NEMOURS
Jacksonville, FL
PARENTAL PERMISSION AND INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

You have been asked to be in a research study with your child. This form explains the research, your rights and your child's rights as research participants, and any responsibilities that you may have as a result of you and your child's participation. You should understand the research study before you agree to be in it and to permit your child to be in it. ***Read this 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?

Long-Acting Beta Agonist Step Down Study (LASST) – Ancillary Study "Assessment of the Research Consent Process"

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 - Jacksonville	**Nemours - Delaware**	**Nemours – Orlando**	**Nemours – Pensacola**
Principal Investigator	Kathryn Blake, PharmD			
Co-Investigators	John Lima, PharmD David Schaeffer, MD Division of Pulmonology Tim Wysocki, PhD Holly Antal, PhD Behavioral Pediatrics Paul Garfinkel, MSH	Aaron Chidekel, MD Division of Pulmonology Christopher Chang, MD Division of Allergy/Immunology	Jason Lang, MD Division of Pulmonology	To be named Division of Pulmonology
Address	Nemours Children's Clinic 807 Children's Way Jacksonville, FL 32207	Alfred I. duPont Hospital for Children 1600 Rockland Rd. Wilmington, DE 19803	Nemours Children's Clinic 1717 S. Orange Ave., Suite 100 Orlando, FL 32806 13535 Nemours Parkway, Orlando, Florida 32827	Nemours Children's Clinic-Pensacola 5153 N. 9th Ave Pensacola, FL 32504
Daytime Phone	Day: (904) 697-3788 (Division of Pulmonology) Day: (904) 697-3529 (Research) Day: (904) 697-3785 (Behavioral Pediatrics)	Day: (302) 651- 6400 (Division of Pulmonology) **Day: (302) 651-4200 (Division of Allergy/Immunology)** Day: (302) 651-6536 (Research)	Day: (407) 650-7270 (Division of Pulmonology) Day: (407) 650-7175 (Research)	(850) 473-4553

After Hours Phone (Nemours operator)	Night: (904) 697-3600	Night: 302-651-4000 (Nemours operator)	Night: (407) 650-7000 (Nemours Operator)	(850) 505-4700
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 or your child's rights as a research subject, what to do if you or 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.
Carlos Rose, M.D., Co-chair, Nemours Institutional Review Board 2 at (302) 651-5970.
Paul Garfinkel, MSH, Director, Nemours Office for Human Subjects Protection, at (904) 697-4023.
Email address: NOHSP@nemours.org.

4. WHAT IS THE PURPOSE OF THE STUDY?

We know that a lot of parents and their children do not always fully understand medical information given to them about being in a study. We are trying to find ways to improve how well a parent who is considering having their child participate in a research study understands the medical information given to them.

But first, we have to find out how well the study staff and the parent communicate on important medical information a parent needs to know before their child enters the study. The purpose of this study is to evaluate how well study information is communicated between the parent and study staff and also between your child and the study staff.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

The National Institutes of Health is the Sponsor of this study. The National Institutes of Health will pay Nemours its costs in conducting this study.

6. WHO CAN BE IN THE STUDY?

Any parent and their child who is 12 to 17 years old and who is being screened for the main study "Long-Acting Beta Agonist Step Down Study" can be in this study.

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

Overall about 150 parents (mother, father, or legal guardian) and their child who is screening for the main study "Long-Acting Beta Agonist Step Down Study" will be enrolled in this study. Participants will be enrolled from Nemours Children's Clinic in Jacksonville, Orlando, and Pensacola, Florida, and Wilmington, Delaware.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Participation will last for about a little over 1 hour at the screening visit for the main study. At Visit 6 (20 weeks from now), we will need about 30 minutes to complete the study procedures.

9. WHAT ARE THE RESEARCH PROCEDURES?

After you and your child agree to be in this study, you will be given the parental permission form for your child that explains the main study "Long-Acting Beta Agonist Step Down Study". Your child will be given a

form explaining the study also. After you and your child have had a chance to review the forms, the coordinator will sit down with both of you and review each section of the form in detail and ask you/your child what questions you/your child may have as you go along. The conversation between you/your child and the study staff will be audio recorded on the computer and later analyzed at Nemours. After you/your child and the study staff review the form, the study staff will ask you/your child some questions about the study. The audio recording will continue for this part too. There will be plenty of time for the study staff to answer all your questions.

