Boiled Peanut Oral Immunotherapy for the Treatment of Peanut Allergic Pediatric Patients

NCT04090203

Informed Consent Form v04/06/2020

Assent Form v05/29/2019

The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Boiled Peanut Oral Immunotherapy
Sponsor: Dr. Alton Melton
PI: Dr. Jaclyn Bjelac (216) 445-1449
Study Coordinator: Navneet Singh (216) 445-2246
After hours phone contact #: (216) 445-1449
Pediatric Allergy Research Pager# (216) 207-3704

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.**
- **For the purposes of this document, "you" refers to "your child" if you are a parent providing consent.**

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

Peanut allergy is becoming more common. Being a child with peanut allergy can be stressful .As parents, having a child with a peanut allergy can be very stressful. Trying to avoid peanut entirely can be very difficult. Worrying that your child might accidentally eat peanut and have an allergic reaction can make many people feel anxious. Right now, the only way to treat the allergy is to avoid peanuts and have emergency medications close by in case peanuts are eaten accidentally. Some new treatments are being studied.

One of these treatments is called oral immunotherapy (OIT). This means that over a number of weeks or months, you will eat tiny amounts of peanut every single day. The amount will slowly be increased until you can eat a larger amount of peanut without having an allergic reaction. This treatment is still being studied and is not widely available because there are still some problems that need worked out. One problem is a lot of side effects, like itchy mouth or upset stomach. The purpose of this study is to see if we can find a way to give oral immunotherapy with less side effects.

Based on previous research, we think that there will be less side effects if we use a boiled peanut for oral immunotherapy instead of roasted peanuts. This study will help us find

out if this is true. If it is true, this will help us treat more children with peanut allergy in the future.

This study will use peanut as an investigational agent. We will use 2 different kinds of peanut, roasted peanut and boiled peanut. Both kinds of peanut are commercially available, meaning you can buy these kinds of peanuts in the store or online. However, using peanut as a drug to treat peanut allergy is investigational. This means it has not been approved by the FDA.

If your child is enrolled in the study, he/she will receive roasted peanut material to consume at the Oral Food Challenges during the first and last visits. In addition, he/she will receive boiled peanut material to consume throughout the remainder of the trial.

What is involved if you decide to take part in this research study?

If you decide to take part in this study, your enrollment will consist of 10 study visits over an 18 week period.

SCHEDULE OF VISITS

Visit Number	When	Where	Time Needed	What Happens
1	Week 1	CCF Main Campus Pediatric Allergy Clinic	4-6 hours	Oral food challenge to confirm your child is allergic to peanut
2	1-4 weeks later	CCF Main Campus Clinical Research Unit (M51)	4-6 hours	-Initial Escalation day to start tiny doses of peanut -Allergy skin test -Blood draw
3	2 weeks later	CCF Main Campus Clinical Research Unit (M51)	2 hours	Updosing (where your child eats a little bit higher dose of peanut)
4	2 weeks later	CCF Main Campus Clinical Research Unit (M51)	2 hours	Updosing (where your child eats a little bit higher dose of peanut)
5	2 weeks later	CCF Main Campus Clinical Research Unit (M51)	2 hours	Updosing (where your child eats a little bit higher dose of peanut)
6	2 weeks later	CCF Main Campus Clinical Research Unit (M51)	2 hours	Updosing (where your child eats a little bit higher dose of peanut)
7	2 weeks later	CCF Main Campus Clinical Research Unit (M51)	2 hours	Updosing (where your child eats a little bit higher dose of peanut)

8	**2 weeks later**	**CCF Main Campus** **Clinical Research Unit (M51)**	**2 hours**	**Updosing (where your child eats a little bit higher dose of peanut)**
9	**2 weeks later**	**CCF Main Campus** **Clinical Research Unit (M51)**	**2 hours**	**Updosing (where your child eats a little bit higher dose of peanut)**
10	**4 weeks later**	**CCF Main Campus** **Clinical Research Unit (M51)**	**2 hours**	**-Oral food challenge** **-Allergy skin test** **-Blood draw**

Screening Visit

This is the visit where we determine if your child is a good fit for the study. At this visit you will be going over and signing this document (in addition to the assent form if applicable). Additionally, we will collect vital, ask basic demographic information, ask about any medications you are taking at home, ask you to fill out a questionnaire and if applicable perform a test called spirometry (all patients ages 5+ and/or at the physicians discretion) and a urine pregnancy test (on all females of childbearing potential).

