Nemours Children's Health: Parental Permission for
A Child's Participation in a Research Study and HIPPA Authorization

We are asking you to permit your child to be in a research study. If you are a parent or legally authorized representative of a child who may take part in this study, permission from you is required. This form explains the research, your child's rights as a research participant, and any responsibilities that you may have as a result of your child's participation. You should understand the research study before you agree to permit your child to be in it. ***You will receive a copy of this form. Read this permission 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 your child for a research study.** It is up to you whether you choose to allow your child to participate or not. If you choose not to allow your child to participate or decide to withdraw your child after enrolling, there will be no penalty or loss of benefits to which your child is 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.** Your child's participation in this study will last about one week.
- **Procedures and Activities.** In this study, your child will get randomly grouped into one of the two study groups. Group A will only get an x-ray to help see if your child has an elbow fracture, which is the standard Emergency Department treatment. If your child is sorted into Group B, he or she will get an ultrasound, and maybe an x-ray if necessary. You and your child will be asked to fill out a questionnaire. The study team will then also follow up with

you and your child after one week to make sure your child is healing well. Both x-ray and ultrasound imaging have small (1-2%) risks of missing a fracture that is there, so if your child still has pain in their 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 your child is 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 your child. If your child is sorted into Group B, they will receive an ultrasound, which is non-standard for Nemours but is a safe diagnostic tool. Ultrasound does not expose your child to any radiation and usually causes no pain or discomfort. The ultrasound machine will only touch your child's skin for evaluation of their elbow. Group B may also receive an x-ray if your child continues to feel pain in their elbow after one week. Because your child's diagnosis and outcomes will be recorded for this research study, there is a small risk of loss of privacy.
- **Benefits**. Your child might not directly benefit from this study, but it will help us to learn if ultrasounds are a better way to take pictures of 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.
- **Alternatives.** Participation is voluntary and the only alternative is to choose not to participate. If you choose not to participate, your child will 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 child's rights as a research participant, what to do if your child is 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 person 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 your child 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 your child still has pain in their elbow the study team will ask you and your child 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?

Nemours Orlando emergency department patients aged 0 up to 18 years old with elbow pain in one spot after injury.

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 child's participation in this study will last about one week. Your child's participation in the study will be, in total, the ultrasound or x-ray scan done in the Emergency Department to see if your child has a fracture in their elbow, and then a follow up with the study team one week later. The study team will reach out to you and your child over the phone or the Nemours mobile app to find out how your child is healing. If your child still has pain in their 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 and your child to see if you are comfortable participating in this study. If you agree, the study team will randomly assign your child 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, which is normal procedure in the Nemours Emergency Department. If your child gets an x-ray, they 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 child's 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 machine to your child's room and will take the picture there. They 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 your child fill out a questionnaire after the first scan that will record your child's experiences with the scan. This will include questions about any pain they experienced and how they felt about the scan. If any of the questions make you or your child 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 children in both groups A and B, the study team will follow up with you and your child by phone or through the Nemours mobile app next week to make sure your child is healing well. If your child needs to come back to the orthopedic clinic for more care, the study team will talk to you more then. If not, the phone or Nemours app 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 your child is still experiencing pain, the follow up might include an exam and possibly an x-ray by an orthopedic surgeon to help figure out why your child is still hurting. Patients whose ultrasound does not find a fracture may need an x-ray evaluation also, depending on how the injury is healing.

Your child's personal information will not be kept beyond this study. To protect your child's privacy, his or her data will be deidentified after this study is over. Your child's 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 your child.

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

Any research has some risks (things that could make your child sick, make your child feel uncomfortable, or hurt your child). 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 and 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 child's 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 your child 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 your child to any radiation. It is a non-invasive tool, which means it usually causes little or no pain and discomfort. The ultrasound has about 98% sensitivity in diagnosing elbow fracture, which means that there is very low (2%) chance that a fracture may be missed in the ultrasound examination of your child's elbow. X-rays have about the same chance of missing a fracture. Because of this, if your child is in Group B and gets 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 child's privacy and confidentiality. The study team will be de-identifying your child's data. This means that all information that could potentially show who your child is will be removed from the research documents. All patient data will also be saved in a password protected file. To make your child's data safer, their data will be deidentified after the end of the study.

