Nemours
Parental Permission for
Participation in a Research Study
Nemours PP Template March 2018

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?

Evaluation of pain alleviating strategies during allergy shots (Subcutaneous immunotherapy): A randomized controlled study (**P**ain **P**erception with **A**llergy **S**hot **T**echniques: PPAST)

KEY INFORMATION

A. The information in this form is being used to seek your consent for a research study. Allowing your child to be in the study is up to you.
B. This study is done to evaluate and compare the efficacy of the standard of care method and three non-pharmacological pain control devices in decreasing the perception of pain during subcutaneous immunotherapy injections (allergy shots) in a pediatric allergy/immunology clinic setting. Participation in the study will occur during two routine allergy shot clinic visits.
C. The risks associated with study participation are the same risks your child could experience if they did not participate in the study. Potential risk for the study participants may be possible allergic reaction/skin irritation from the cold spray or ice pack or an increased level of anxiety.
D. The potential benefit associated with this research study includes a better understanding of which distraction technique is more beneficial to use in children receiving allergy shots in order to decrease the perception of pain and reduce anxiety related to allergy shots.
E. If you decide not to allow you child to participate in this study, your child can still receive their allergy shots with the standard of care Pain Ease Spray.

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
Principal Investigator	Jennifer Pfieffer MSN, APRN, PCNS-BC, CPEN
Co-Investigator(s)	Karen Gee BSN, RN, CPN- Kristine Wehmeier BSN, RN, AE-C Emily Hoehn BSN, RN, CPN Monarie Lacanilao BSN, RN Tracy DeSanto BSN, RN, CPN Amanda Davis BSN, RN

	Tara Spruill MSN, RN, CPN Jamie Thibodeaux BSN, RN, CPN Ejaz Yousef MD
Study Coordinator(s)	Isabel Delgado BSH Elizabeth DeLuca BSN, RN, CCRC Mary Warde BSN, RN, CCRC
Address	807 Children's Way Jacksonville, FL 32207
Daytime Phone **After Hours Phone**	904-697-3795 904-697-3600
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 2 at 904-697-3415
Director, Nemours Office of Human Subjects Protection at 302-298-7613
Email address: NOHSP@nemours.org

4. WHAT IS THE PURPOSE OF THE STUDY?

Subcutaneous Immunotherapy (Allergy shots) is a potentially disease-modifying therapy that is effective for the treatment of allergic rhinitis/conjunctivitis, allergic asthma and stinging insect hypersensitivity. Pain, which results from the irritation of nearby nerves is a common concern of patients, particularly in children, during or after the allergy shots. This can be a stressful and negative experience for children. There are various distraction techniques available on the market to minimize the pain in general. However, there is a lack of published research to use these techniques, in children receiving allergy shots.

The purpose of this study is to evaluate and compare the efficacy of the standard of care method (Ethyl Chloride/Pain Ease Spray) and three non-pharmacological pain control devices (Buzzy Bee I, Buzzy Bee II and Shot Blocker) in decreasing the perception of pain during subcutaneous allergy shot in a pediatric allergy/immunology clinic setting.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

The Nightingale Grant through the Nemours Foundation is funding the study.

6. WHO CAN BE IN THE STUDY?

Male or female children aged 4-17, who are on allergy shots and have received a minimum of three allergy shots prior to enrollment can participate in this study.

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

There will be approximately 100 participants in this study. All participants will be enrolled at Nemours.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Participation in the study will occur during two routine allergy shot clinic visits. The duration of participation will depend on the frequency of your child's allergy shot treatment plan. No follow up visits are required.

9. WHAT ARE THE RESEARCH PROCEDURES?

Visit 1:

Children aged 4-17 years who present to receive their injection(s) in the allergy clinic will be screened by the Principal Investigator or Co-Investigator for study inclusion and exclusion criteria. During your child's routine post-allergy shot 30-minute wait time, the investigator and the research coordinator will provide you and your child an overview of the study design, the risk and benefits assessment and study requirements. After obtaining parental permission and child assent, your child will be considered enrolled in the study. Once your child has a subject ID assigned to them, they will be ready to be randomized at their next routine allergy shot visit.

Visit 2:

At your child's future allergy shot clinic visit you will be asked if your child took any pain-relieving medicines, like Tylenol or Advil, within eight hours before coming to the clinic.

