Approved by the Nemours IRB
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[1173700]

Nemours
Parental Permission for Participation in a Research Study

Nemours PP Template July 2020

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? A Food Additive Removal Diet for Pediatric Eosinophilic Esophagitis (FREE)**

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	Nemours - WIL	Seattle Children's Hospital
Principal Investigator	James Franciosi, MD	Zarella Molle-Rios, MD	David Suskind, MD
Co-Investigator(s)	Jolanda Denham, MD Pablo Palomo, MD Roberto Gomez, MD Richard Sandler, MD Hadeel Al-Atrash, MD	Erika Kutsch, MD	Dale Lee, MD
Study Coordinator(s)	Shannon Henry, MA	Stacey Price, RN	Mason Nuding Stephanie Lammers Madeline Ford
Address	Nemours Children's Hospital 13535 Nemours Parkway Orlando, FL 32827	Nemours/Alfred I. duPont Hospital for Children 1600 Rockland Road Wilmington, DE 19803	Seattle Children's OB.9.620.1 - Gastroenterology and Hepatology 4800 Sand Point Way NE Seattle, WA 98105
Daytime Phone After Hours Phone	407-650-7713 407-650-7000	302-651-5928	206-987-2521
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?

We are conducting a research study to compare two diet therapies in children diagnosed with eosinophilic esophagitis. The two diets are (1) the dairy elimination diet (eliminating cow's milk from your diet), and (2) a diet eliminating dairy and food additives.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

The Sponsor of this study (An Anonymous Donor) will pay the costs to conduct this study.

6. WHO CAN BE IN THE STUDY?

Children aged 2-18 who have been diagnosed with Eosinophilic Esophagitis can be in this study. Families must also have access to the internet to complete questionnaires each week and they must have access to a telephone to complete telephone follow up calls.

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

Up to 72 children are expected to participate in this study. Children will be enrolled at Nemours Children's Hospital (Orlando, FL), Alfred I Dupont Hospital for Children (Wilmington, DE), and Seattle Children's Hospital (Seattle, WA). Children will also be enrolled remotely throughout the United States.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Participation in this study will last 12 weeks. You and your child will be asked to complete follow up calls with the study Coordinator that will take 15-20 minutes.

You and your child will be asked to complete surveys that will be sent to your email. The surveys will take about 20-30 minutes to complete.

The dietician will call you four times during the study to give you reminders about what your child can or cannot eat on the diet. These calls will take 10-15 minutes.

9. WHAT ARE THE RESEARCH PROCEDURES?

The following is a list of some of the tests and procedures that may happen during the study:

VISIT 1 / Baseline / Screening Visit

At the first visit, your child will be evaluated for suitability for the study. Procedures will include:

- Review of demographic information (e.g. age, race, gender)
- Review of your child's medical record and medical history (including diet and overall health, results from endoscopies, pathologist reports, and medications)
- Review of the family's medical history
- Your doctor will explain the benefits and risks of each treatment option.
- If your child is eligible and you decide to participate in the study:
    - You will complete study questionnaires regarding your child's symptoms and quality of life. This should take about 20-30 minutes.

- Your child will be randomized (like flipping a coin) to either (1) the dairy elimination diet or the (2) dairy elimination and food additive elimination diet. You and your child will receive dietary counseling and written information about the foods your child can and cannot eat on the diet. You will also be asked to tell us what your child ate in the last three days.

VISITS 2-12 (Follow-Up Calls)

ALL participants will have the following:

- Study questionnaires: You will complete study questionnaires regarding your child's symptoms and quality of life. This should take about 20-30 minutes. The questionnaires will be sent to your email every other week. You may complete them using a smart phone or a computer.
- Follow-Up Calls: Either the study Coordinator or the Dietician will call you each week your child is in the study. You will answer questions about your child's dietary intake. The phone call will take about 15-20 minutes.

VISIT 13 (Final Visit)

ALL participants will have the following for the final visit:

- Review of your child's medical record and medical history (including diet and overall health, results from endoscopies, pathologist reports, and medications)
- You will complete study questionnaires regarding your child's symptoms and quality of life. This should take about 20-30 minutes.
- You will answer questions about your child's dietary intake. This will take about 15-20 minutes.

Final Endoscopy

- Your child's doctor will perform an endoscopy with biopsies as part of your child's standard of care treatment. Results will allow us to evaluate his or her response to the therapy.

Pathology Review

The remainder of the esophageal samples obtained during your child's routine endoscopies will be shipped to Nemours Children's Hospital in Orlando, FL. The samples will not have your child's name, but they will have your child's study ID number. The pathologist at Nemours Children's Hospital will evaluate your child's samples from before they started the study and after they completed the study. The samples will be shipped back to your doctor.

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.

Diets: Because people are advised not to eat foods they normally would eat, elimination diets may reduce eating pleasure.

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

Your child may respond to one of the elimination diets, but we cannot be certain these will be effective. The diets might reduce the symptoms of Eosinophilic Esophagitis. For example, your child might experience less chest pain, find it easier to swallow, and be less likely to get food stuck in the throat or to regurgitate or vomit. The weekly questionnaires will allow the study staff to carefully monitor your child's symptoms.

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.

The study staff is available Monday - Friday from 8:00am to 5:00pm. During these hours, you should call (407)567-3411 for medical advice.

During evenings, weekends, and holidays, you should call 1-800-767-5437. You will reach the Nemours operator. Ask to page the Gastroenterologist 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.

You may ask the researcher to destroy your child's 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 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. These choices include medications like proton pump inhibitors or swallowed steroids.

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?

The study doctor may stop your child's participation in this study at any time without your consent. This may happen if:

- Staying in the study would be harmful to your child.
- The study is canceled.
- Your child is not following the treatment plan

If you decide to withdraw your child from the study, your request must be in writing.

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

There are no costs to you for your child's participation in the study.

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

Your child will be given a gift card after completing the first visit ($25.00), after completing 2 weeks of surveys ($25 each completed week), and after completing the final visit ($50.00) for a possible total of $125.00. Your child will not receive payment for an incomplete visit (e.g. did not fill out surveys or did not complete follow-up calls).

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.

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 data we collect will not be labeled with PHI, but it will have a numerical identifier that will be linked to PHI. The identifiers will be stored in a password-protected file on a secured network that can only be accessed by the research team.

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.

For Nemours patients, identifiable health Information will not be disclosed outside of Nemours. De-identified health information will be disclosed to Seattle Children's Hospital. This means it will not contain names, dates, or other information that could link your child's health information to your child.

For patients of other providers, your child's identifiable health information will be released to Nemours for purposes of conducting the research.

The PHI that will be disclosed by your child's provider to Nemours for research purposes are listed in the table below

Type of Identifiable Health Information:	**Disclosed:**
History and Physical	☒
Results of Procedures	☐
X-Ray Reports	☐
Surgery Reports	☐
Genetics Studies	☐
Demographics (information about race, ethnicity, gender, age)	☒
Questionnaires	☒
Other: Pathology Reports, Personal Information (name, phone numbers, and email)	☒

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 not have an expiration date.
- 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) ☐

NEMOURS

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.)