then also follow up with you after one week to make sure your injury is healing well. Both x-ray and ultrasound imaging have small (1-2%) risks of missing a fracture despite a negative evaluation, so if you still have pain in your elbow, the study team will ask you to come back next week for an additional exam and evaluation. Both x-rays and point of care ultrasounds are Food and Drug Administration (FDA) approved.

- **Risks.** If you are sorted into Group A, there will only be the normal risks of a small amount of x-ray radiation. The amount of radiation from one x-ray is not dangerous to you. If you are sorted into Group B, you will receive an ultrasound, which is non-standard for Nemours, but is a safe diagnostic tool. Ultrasound does not expose you to any radiation and usually causes no pain or discomfort. The ultrasound machine will only touch your skin for evaluation of your elbow. Group B may also receive an x-ray if you continue to feel pain in your elbow after one week. Because your diagnosis and outcomes will be recorded for this research study, there is a small risk of loss of privacy.

- **Benefits**. You might not directly benefit from this study, but it will help us to learn if ultrasounds are a better way to examine a patient's possible elbow fracture. This might help other patients have easier experiences in the Emergency Department when they get injured, because point of care ultrasounds might be a less painful type of scan.

- **Alternatives.** Participation is voluntary and the only alternative is not to participate, and to receive normal care in the Nemours Emergency Department.

If interested, please continue to the detailed consent.

2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS CHILDREN'S HEALTH?

If you have a question, complaint, or problem related to the study, you can call the investigator anytime at the numbers listed below.

	Nemours – ORL
Principal Investigator	Jason Malone, DO
Co-Investigator(s)	Amit Patel, MD
Address	6535 Nemours Parkway, Orlando, FL 32827
Daytime Phone **After Hours Phone**	407-319-3487 1-800-SOS-KIDS (1-800-767-5437)

3. WHOM SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?

If you have questions about your rights as a research participant, what to do if you are injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed below.

Director, Nemours Office of Human Subjects Protection at 302-298-7613
Email address: NOHSP@nemours.org

4. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this research is to use the point of care ultrasound process to diagnose elbow fractures in children, and to learn whether using ultrasound instead of x-ray affects patient and family satisfaction with the Emergency Department visit. Nemours currently uses the x-ray method as the standard way to examine elbow fractures in children, but we want to find out if the ultrasound method might be easier for patients and families. Both x-rays and point of care ultrasound devices are FDA approved for use with the type of fracture you might have. None of the imaging or devices in this study are experimental. Both x-ray and ultrasound imaging have small (1-2%) risks of missing a fracture that is there, so if you still have pain in your elbow the study team will ask you to come back next week for an additional exam and evaluation.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

The Pediatrics Orthopedics Society of North America (POSNA) is the Sponsor of this study. POSNA will pay Nemours Orlando for its costs in conducting this study.

6. WHO CAN BE IN THE STUDY?

Patients aged 0 up to 18 years old with elbow pain in one spot after an injury who come to the Nemours Orlando emergency department.

7. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

There will be 225 patients in this study. Patients will be divided into two groups. Group A, who will only receive the normal x-ray imaging, will have 100 participants. Group B, who will receive the non-standard ultrasound imaging first and might receive x-ray imaging too if needed, will have 125 participants.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Your participation in this study will last about one week. Your participation in the study will be, in total, the initial ultrasound or x-ray scan to see if you have a fracture in your elbow, and then a follow up with the study team one week later. The study team will reach out to you over the phone or the Nemours mobile app to find out how you are healing. If you still have pain in your elbow after one week, the study team will ask you to come back into the Nemours orthopedic clinic for a follow up visit.

9. WHAT ARE THE RESEARCH PROCEDURES (What will happen in the study)?

The study team will first talk to you to see if you are comfortable participating in this study. If you agree the study team will randomly assign you to a group, either A or B. The study's design, of splitting patients into Group A (receiving standard x-rays) and Group B (receiving non-standard ultrasounds first, and also receiving standard x-rays if elbow pain continues after one week), will help the study doctors compare how each group does with the different types of scans. There is 50% chance of being in Group A or Group B.

Group A will get a standard x-ray of their elbow to help diagnose any fractures, as is normal procedure in the Nemours Emergency Department. When you get an x-ray, you will be taken to a different room and the x-ray will be taken there. Group B will get a point of care ultrasound while they are in the Nemours Emergency Department, and if your pain persists you will be asked to come back to the Nemours Orthopedics clinic for a standard x-ray in a week. A point of care ultrasound is different because it is a movable machine that uses a wand to take pictures of the inside of someone's body without radiation. The study doctor will bring the point of care ultrasound to your room and will take the picture there. You will not need to be moved to a different room for the scan.