If your child needed this kind of medicine, your child's allergy shot appointment will be the same as before the study. The study visit 2 will be completed at another routine allergy shot appointment.

If your child did **not** take any pain relieving medicine within the previous eight hours, this will be study visit 2 and your child's study group assignment will be determined. Your child will be presented with a basket containing envelopes. The investigator will instruct your child to select one envelope from the basket. The envelope selected at random by your child will determine the distraction method to be utilized prior to the allergy shot(s). The possible group assignments, one of three currently marketed distraction devices or the control group utilizing the current standard of care option, are listed below.

The four study groups are:

- Interventional Groups
  1. Shot Blocker®
  2. Buzzy I (*with ice pack-wings)*
  3. Buzzy II (*without ice pack-wings)*
- Control Group
  4. Ethyl Chloride/Pain Ease Spray

<u>Before applying the assigned distraction method</u>:

- Prior to your child's allergy shots, the investigator will interview you to obtain the information needed to complete the Parent Demographic-Health-Treatment Questionnaire.
- The investigator or study staff will review the Wong-Baker FACES Pain Rating Scale with your child. The child will be given a Wong-Baker FACES Pain Rating Scale form and asked to circle the face which most closely matches their current level of pain awareness prior to any intervention.
- The investigator or study staff will review the Numeric Pain Rating Scale you. You will be instructed to circle the number on the scale which most closely matches their perception of your child's pain level immediately after receiving the allergy shot.

<u>Application of the distraction method and administration of the allergy shot</u>:

- The investigator will apply the assigned distraction method per method specifications to the shot site area (subcutaneous region of the back of the upper arm).

- The investigator will administer your child's allergy shot(s) within the time frame specified for the assigned distraction device utilized or per the standard of care guidelines for the Pain Ease Spray, as appropriate. If the child's treatment plan includes more than one shot, the assigned group technique will be utilized for all shots at the visit.

Post allergy shot procedures:

- Immediately following the allergy shot, your child will be provided with a second Wong-Baker FACES Pain Rating Scale form and be asked to circle the face which most closely matches their post-shot level of pain awareness.
- Immediately following the allergy shot, you will be reminded to circle the number on the Numeric Pain Rating Scale which most closely matches your perception of your child's post-shot pain level.
- You and your child will complete the routine 30 minute wait time for post allergy shots.

Study participation is complete at the end of Visit 2.

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 associated with study participation are the same risks your child could experience if they did not participate in the study. Potential risk for the study participants may be possible allergic reaction/skin irritation from the cold spray or ice pack or an increased level of anxiety.

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

The potential benefit associated with this research study includes a better understanding of your child's response to their assigned distraction technique. This study may help identify which technique is more beneficial to use in children receiving subcutaneous immunotherapy to decrease the perception of pain and reduce anxiety related to immunotherapy treatment.

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 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. However, this study requires the participation of both you and your child. For the parent, your participation involves answering your child's Parent Questionnaire: Demographic – Health – Treatment Questionnaire. You will also be asked to use the numeric rating scale to identify what pain level you perceive your child to be in just after receiving

their allergy shots. 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.

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. There may be other research or treatment choices that could be considered for your child. Your child can still receive their allergy shots with the standard of care Pain Ease Spray.

The study doctor can provide detailed information about the benefits and risks of the various treatment options available to your child. You should feel free to discuss these alternatives with the study doctor or your child's personal physician.

15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?

If a child or parent's behavior show that they do not want to cooperate with the study requirements, the investigator might have to stop their participation in the study. Usual care and comfort measures will continue during the visit, however.

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

You and your child will not incur any costs for participating in this study. The cost of your child's allergy shots will be billed to your insurance or other third-party payer as routine clinical care. You may be responsible for any co-pays or deductibles.

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

No payment will be provided to you or your child for participating 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 not be used by Nemours researchers and will not be given to people outside of Nemours for this research.

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 will receive a participant identification number at Visit 1 which will be used for all data collection.

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.

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 consent to participate and 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 consent to participate give permission for my child to participate in this study. By signing this form, I am not giving up any rights to which I and my child is entitled under law.

I understand that:

- I can withdraw permission for my and 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 and 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.
- My PHI and 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 and 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 and or 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 and myself 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) ☐