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

Your child 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 your child receives 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 your child has been injured while in this study or has 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.

13. 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 child's usual medical care if you decide not to allow your child to be in the study or decide to stop your child's participation in the study. No one will be angry with you or your child or

treat your child any differently than before your child was asked to be in the study. If you withdraw your child from this study, your child may continue treatment with their doctor, or you may seek treatment for your child from another doctor of your choice.

If you withdraw your child 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 child's medical records.

You may ask the researcher to destroy your child's 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 child's information or samples.

14. 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 child's care.

15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?

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

16. 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 your child might receive.

17. WILL MY CHILD 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.

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

Any new information that may change your mind about your child 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 your child is 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.

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

Identifiable health information about your child will be used by Nemours researchers, but will not 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 your child. (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 child's identity will be protected as much as possible. Nemours protects your child's health information by storing records in files or computers that can only be used by authorized Nemours staff. Your child's information will be completely deidentified, which means that all information linking it back to your child will be removed.

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 child's Nemours' medical record along with the information about your child's regular office visits. This will help other doctors to know about the research study your child is in and give them extra information from the research that might help them take better care of your child. The same information might also be seen by anyone who can look at your child's 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 permit my child to participate in this study. I understand that my child may also have to agree to participate in the study before she / he will be allowed to be in this study. I have read this permission form or have 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 give permission for my child to participate in this study. By signing this permission form, I am not giving up any rights to which my child is entitled to under the law.

I understand that:

- I can revoke permission for my child's participation in this study and for the use and / or disclosure of my child's 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 child's 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 permission, the use and / or disclosure of my child's PHI described in this form will expire when the research study is complete, and analysis and publication have ended.
- My child's 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 permission form.
- If I refuse to sign this permission form, my child will not be allowed to participate in this research study.
- I have the right to ask Nemours to tell me who has received my child's protected health information.
- I have the right to revoke my permission for the use and disclosure of my child's health information at any time, which would end their participation in this study.
- I will receive a signed and dated copy of this form.

Parent / Legal Guardian Signature Section

My signature indicates that:

- I have read and understand the above statements (which if needed have been interpreted for me by a professional interpreter) and that I agree with each statement above.
- As their parent(s) or legally authorized representative(s), I(we) give my(our) permission for the minor child named below to participate in the research study described in this Parental Permission Form.
- I(We) give the researchers and Nemours permission to use and / or disclose my(our) child's individually identifiable health information for this research study as described in this form.

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

Name of Parent / Legally Authorized Representative (**Print**) _____

Signature of Parent / Legally Authorized Representative (#1) _____ Date _____

Check Relation to Participant: ☐ Parent ☐ Legally Authorized Representative
(Legally Authorized Representatives must have documented authority to give permission for a child's participation in a research study according to the laws of the State in which the treatment occurs.)

Second parent signature ☐ **N/A**
Do NOT check this box if the IRB determined that two (2) parent signatures are required as noted in the IRB final approval correspondence.

Name of Parent / Legally Authorized Representative (**Print**) _____

Signature of Parent / Legally Authorized Representative (#2) _____ Date _____

Check Relation to Participant: ☐ Parent ☐ Legally Authorized Representative
(Legally Authorized Representatives must have documented authority to give permission for participation in a research study according to the laws of the State in which the treatment occurs.)

Study Team Member Signature Section

I, the undersigned, certify that to the best of my knowledge the parent(s) / legally authorized representative(s) signing this permission had the study fully and carefully explained and that they understand(s) the nature, risks and benefits of their child's participation in this research study.

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

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