



Nemours Parental Permission for A Child's Participation in a Research Study

You have been asked 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**: Using Ultrasound as an Alternative to Radiography in Measuring Magnetically Controlled Growing Rods (MCGR) in Tibia and Femur Lengthening Patients

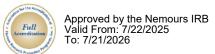
Key Information for You to Consider

- 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	

3. WHO 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 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)

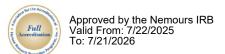
8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

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 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 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 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.

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 child's usual medical care if you decide not to permit 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 his / her doctor, or you may seek treatment for your child from another doctor of your choice.

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.

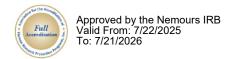
14. WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?

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 MY CHILD BE PAID FOR BEING IN THIS STUDY?

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.

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. 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.

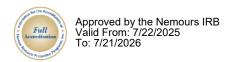
Limits on Protection of Privacy and Confidentiality

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 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 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 form, I am not giving up any rights to which my child is entitled under law.

I understand that:

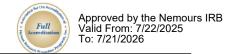
- I can withdraw permission for my child's participation in this study and for the use and / or disclosure of my child's PHI by contacting the person in charge of the study listed on the first page of this form.
- The use and/or disclosure of my child's PHI will stop after Nemours receives the withdrawal 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 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 his/her participation in this study.
- I will receive a signed and dated copy of this form.

Parent / Legal Guardian Signature Section

My signature indicates that:

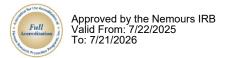
- As his or her parent(s) or legally authorized representative(s), I(we) give my(our) permission for the minor child named below to participate in the research study described in this Parental Permission Form.
- I(We) give the researchers and Nemours permission to use and / or disclose my(our) child's individually identifiable health information for this research study as described in this form.



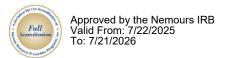


Name of Participant (Print)	Participant Date of Birth
Name of Parent / Legally Authorized Representative (Pri	nt)
Signature of Parent / Legally Authorized Representative (#1)	Date
Check Relation to Participant: Parent Legally Legally Authorized Representatives must have document barticipation in a research study according to the laws of the	
Second parent signature Do NOT check this box if the IRB determined are required as noted in the IRB final ap	that two (2) parent signatures
Name of Parent / Legally Authorized Representative (Pri	nt)
Signature of Parent / Legally Authorized Representative (#2)	Date
Check Relation to Participant: Parent Legally Legally Authorized Representatives must have documente research study according to the laws of the State in which	
Study Team Member Signature Section , the undersigned, certify that to the best of my keepresentative(s) signing this permission had the study fully understand(s) the nature, risks and benefits of their child's	and carefully explained and that she / he (the
I, the undersigned, certify that the participant completed signing this permission.	no research procedures for this study prior
Name of Person Obtaining Permission (Print) (Investigator or Designee)	
Signature of Person Obtaining Permission (Investigator or Designee)	Date
A copy of the signed form was provided to Parent(s) / Leg	ally Authorized Representative(s) \square
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NEMOURS

ADDENDUM FOR OPTIONAL TESTING OR FUTURE USE OF SAMPLES OR DATA Version January 2024

Name of Parent / Legally Authorized Representative (Print) Signature of Parent / Legally Authorized Representative Date (#1)**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 Date (#2)☐ Legally Authorized Representative **Check Relation to Participant**: Parent (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.)