Visit 1: /Peanut Challenge

To find out if your child qualifies for this study, first we will perform a peanut challenge. Your child will come to the clinic and we will give them small doses of peanut. Then the dose will be increased several times. If your child has an allergic reaction, we will treat the allergic reaction and will invite you to participate in the study. Spirometry will also be performed at this visit, before the oral food challenge, on children ages 5 and up or if the physicians feels the child is developmentally capable of the test.

If your child reacts to peanut challenge and you and your child agree to participate in the study, you will be assigned to receive oral immunotherapy using boiled peanut material and scheduled to come in for your Initial Dose Escalation Visit.

Visit 2: Initial Dose Escalation Visit

The Initial Dose Escalation Visit will take place at the Clinical Research Unit (CRU) at Main Campus. The CRU is an area specifically designed for research studies where your child can be monitored very closely. We will give a very small amount of peanut (even less than the amount during the food challenge). Then the dose will be slowly increased. We will find out the highest dose that your child can eat without having an allergic reaction. Then we will have your child continue eating this amount at home once a day until the next study visit. During visit two a blood draw and skin prick test will also occur. Before any dose is given we will also measure your ability to push air out of your lungs with a test called a "peak flow test."

Visits 3-9: Updosing Visits

During visits 3-9, you will return to the clinic every 2 weeks. Each time we will increase the amount of the peanut you are to consume. You will continue eating that higher dose of peanut daily (at home) until your next study visit. So you will come to the clinic approximately 7 times over approximately 12 weeks. This part of the study might last a little longer if you are having side effects. In this case, we might have to increase the dose slower. Before any dose is given we will also measure your ability to push air out of your lungs with a test called a "peak flow test."

*Visit 10: Final Study Visit (2 part or 2 day visit) and Beginning of Optional Maintenance

At this Visit an oral food challenge similar to the one given at visit 1 will be repeated. The difference in this challenge is that this food challenge will be blinded, meaning neither you nor the study team will know if your child is receiving peanut powder or a placebo. You will be asked to come back to clinic with your child either later in the day or the following day to receive an additional food challenge (either peanut powder or the placebo). A blood draw and skin prick test will occur as well. These are identical to the ones that were done at visit 2. Spirometry will also be performed at this visit, before the oral food challenge, on children ages 5 and/or at the physician's discretion. Additionally, a urine pregnancy test will be done on all females of child bearing potential.

Once you have reached the maximum dose of peanut, you will be offered the opportunity for ongoing once daily consumption of the maintenance dose. This ongoing maintenance is optional and will not be paid for by the study. If the ongoing maintenance is done, the therapy will be one dose down of roasted peanut from the exit dose of boiled peanut Additionally, someone from the physician's office will contact you via phone every 3 months to make sure the continued therapy is acceptable and to talk about the benefits of continuing/stopping the therapy.

What tests will be performed as part of your participation in the study?

You will have a total of 1.6mL of blood drawn at study visit 2 and study visit 10 to test for: peanut specific IgE concentration, peanut component testing (peanut specific IgE concentration for Ara h 1, 2, 3, 8 and 9), and peanut specific IgG4 concentration.

You will have skin prick testing with peanut extract, a negative control, and a positive control (histamine) performed at study visit 2 and study visit 10. This skin prick testing will provide evidence of immediate IgE mediated peanut hypersensitivity.

If you are a female of childbearing potential. You will have a urine pregnancy test performed before the start of study participation and before the final oral food challenge.

Spirometry will be done on all patients ages 5 and up and/or at the physician's discretion at the screening visit and at the final food challenge visit.

A Peak Flow Test (blowing into a device) will be done at the initial dose escalation visit as well as all study visits after that.

What are your responsibilities during the study?

You will need to come to the Cleveland Clinic Main Campus for each of the visits listed in the Schedule of Visits above

If you are sexually active you must use two forms of contraceptive while receiving study therapy and for thirsty days after therapy has stopped.

You will consume a dose of the provided peanut every single day at home. We will send you with doses of the peanut in small medicine cups. Each day, you will mix the peanut with another food, such as applesauce or pudding and eat this mixture. Every effort should be made to consume the peanut at the same time each day using the same method of ingestion.

At Visit 1, you will review and update your FARE's Food Allergy & Anaphylaxis Emergency Care Plan. This plan will outline the recommended treatment in case of an allergic reaction occurs during your enrollment in the study. This plan is signed by a physician, and includes emergency contact information. Keep your plan in a place where others can find it, and make sure you and others understand what to do in case of an emergency.