While you are in the Emergency Department, the study team will have you fill out a questionnaire after the first scan that will record your experiences with these scans. This will include any pain you experienced, and how you felt about the scan. If any of the questions make you uncomfortable, you do not have to answer them. Please talk to the study team if you are uncomfortable with any of the information they are asking for.

For participants in both groups A and B, the study team will follow up with you by phone or through the Nemours mobile app next week to make sure you are healing well. If you need to come back to the orthopedic clinic for more care, the study team will talk to you then. If not, the phone or application conversation will be the last part of the study that you complete. If you come back to the Nemours Orthopedics clinic for a follow up visit because you are still experiencing pain, the follow up might include an exam and possibly an x-ray by an orthopedic surgeon to help figure out why you are still hurting. Patients with a negative ultrasound evaluation may need an x-ray evaluation also, depending on how the injury is healing.

Your personal information will not be kept beyond this study. To protect your privacy, your data will be deidentified after this study is over. Your information might be used for other research studies in the future without asking your permission, but there will be no way to trace that information back to you.

10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?

Any research has some risks (things that could make you sick, make you feel uncomfortable, or hurt you). The risks with the most chance of happening to someone in this study are listed below. Also, there is a chance of other risks that almost never happen, or unknown risks.

The risks of an x-ray are very low, as it is part of the normal treatment for an elbow fracture in children. An x-ray exposes patients to a very small amount of radiation, which will not cause any problems for your health. The standard x-ray imaging process has a 1-2% chance of missing a fracture, also known as producing a false negative. This is about the same level of risk of a false negative as the point of care ultrasound. It is also standard practice to have you do a urine pregnancy test before they get an x-ray. The results of that test will be private.

Point of care ultrasound is a safe diagnostic tool and does not expose you to any radiation. It is a non-invasive tool, which means it is associated with little or no pain and discomfort. The ultrasound has about 98% sensitivity in diagnosing an elbow fracture, which means that there is a very low (2%) chance that a fracture may be missed in the ultrasound examination of your elbow. X-rays have about the same chance of missing a fracture. Because of this, if you are in Group B and get a negative ultrasound evaluation, it might be necessary to come back next week for an exam and for evaluation with an x-ray. Please feel free to discuss this option with the study team.

There is also a small potential risk to your privacy and confidentiality. The study team will be de-identifying your data. This means that all information that could potentially show who you are will be removed from the research documents. All patient data will also be saved in a password protected file. To make your data safer, their data will be deidentified after the end of the study.

11. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

You might not directly benefit from this study, but it will help us to learn if ultrasounds are a better way to examine a child's possible elbow fracture. This might help other families have easier experiences in the Emergency Department when they get injured, because point of care ultrasounds might be a less painful type of scan.

12. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?

Nemours will assure that you receive treatment, if needed, for study-related injuries. Neither Nemours nor the study doctor has a program to pay for medical care provided to treat the injury. If you have health insurance, it may, or may not, pay for the cost of treatment resulting from a study-related injury.

If your insurance does not pay, or if you do not have insurance, you understand that you may be responsible for paying for the cost of treatment.

If you think that you have been injured while in this study or have a problem related to the study, you should tell one of the study doctors as soon as possible. The study doctor or research staff will tell you what you should do. The study doctor(s)' names and phone numbers are on the first page of this form.

12. IS BEING IN THE STUDY VOLUNTARY?

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your usual medical care if you decide not to be in the study or decide to stop your participation in the study. No one will be angry with you or treat you any differently than before you were asked to be in the study. If you withdraw from this study, you may continue treatment with your doctor, or you may seek treatment from another doctor of your choice.

If you withdraw from the study, the study doctor may ask your permission to continue study follow-up, and all clinical data related to the study may continue to be collected from your medical records.

You may ask the researcher to destroy your information or samples. Your request must be in writing. The researcher will tell you if this is possible. There may be legal reasons for keeping your information or samples.

13. WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?

You can refuse participation in this study. The alternative to this study is not participating and receiving normal care in the Nemours Emergency Department. If you do not want to be part of this study, nothing will change about your care.

14. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?

The only situation in which you would be removed from the study is if you do not complete the one-week follow up with the study team. You always have the option to remove your information. Please discuss this option with the study team if that is what you want to do.

15. WHAT ARE THE COSTS OF BEING IN THIS STUDY?

This study will only include the initial Emergency Department visit and a one-week follow-up visit. There will be no additional costs for participants beyond the standard treatment costs for this kind of injury. There will be no costs for the ultrasounds that you might receive.

