Nemours
Informed Consent for
Participation in a Research Study
Nemours IC Template January 2024

1. WHAT IS THE TITLE OF THE STUDY?

Using Ultrasound as an Alternative to Radiography in Measuring Magnetically Controlled Growing Rods (MCGR) in Tibia and Femur Lengthening Patients

Key Information for You to Consider
• **Voluntary Consent**. You are being asked **to volunteer your child** for a research study. It is up to you whether you choose to allow your child to participate or not. There will be no penalty or loss of benefits to which your child are otherwise entitled if you choose not to allow your child to participate or discontinue participation. • **Purpose**. The purpose of this research is to evaluate the efficacy of ultrasound imaging as an alternative to radiographs in assessing the bone lengthening measurements in a pediatric cohort • **Duration.** It is expected that your child's participation will last 14 weeks. • **Procedures and Activities.** Your child will be asked to have ultrasound imaging and measurements in addition to the standard-of-care x-rays. • **Risks.** There is no risk of additional radiation as the ultrasound does not include any radiation. There may be a mild discomfort associated with ultrasound imaging. • **Benefits**. The study does not involve direct benefit to participants. Knowledge gained by this study may save future patients from exposure to radiation. • **Alternatives.** Participation is voluntary and the only alternative is to not participate, which will entail standard-of-care x-ray imaging at each follow-up visit without additional ultrasound imaging. **If interested, please continue to the detailed consent.**

2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?

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	Dr. Jason Malone
Co-Investigator(s)	Jason Liu, Dr. Amit Patel, Dr. Cassidy Foley, Dr. Julia Fink, and Kaitlin Maher PA-C
Study Coordinator(s)	Dr. Jason Malone
Address	6535 Nemours Parkway Orlando, FL 32827
Daytime Phone After Hours Phone	407-319-3487 954-328-7154
Long Distance	1-800-SOS-KIDS (1-800-767-5437)

3. WHO 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.

Chairperson, Nemours IRB 1 at 302-298-7613
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 evaluate the efficacy of ultrasound imaging as an alternative to radiographs in assessing the bone lengthening measurements in a pediatric cohort.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

Nemours Children Hospital and the University of Central Florida College of Medicine are the Sponsors of this study. Nemours Children Hospital and the University of Central Florida College of Medicine will pay Nemours for its costs in conducting this study.

6. WHO CAN BE IN THE STUDY?

Any pediatric patient between the ages of 8 to 21 years old at Nemours Orlando undergoing a tibia or femur lengthening procedure with an intramedullary mechanical rod.

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

About 10 pediatric patients will be in the study (5 tibia and 5 femur lengthening patients)

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Per standard of care all children undergoing lengthening procedures require 14 weekly follow up visits. No increase in the number of visits will occur from participation in the study.

9. WHAT ARE THE RESEARCH PROCEDURES?

- All patients will follow up weekly for clinical exam and imaging with no change to current workflow or standard of care.
- All patients will receive or undergo standard AP and Lateral x-rays
- All enrolled patients will have ultrasound imaging and measurements in the same locations as the x-rays.

- All measurements will be stored in a password protected file with no patient identifiers and will be safely discarded at the end of the study.

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. There is no risk of additional radiation as the ultrasound does not include any radiation. There may be a mild discomfort associated with ultrasound imaging.

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

The study does not involve direct benefit to participants. Knowledge gained by this study may save future patients from exposure to radiation.

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 insurance does not pay for study-related injuries, or if you do not have insurance, then Nemours Children Hospital will pay for all reasonable medical costs related to the treatment of a study-related injury.

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.

The study staff is available Monday - Friday from 8:00am to 5:00pm. During these hours, you should call Dr. Malone for medical advice.
During evenings, weekends, and holidays, you should call 407-567-4574 You will reach the Nemours operator. Ask to page the attending physician on call.

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 usual medical care if you decide not to be in the study or decide to stop being 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.

In the event that 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. *Withdrawal from the study only entails lack of ultrasound imaging. X-ray imaging will continue to be conducted at each follow-up visit per standard-of-care protocol.*

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.

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

You can refuse to permit your child to participate in this study.

15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?
Yes, if Dr. Malone finds the patient to be ineligible for the study.

16. WHAT ARE THE COSTS OF BEING IN THIS STUDY?
There is no financial cost to the patient for being in this study.

17. WILL I BE PAID FOR BEING IN THIS STUDY?
No.

18. 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 participation 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 you are 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.

19. WHAT INFORMATION ABOUT ME 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. 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.

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);
- Nemours internal audit staff.

Disclosure of Health Information to Others
To minimize the minimum risk of breach of confidentiality, data will stored on a password protected Nemours computers. Additionally, the excel sheets on which the data is collected will also be password protected. Identifiable Health Information will not be disclosed outside of Nemours Children Hospital.

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 organizations 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 withdraw consent for participation in this study and 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.
- The use and / or disclosure of my PHI will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- Unless I withdraw consent, 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 be 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 authorization for 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 ☐

Nemours

Addendum for Optional Testing or Future Use of Samples or Data

Version January 2024

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