You will be provided with a take home Dosing/Adverse Events Recording Sheet to record the time you consume the dose of peanut each day. You will also record any allergic reactions that may occur, the symptoms associated with those reactions, and any treatments required. . You will be instructed to look for objective signs of a reaction for up to 2 hours after ingestion including: rash/hives, lip/mouth itching, nausea/upset stomach, vomiting, cough/wheeze, or other.

When an allergic reaction occurs at home, your parent/caregiver should administer the rescue medication available that corresponds with the severity of the reaction. All subjects will be prescribed an epinephrine auto-injector to have available for rescue at home. All subjects will also be prescribed an oral antihistamine, cetirizine (Zyrtec), to have available for rescue at home. If patient is allergic to cetirizine (Zyrtec), patient will be instructed to take diphenhydramine (Benadryl). All subjects with an underlying diagnosis of asthma will be prescribed a short acting beta-agonist (albuterol or levalbuterol) to use for rescue at home.

All potential allergic reactions should be recorded on the Dosing/Adverse Events Recording Sheet. The nature and severity of the AE as well as the implications for ongoing treatment will be discussed by a physician investigator with you at the next in-person study visit. If you have concerns about the reaction, you can contact a study team member at any time using the contact information provided within this form.

In the event a reaction symptom occurs that is life threatening in the opinion of your parents and/or caregivers, you should call 911 and seek medical care immediately.

At enrollment and after completion of the study, you will be asked to complete previously validated, age specific food allergy quality of life questionnaires27

You will have to return the used medicine cups and completed Dosing/Adverse Events Recording Sheet to the clinic at each follow up visit.

If your child is having serious side effects, you will need to call study personnel to let them know. If you child is ill or there is any other reason that you are unsure whether to give them peanut that day, you will need to call study personnel. You will be provided with this contact information.

A Dosing/Adverse Event Recording Sheet should be filled out for each day enrolled in the study. If a dose is missed for any reason, a Dosing/Adverse Event Recording Sheet should still be filled out documenting the date and a dose of "0" at the top. Subject nonadherence to OIT, specifically defined by 12 (approximately 10%) nonconsecutive missed doses could lead to discontinuation of study intervention and removal from the study.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

Your participation in this study is voluntary. You do not have to be in this study to receive treatment for your peanut allergy. If you choose not to participate, you can still receive treatment using standard of care treatment options, which could include oral immunotherapy with roasted peanut product.

Standard care for peanut allergy is to avoid peanut. There are no FDA approved treatment options currently available for peanut allergy. This means you will be instructed to have your child completely avoid peanut and use the appropriate rescue medications as needed.
As part of standard care, your doctor may recheck allergy tests in the future to see if there is any sign that you are outgrowing the peanut allergy. We only expect about 20% of children with peanut allergy to outgrow it.

3. RISKS

What are the risks of participating in the research study?

There is a risk for children to have an allergic reaction to the peanut powder used in this study. This is most often mild symptoms such as mouth itching or stomach upset. Sometimes the allergic reaction be severe and life-threatening.

Common symptoms: mouth itching, nausea, vomiting

Less common symptoms: sneezing, hives, itching, diarrhea, coughing, wheezing

Rare symptoms: lightheadedness or loss of consciousness, difficulty breathing

If you experience an allergic reaction in the clinic, you will be treated with medications. If the reaction is mild, they may be treated with an antihistamine like Zyrtec or Benadryl. If the reaction is severe, they may be treated with an EpiPen. Other treatments could include albuterol (a breathing treatment) or fluids in an IV.

You will be prescribed medications to have available at home as well. All subjects will be prescribed an epinephrine auto-injector and an oral antihistamine, cetirizine (Zyrtec), to have available for rescue at home. All subjects with an underlying diagnosis of asthma will also be prescribed a short acting beta-agonist (albuterol or levalbuterol) to use for rescue at home.

It is also possible that the peanut allergy can come back after the peanut powder is stopped and the child is no longer eating peanut every day. We don't yet know how often this happens.

Finally, some children treated undergoing oral immunotherapy develop EoE or eosinophilic esophagitis. This is a condition where there is inflammation in the esophagus. It can cause symptoms like difficulty swallowing, the feeling of food getting stuck, or heartburn.

In the other studies using peanut oral immunotherapy, EoE happens in 3-4% of patients.

Symptoms suggestive of Eosinophilic Esophagitis (EoE) will prompt discontinuation of oral immunotherapy and begin once weekly symptom monitoring phone calls with study staff. If symptoms fail to resolve after 1 month off therapy, consultation with Gastroenterology will be considered for further evaluation and management. In most oral immunotherapy studies, when children develop EoE, it resolves or goes away once the immunotherapy is stopped.