16. WILL I BE PAID FOR BEING IN THIS STUDY?

You will not be paid for being in this study. No arrangement exists that would allow participants to share in any profit generated from this study or future research.

17. WILL I BE TOLD OF ANY NEW INFORMATION THAT MIGHT AFFECT MY WILLINGNESS TO STAY IN THE STUDY?

Any new information that may change your mind about being in this study will be given to you. A committee called the Institutional Review Board (IRB) will review this study at least once per year. If the IRB finds that there is new information that you should know about while taking part in this study, it will ask the study

doctor to tell you about it. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

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.

18. WHAT INFORMATION ABOUT YOU WILL BE USED OR DISCLOSED? (AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION)

Identifiable health information about you will be used by Nemours researchers and may be given to people outside of Nemours for this research. This is done to conduct the research study, to monitor the safety of research participants, and for auditing. Federal law requires us to tell you about, and get your approval for, research use and disclosure of health information that includes "identifiers" that can connect the health information to you. (Names, initials, date of birth, addresses, phone numbers, and social security numbers are examples of identifiers.) This identifiable health information is called Protected Health Information (PHI).

Use of Health Information by Nemours Staff

The health information that will be used within Nemours includes all data collected for this study, as described in this form.

Your identity will be protected as much as possible. Nemours protects your health information by storing records in files or computers that can only be used by authorized Nemours staff.

The people within Nemours that may use this health information include:

- The investigators listed on the first page of this permission form and their staff;
- The Nemours Institutional Review Board (IRB). (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of research participants), and;
- Nemours internal audit staff.

Disclosure of Health Information to Others

Information from this research study will also be contained in your Nemours' medical record along with the information about your regular office visits. This will help other doctors to know about the research study you are in and give them extra information from the research that might help them take better care of you. The same information might also be seen by anyone who can look at your medical records, such as your insurance company.

Identifiable health information will not be disclosed (given) to anyone outside of Nemours Children's Health Orlando.

Limits on Protection of Privacy and Confidentiality

Only health care organizations have to follow laws and rules about protecting the privacy of health information. If health information containing peoples' identities is given to other kinds of companies or

organizations, they are not required by law to safeguard the privacy and confidentiality of that information. Nemours expects these companies and organization to protect the privacy and confidentiality of research participants, but it is not possible for Nemours researchers to assure that this happens.

Government agencies that may look at records for this research study, including the above health information, include:

- The U.S. Food and Drug Administration
- The U.S. Department of Health and Human Services
- Other agencies of State and local government as required by law

The research results may be presented at scientific meetings or in print. Participants' identities will not be disclosed in those presentations.

20. SIGNATURES:

I am making a decision whether or not to participate in this study. I have read this form, or had it read to me in a language that I understand. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly consent to participate in this study. By signing this form, I am not giving up any rights to which I am entitled under law.

I understand that:

- I can revoke consent for my participation in this study and authorization for the use and / or disclosure of my PHI by contacting the person in charge of the study listed on the first page of this form and sending the revocation request via email to privacy@nemours.org or via mail to 10140 Centurion Parkway North, ATTN: Chief Privacy Officer, Jacksonville, FL 32256.
- The use and/or disclosure of my PHI will stop after Nemours receives the revocation notice.
- My revocation does not affect any disclosures made prior to the revocation being received and processed.
- I have the right to inspect or copy the PHI to be used or disclosed, as permitted under federal law (or state law, to the extent the state law provides greater access rights).
- I will receive a copy of this Authorization.
- Unless I revoke authorization, the use and / or disclosure of my PHI described in this form will expire when the research study is complete, and analysis and publication have ended.
- My PHI may be disclosed again by the person or organization (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this consent form.
- If I refuse to sign this consent form, I will not be allowed to participate in this research study.
- I have the right to ask Nemours to tell me who has received my protected health information.
- I have the right to revoke my authorizationfor the use and disclosure of my health information at any time, which would end my participation in this study.
- I will receive a signed and dated copy of this form.

My signature indicates that:

- I give my consent to participate in the research study described in this form.
- I give the researchers and Nemours authorization to use and /or disclose my individually identifiable health information for this research study as described in the section on use and disclosure of PHI.

Name of Participant (**Print**)	Participant Date of Birth
Signature of Participant	Date

I, the undersigned, certify that to the best of my knowledge the participant signing this consent had the study fully and carefully explained and that she / he understands the nature, risks and benefits of his / her participation in this research study.

I, the undersigned, certify that the participant completed no research procedures for this study prior to signing this consent.

Name of Person Obtaining Consent (**Print**) (Investigator or Designee)	
Signature of Person Obtaining Consent (Investigator or Designee)	Date

A copy of the signed form was provided to Participant. ☐