Challenging to Food With Escalating Thresholds for Reducing Food Allergy
Scott H Sicherer, M.D
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STUDY INFORMATION:

Study Title: Title: **C**h**A**llenging to **F**ood with **E**scalating **T**hr**E**sholds for **R**educ**I**ng Food **A**llergy (CAFETERIA)

Study site(s): Icahn School of Medicine at Mount Sinai

Principal Investigator (Lead Researcher): Scott H. Sicherer, MD

Physical Address Icahn 6th Floor Room L686

Mailing Address: 1 Gustave L Levy Place Box 1198, NY, NY 10029

Phone: 212-241-5548

SUMMARY OF THIS RESEARCH STUDY:

This Research study may determine whether allowing ingestion of sub-threshold amounts of peanut in subjects with a high threshold (those who tolerate at least 143 mg peanut protein on supervised double-blind, placebo controlled oral food challenge [DBPCFC]) will be associated with attaining even higher thresholds over time compared to those avoiding peanut. The study may also explain immune mechanisms induced by daily ingestion of sub-threshold amounts of peanut, and to identify biomarkers of and functional pathways underlying desensitization potential. This study will test if peanut ingestion is associated with immune processes.

This document explains a research study you might be interested in allowing your child to join. Participation in the study is voluntary. You can agree to allow your child to join or not. Your decision will not limit your child's ability to receive care at Mount Sinai. You should only agree for your child to take part if you understand the study and if all of your questions about the research study are answered. If you allow your child to join the study, the research team must share any new information with you that may change your mind about your child taking part.

The purpose of this research study is:

- To learn about the amount of peanut people can eat before they start to have symptoms of peanut allergy.
- To find children who are able to eat small amounts of peanut (about a third of a peanut or more) and compare having them eat those amounts and more, to having them continue to avoid peanut. Usually, people who have symptoms from eating peanut are told to avoid it.
- To see if a child who is able to eat small amounts of peanut can eat even more over time. We also want to see if this would be safe and helpful.
- To understand more about peanut allergy through laboratory studies that are part of this study.

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If you choose to allow your child to take part in this research study, these are some of the things that may be involved:

- The study takes place at Mount Sinai Hospital. All of the things described here are for research purposes. You and your child will interact with study staff including doctors, nurses, and coordinators.
- The study begins with a screening visit that typically takes 3 days.
- At the screening visit, your child will have a feeding test, also known as an oral food challenge, where he/she will be fed peanut to find out if they are allergic to a very small amount (about less than a third of a peanut).

If your child cannot eat the small amount of peanut or can eat a large amount (more than an amount similar to 4 and a half teaspoons of peanut butter) without a reaction, they will not continue to have visits for the study. The tests taken during the screening visit will be used to learn more about peanut allergy.

Your child may benefit from taking part in this research. Some potential benefits may be learning from the feeding test if your child is or is not allergic to peanut and the amount that may trigger a reaction.

Instead of taking part in this research, your child may include avoiding peanut, following your allergist's advice about management, pursuing other studies about peanut allergy, or using FDA approved therapies as they become available.

STUDY PARTICIPATION:

Your child may qualify to take part in this research study because the screening eligibility for the study population are those age 4-14 years, strictly avoiding peanut and having a history of sensitization (detectable peanut IgE >0.35 kUA/L). These children must also be generally healthy and able to undergo study procedures.

Your child's participation in this research study is expected to last up to 120 weeks (about 2 years).

There are 150-200 people expected to take part in this research study at Icahn School of Medicine at Mount Sinai Hospital.

Funds for conducting this research study are provided by National Institutes of Health.
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 this website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

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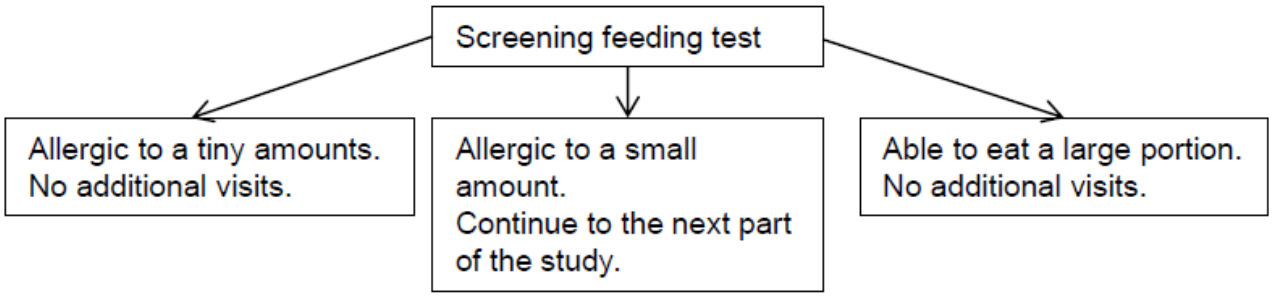
The study start with screening feeding test result is summarized in this Figure:



Children who can eat a small amount of peanut will continue in the study. They will have an equal chance (50:50 chance) to be in one of the 2 groups. One group will continue avoiding peanut and the other group will eat peanut every day measured in a specific way at home. The study treatment for your child is by chance, like flipping a coin. Neither you, your child, nor the study doctor will choose what study treatment your child will get.

Everyone continuing in this study:

- Will receive instructions on how to treat allergic reactions.
- Must have emergency plans to treat an allergic reaction.
- Must have self-injectable epinephrine, which is used to treat an allergic reaction. This includes a severe allergic reaction (anaphylaxis).
- Will keep a diary to log all symptoms.
- Is asked to notify the study physicians immediately for any allergic reactions (other than very mild ones that are logged in a diary).
- Will have monthly phone calls (if there is no visit that month) to see how things are going.
- Will have an in-person visit at 16 weeks after the first feeding test.