Please note that any treatment required for Eosinophilic Esophagitis (EoE) will not be paid for by the research study. If this occurs, you or your insurance company will be billed.

4. BENEFITS

What are possible benefits of participating in the research?

You may or may not benefit by participating in this research. Based on currently available data, it is possible that patients treated with this novel regimen of boiled peanut will demonstrate lower rates of adverse events while obtaining similar immunologic markers of peanut desensitization and possible tolerance compared with those treated with OIT utilizing a traditional roasted peanut product.

This research will also benefit a society as a whole. It will help people with peanut and other food allergies in the future if we can find ways to safely treat patients with oral immunotherapy.

5. COSTS

Are there any costs to you if you participate in this study?

You and your insurance company will be billed the usual and customary charges for all items and services except those required specifically and solely for this study. You are responsible for paying any deductibles, copayments, or co-insurance that are a normal part of your health insurance plan. Because you are participating in this study, the following services are considered to be "research only" and will be paid for by the study sponsor and will not be billed to you or your health insurance plan. These services include:

All study visits
Study medication (boiled peanut)
Blood tests & skin prick testing

6. COMPENSATION

Are there any payments to you if you participate in this study?

You will receive a parking pass for all study related visit. Beyond this, you will not be provided any financial compensation to take part in this research.

7. RESEARCH RELATED INJURY

What will happen if your child is injured as a result of taking part in the research?

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional

Review Board at (216) 444-2924. Study participants may also contact the Clinical Research Unit (CRU) Research Subject Advocate (RSA), at 216-445-7846 with regard to questions about study participation and research subject protections.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Dr. Jaclyn Bjelac, M.D. at The Cleveland Clinic, 9500 Euclid Avenue, Mail Code R3, Cleveland, Ohio 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

By signing this informed consent form, you are authorizing access to your medical records. If you choose not to sign this consent form, you will not be permitted to participate in this research study. This Authorization does not have an expiration date.

If you have any questions, you can ask the Principal Investigators, Dr. Jaclyn Bjelac and/or research staff. You will be given a signed copy of this authorization form for your records. By signing this informed consent form, you authorize the use of your identifiable information as described in this form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, please contact the study team at any of the phone numbers below.

Dr. Jaclyn Bjelac
Pediatric Allergy and Immunology
9500 Euclid Ave R3
Cleveland, OH 44195
Phone: (216) 445-1449
Email: bjelacj2@ccf.org

Dr. Kara McNamara
Pediatric Allergy and Immunology
9500 Euclid Ave R3
Cleveland, OH 44195
Phone: (216) 444-4828
Email: mcnamak@ccf.org
Navneet Singh (Research Coordinator)
9500 Euclid Ave, M3
Cleveland, OH 44195
Phone: (216) 445-2246

Clinical Research Unit
9500 Euclid Ave M51
Cleveland, OH 44195
Phone: (216) 445-5470

Pediatric Allergy Research Pager# (216) 207-3704

Study participants may also contact the Clinical Research Unit (CRU) Research Subject Advocate (RSA), at 216-445-7846 with regard to questions about study participation and research subject protections. The Institutional Review Board Contact is also available for any study related questions at 216-444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

The investigator may stop your participation in the study at any time for any of the following reasons:

If it is determined that your continued participation would be harmful for your health as shown by a change in your laboratory values or medical condition
If you do not follow the schedule of visits and treatments for any reason
If the study objectives are changed or the study is cancelled

11. SIGNATURES

Permission of Parent/Legal Guardian (If child less than 18)

You and your child have had the above research study explained to you and your child in language that you and your child can understand, and you give permission for your child's participation.

_____ _____

Parent/Guardian Signature Date

_____ _____

Printed name of Parent/Guardian Relationship to child

I have had the above research study explained to me in language I understand and I agree to participate.