After the study staff has finished with the questions and you and your child have signed the forms, there is one last short part we need for this study. To help us learn how well patients and in this case, you as a parent, understand general medical information, we will give you and your child some health information to look at and then ask you a few questions about that information. Your answers will help doctors learn how to provide medical information in ways that parents and their children will understand. This part will take about 3 to 5 minutes.

At Visit 6 of the main study, the study staff will repeat the audio recording and have you and your child complete the same questionnaire that asks about the study information. It is necessary that the same parent come with their child at the screening visit and again at Visit 6. This is to help us understand how well the study staff communicates the study information to you and your child throughout the study.

10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?
Any research has some risks (things that could make you or your child sick, feel uncomfortable, or hurt). However, there are no known risks with being in this study.

11. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?
There may be no direct benefit to you from taking part in the study. You may feel better knowing that by being in this study, you may help others. The information from this study may be helpful in the future to other people with asthma.

12. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?
There are no health problems or injury that could result from the procedures in this study.

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 and/or your child decide not to be in the study or decide to stop being 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 stop your/your child's participation in 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/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 participate in this study.

15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?
There is no reason for the researchers to remove anyone from this study.

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

There will be no cost for your participation in this study.

17. WILL PEOPLE BE PAID FOR BEING IN THIS STUDY?

Your child will receive a $10 Walmart gift card at this visit and Visit 6 for participating in this audio-recording of the communication between you, your child, and the study staff. There is additional payment if your child participates in the main study, "Long-Acting Beta Agonist Step Down Study" which is described in the documents for that study.

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

There will not be any new information to give you after you finish this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law if it is funded by the National Institutes of Health. This web site will not include information that can identify you or your child. 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 ME WILL BE USED OR DISCLOSED?

Identifiable health information about you or 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 you or 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 Section 9 of this form.

Your identity and your child's identity will be protected as much as possible. Nemours protects your and your child's health information by storing records in files or computers that can only be used by authorized Nemours staff. Study staff will assign you a unique number and special code that will be used in place of your name. All of your data will also be given this code.

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 Identifiable Health Information to Others

Information from this research study will also be contained in your child's Nemours' medical record if they are seen at Nemours, 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.

The PHI that will be given (disclosed) to people or groups outside of Nemours for research purposes are checked in the table below:

Type of Identifiable Health Information:	Disclosed
History and Physical	☒
Results of Procedures	☒
Demographics (information about race, ethnicity, gender, age, DOB)	☒
Questionnaires	☒
Routine lab results	☒
Alpha-numeric code (using participants initials)	☒

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 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 he/she will be allowed to be in this study. I have read, or had read to me in a language that I understand, all of the above. 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 and give permission for my child 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 permission for participation in this study and for the use and/or disclosure of 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 / 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 PHI described in this form will not have an expiration date.
- My / 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, I / my child will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my / 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 my / my child's participation in this study.
- I will receive a signed and dated copy of this form.

My signatures indicate that:

- I give the researchers and Nemours permission to use and/or disclose my / my child's individually identifiable health information, for this research study, as described in Section 19.
- As his or her parent or guardian, I give my permission for the minor child named below to participate and give consent for my participation in the research study described in this form.

Name of Adult Participant (Print)	Signature of Adult Participant
Name of Minor Participant (Print)	Minor Participant Date of Birth:
Signature of Parent / Guardian	Printed Name of Parent / Guardian / Date

Check Relation to Minor Participant: __ Parent __ Guardian: (Guardians 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.)

I the undersigned, certify that to the best of my knowledge the parent/legal representative signing this consent/permission form had the study fully and carefully explained and that he/she understands the nature, risks and benefits of participation in this research study.

Name of Person Obtaining permission (Investigator or Designee)	Signature of Person Obtaining permission	Date

Copy of the signed form was provided to Parent/ Guardian on [Date] _____