Approved by the Nemours IRB
Valid From: January 15, 2018
to July 20, 2018
[1074554]

Nemours
Parental Permission for Participation in a Research Study

Nemours PP Template May 2017

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. **WHAT IS THE TITLE OF THE STUDY?** Emergence agitation (EA) and pain scores in pediatric patients following sevoflurane anesthesia for adenoidectomy and tonsillectomy with or without adenoidectomy comparing opioid-only, analgesia with either IV or oral acetaminophen plus opioid analgesia, a multi-center double-blinded study

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 – JAX	Nemours - ORL
Principal Investigator	Robert Bryskin, MD	Carlos Archilla, MD
Co-Investigator(s)	Stefanie Schrum, MD Joseph Dayan, MD	Julie Wei, MD Anuja Mehta, MD Carol Klim, MD Jeremy Driscoll, BS Brian Bender, CRNA Timothy Maul, PhD
Study Coordinator(s)	Nancy Archer, RN	Kristin McCrary, MS
Address	807 Children's Way, Jacksonville, FL 32207	13535 Nemours Pkwy Orlando, FL
Daytime Phone After Hours Phone	(904) 697-3600	(407) 567-4000
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 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 302-651-5970
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 study is to establish if the addition of Tylenol (acetaminophen), both oral or intravenous, to the standard opioid medication decreases post-operative agitation. Acetaminophen is an FDA approved product in children. However, it has not been approved to prevent emergence agitation in children.

Agitation following general anesthesia (sleep during surgery) is a frequent and undesirable event in children. We want to find out if giving one mode of pain medication causes less agitation compared to another mode by using medications that doctors commonly give children for pain relief during their surgery.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

University of Central Florida is the Sponsor of this study at Nemours Children's Hospital in Orlando. At Wolfson Children's Hospital, Nemours is the Sponsor. The University of Central Florida, College of Medicine will pay Nemours for medications and supplies beneficial in conducting this study. You will not be responsible for any study associated expenses.

6. WHO CAN BE IN THE STUDY?

Pediatric patients between 24 months and 7 years of age undergoing minor ENT (Ears/Nose/Throat) procedures (tonsillectomy and/or adenoidectomy) are included in this study.

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

There will be about 150 participants planned for the entire study. The study will take place at Nemours Children's Hospital in Orlando, FL and Wolfson Children's Hospital in Jacksonville, FL.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Participation in this study will last for the duration of the surgery to the time your child is discharged from the Post-Anesthesia Care Unit (PACU). There will be a follow-up phone call within 24 hours from date of surgery. Study enrollment is anticipated to be completed by March 2018.

9. WHAT ARE THE RESEARCH PROCEDURES?

After agreeing to participate in the study, your child will be randomly assigned to one of three groups: IV fentanyl plus IV acetaminophen and oral placebo, IV fentanyl plus PO acetaminophen and IV placebo or IV fentanyl plus oral placebo and IV placebo.

Prior to surgery, your child will receive the randomly assigned cherry-flavored syrup. The syrup will be prepared by the pharmacy and will contain either acetaminophen (Tylenol) or a placebo (a liquid that has no active medicine in it). No pre-surgery sedation will be offered to your child. Your child will be awake when he/she enters the operating room and you will be allowed to accompany your child on the way to the operating room.

During the surgery, your child will receive an opioid-based medicine (fentanyl) and the randomly assigned intravenous (IV) acetaminophen or a placebo of normal saline (like normal body fluid). After your child's surgery is complete, a nurse in the Post-Anesthesia Care Unit (PACU) will measure the level of agitation your child experiences while waking up from the anesthesia, using a numbered scale made specifically for children. This scale is used in most children's hospitals around the country for any child that undergoes surgery that requires anesthesia. This scale measures things such as eye contact, awareness, restlessness, and ability of your child to be comforted. The nurse will also measure the level of pain using standard pediatric pain assessment tools. Once your child is ready to leave the PACU, this will mark the

end of his/her participation in the study. However, we will contact you once more by phone, within 24 hours of the surgery, to check on your child and ask you some study questions about your child's recovery.

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 associated with participation in this study are minimal as the medications observed are medications frequently used for the treatment of surgical pain. Rare side effects 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.

Opioid medication (like a medicine called fentanyl) can be associated with itching, nausea/vomiting and breathing problems which are known side effects that are closely monitored and easily treatable. Side effects may be associated with the use of acetaminophen, (like Tylenol), which is one of the most commonly used medications in both children and adults for pain relief. The most common adverse reactions (seen in about 5% of people taking this medicine) in children are nausea, vomiting and constipation. Very rarely serious adverse reactions may include liver injury, serious skin reactions, hypersensitivity, and anaphylaxis (a life threatening allergic reaction). Most cases of liver injury are associated with the use of acetaminophen where the dose exceeds the recommended maximum daily limits, and often involves more than one acetaminophen-containing product. The study pain control dose to be used is a dose consistent with product recommendations to minimize this risk.

Please ask if you have any additional questions or need further clarification about the possible risks of having your child take part in this study.

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

Increased level of monitoring and pain assessments are a potential benefit. Your child may also experience less agitation and pain. Your child's participation in this study will help us identify which pain medication or medication combination is more beneficial to use in children undergoing adenoidectomy or tonsillectomy with or without adenoidectomy surgery in order to decrease agitation and provide better pain control upon waking from surgery.

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

The risk of physical injury from taking fentanyl or acetaminophen or from the research procedures is extremely low. Your child should not participate in this study if they have known reactions to fentanyl or other opioid medications or acetaminophen or any other of their ingredients. In the very unlikely event that injury occurs, please note the following information:

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.

The study staff is available Monday - Friday from 8:00am to 5:00pm. During these hours, you should call the study coordinator for non-emergent medical advice.

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.

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

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

You can refuse to permit your child to participate in this study. If you wish not to participate, your child will proceed with the planned surgery and anesthesia care customized for your child's needs.

15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?

Children may be removed from this study without parental permission if the study doctors feel it is in the best interest of the child. An example of removal from the study is if your surgeon changes the pre-planned surgical technique that could add additional time to the planned surgery. If a child needs to be removed from the study, a member of the research team will contact the parent(s) or legal guardian.

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

The regular cost of treatment for your child's surgical procedure and all standard of care will be billed to your insurance carrier if you have one. There will be no charge to the participant to take part in this study. The study sponsor, UCF, is covering the cost of supplies and medications necessary to conduct this study.

17. WILL MY CHILD BE PAID FOR BEING IN THIS STUDY?

Your child 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 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 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. The PHI obtained in this study includes: name, date of birth, gender, medical history, diagnosis, type of surgery, surgery reports, PACU reports, and Medical Record number.

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 PHI will be stored on a password-protected computer with access limited to Carlos Archilla, MD, and the research team members.

Your child will be assigned a "study number" that contains the instructions for the anesthesiologist (doctor that helps your child to sleep during surgery) as to which pain regimen to give your child to help control surgical pain. The study participant number used for tracking your child during this study, will be connected only by their medical record number, and will be recorded on a paper document stored securely in a protected and limited access location. Research records will be securely locked and only accessed by the research team members.

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.

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 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 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 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 (**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 she / he (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

A copy of the signed form was provided to Parent(s) / Legally Authorized Representative(s) ☐