_____

Printed Name of Child

_____ _____

Child Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Schedule of Activities

Visit		Study Visit 1	Study Visit 2 Visit 1 +1-4 weeks	SV 3 Visit 2 +2 weeks	SV 4 Visit 2 +4 weeks	SV 5 Visit 2 +6 weeks	SV 6 Visit 2 +8 weeks	SV 7 Visit 2 +10 weeks	SV 8 Visit 2 +12 weeks	SV 9 Visit 2 +14 weeks	SV 10 Visit 1 +18 weeks
Procedures	Enrollment/Baseline visit	Oral Food Challenge	Initial dose escalation	Dose escalation visit 1	Dose Escalation Visit 2	Dose escalation visit 3	Dose escalation visit 4	Dose escalation visit 5	Dose escalation visit 6	Dose escalation visit 7	Oral Food Challenge
Informed Consent	**X**										
Demographics	**X**										
Vitals	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Spirometry*	**X**		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Blood Draw			**X**								**X**
Skin prick test			**X**								**X**
Oral food challenge		**X**									**X**
Urine Pregnancy	**X**										**X**
Study Drug Administration			**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	
Study Drug Compliance				**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
AE Review			**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Conmed Assessment	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
FAQL Questionnaire	**X**										**X**

* Spirometry will be performed on all patients ages 5+ and/or at the physicians discretion at the initial study visit as well as the exit oral food challenge. Rather than full spirometry, peak flow will be performed at every updosing visit on all patients ages 4+ and/or if the physician feels that it is developmentally appropriate

The Cleveland Clinic Foundation
Assent (ages 7-12) to Participate in a Research Study

Study title: Boiled Peanut Oral Immunotherapy
Principal Investigator: Jaclyn Bjelac, MD
(216) 445-1449

What is a research study?
A research study is a way to find out new information about something. Children do not need to be in a research study if they do not want to.

Why are you being asked to be a part of this research study?
You are being asked to take part in this research study because you have a condition called peanut allergy. Peanut allergy is a disease that can cause you to have an allergic reaction if you accidentally eat peanut.

Why is the study being done?
This study is being done to look for a treatment for peanut allergy. People have been studying one treatment called oral immunotherapy. It is a good treatment but can cause a lot of side effects. We are trying to find a treatment that will cause less side effects. We will use a different kind of oral immunotherapy.

What will happen to you as part of the research study?
You will come to the Cleveland Clinic many times. There will be 2 different days that you will get a scratch test on your skin and someone will draw blood from your arm using a needle. The other days you come to the Cleveland Clinic you will just eat peanut. Then you will stay in the room for a couple hours to see if you have an allergic reaction. You will also check to see how much air you can blow. You will come to Cleveland Clinic 10 times for study visits.

Will any part of the study hurt, or will anything bad happen to me?
- It might hurt a little when you get the blood drawn. We will take blood from a vein in your arm using a small needle 2 times during the study. The poke may hurt for a little while and you could have a small bruise after it.
- You will also have a skin test for peanut 2 times. The scratch test doesn't really hurt but can make you feel itchy.
- When you eat the peanut, you could have an allergic reaction. This can cause you to have itching in your mouth or an upset stomach. Sometimes it can cause more serious symptoms, like vomiting, having trouble breathing or feeling dizzy. If you have an allergic reaction, you might be given a medicine to help you feel better.

Will this study help me or others?
This study might help you have a lower chance of having an allergic reaction if you eat peanut. We also hope that this study will help us find a better treatment to help other children with food allergies.

Who will see the information collected about you?

Research information is private. The information collected about you during the study will be kept safely locked up. Nobody will know it except the people doing the research. Your information is coded so your name is protected.

What do you get for being in the study?
You will not be paid for being in the study.

Will it cost anything to be in the study?
It will not cost you or your parents extra if you join the study.

Do you have to be in the study?
You do not have to be in the study if you do not want to be in it. If you do not want to be in this study, you just have to tell us. It is up to you. You can also take more time to think about being in the study and to talk with your parents and/or regular doctor about the study.

What if I have questions?
You can ask any questions that you have about the study. If you have a question later, you may call Dr. Jaclyn Bjelac at (216) 445-1449 or Dr. Kara McNamara at (216) 444-4828. You can take as much time as you need to think about being in the study.

What choices do you have if you say no to the study?
The study is extra, so if you choose not to be part of the study then your doctors will still take care of you as before.

You may change your mind at any time, and the person in charge will take you off of the study.

Signatures:

If you sign this form, it means that you have read this form, you have talked about the study with the research team and your parents/guardians. All your questions have been answered, and you want to be in the research study. You will be given a copy of this paper to keep.
If you decide to be in the study, write your name below then sign and date it.

_____	_____	_____
Printed name of Child	Signature of Child	Date

Statement of Person Obtaining Informed Consent Discussion
I have discussed the information with the above participant using language which is understandable and appropriate. I believe I have fully informed him/her of the nature of the study and their commitment. I believe that the participant understood this explanation and assented to participate in this study.

_____	_____	_____
Research Staff Member Name	Signature of Research Staff	Date