Those avoiding peanut:

- Will be seen in the clinic to repeat feeding tests and for other tests to check how they are doing at the end of the study time.
- Be given instructions on how to avoid peanut.

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Those allowed to eat peanut:

- Must avoid all peanut except for the amount/type allowed by the study.
- Will have more frequent clinic visits than the avoider group to see if they can eat even more peanut.
- Will have additional tests, including possibly one more feeding test than the group avoiding peanut.
- May be asked to stop eating peanut every day for two months and then asked to eat more peanut than before they stopped.
- Will be given instructions on what types of peanut products they can buy to eat and how to measure them.

The visits and the things that happen at each visit are as follows:

Screening/baseline visits (3 days, about 4-8 hours/day)

The main purpose of the screening visit is to see how much peanut can be eaten before symptoms happen. As mentioned above, the result may determine that you/your child cannot participate further in the study.

The following happens at these visits:

- Review and sign consent. Child assent according to age.
- Physical exam, vital signs (height, weight, pulse, blood pressure), medical history each day.
- Blowing tests, spirometry or peak flow, to measure your child's breathing (spirometry). Some younger children may not be expected to do this.
- A feeding test in which your child eats small and gradually increasing amounts of peanut. On another day your child will eat small and gradually increasing amounts of something that looks the same but is not peanut. You and the observers will not know on which day you receive which. The test determines if your child has an allergic reaction. Your child will be monitored and any reactions will be treated with medications.
- Skin prick tests with small drops of peanut-containing liquid, saltwater and histamine-containing liquid are scratched into the skin.
- Blood tests before the first feeding and during or after the test. The amount of blood taken at this and any other visit may vary with the child's size, but the amount will not be more than 3 tablespoons per visit. A small plastic tube may be placed into the vein (called a saline lock) to make it easier to take a blood sample when more than one sample is needed over a day).
- Collection of stool (from home or during the visit) and saliva.

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- Quality of life survey questionnaire, demographic and diet questionnaire.
- Urine pregnancy test if your child is a girl past puberty.

Everyone continuing on the study will be contacted to see how they are doing every 4 weeks.

- Because this research study involves the use of peanut butter, a note must be included in your child's electronic medical record that your child is taking part in the research. This way, anyone involved in your child's medical care will know that your child is a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know.

Randomization

No one, not you, or anyone from your medical team or from the research team will be able to choose what group your child is assigned to. It will be by chance, like flipping a coin. Your child will have a(n) 50:50 chance of being in one of the two groups. Neither you nor the Lead Researcher or your child's doctor will know which study drug your child is getting. If there is an emergency, they can get this information.

HIV/AIDS

To take part in this research study, your child's blood will be tested for evidence of HIV, the virus that causes AIDS. People can get HIV through unprotected sexual contact with someone who has HIV, and through contact with blood (as in sharing needles including for piercing, tattooing, and injecting drugs). People who are pregnant with HIV infections can transmit HIV to their infants during pregnancy, delivery or while breastfeeding. There are treatments for HIV/AIDS that can help people stay healthy. People with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from getting HIV or getting infected with a different strain of HIV.

By law, positive test results for HIV/AIDS (as well as other communicable diseases such as hepatitis B, hepatitis C, and syphilis) are reported to the NYS Department of Health so they can study how people get and transmit the disease and notify sexual or needle-sharing partners they may have been exposed. If you wish to have your child tested anonymously for HIV/AIDS, the research team can refer you to a public testing center, but your child will not be able to be in this study. New York State law protects the confidentiality of HIV test results and other related information. It is illegal to discriminate against a person based on their HIV status and services are available to help if this happens. You are free to refuse for your child to get an HIV test, but if you refuse your child cannot be part of this research study.

Pregnancy

If your child can possibly get pregnant, a urine test for pregnancy will be done before your child begins the study and the pregnancy test will be repeated at every food challenge visit.

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Unless your child is sexually abstinent (not having genital sex) the recommended methods of birth control are:

- The consistent use of approved hormonal birth control (pill, patches, or rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual activity),
- Sterilization (a vasectomy, getting tubes tied, or a hysterectomy).

All birth control methods (other than abstinence and sterilization) are only effective if your child uses them properly, starts them at least one month before they begin the research study, and continues using them throughout the research study and for one month after the research study ends. If you are unsure whether the method of birth control your child uses is approved to use while your child is in this study, you should ask the Lead Researcher before your child begins the study. If your child or your child's partner becomes pregnant, or may be pregnant, at any time, you must tell a person from the research team immediately. The team may stop the study drug and refer your child/your child's partner to an obstetrician/gynecologist for follow-up.

Should your child/your child's partner become pregnant, whether or not your child/your child's partner has the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if your child is no longer part of the study. Additional written consent will be obtained to share this information if that happens.

Semen/Sperm:

Drugs can be found in semen and alter sperm. Since your child is taking part in a study using experimental drugs or treatments, it is recommended that 1) your child use a condom, 2) your child does not get a partner pregnant or expose them to semen, and 3) your child does not donate semen. These recommendations apply both while your child is taking the study drug, and for 3 months after your child stops taking the study drug. This is because levels of the study drug may be present in the sperm and/or semen even after your child stops taking the study drug. Your child is encouraged to tell female partner(s) and/or their doctor(s) that they are participating in this clinical trial.

USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep your child's personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. Your child can still be part of the study if you

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do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

(1) Will you allow the researchers to store your child's data and/or samples to use in future research studies?

Please initial your choice: Yes_____ No_____

If you select No, please stop here and move to the next section, **'Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your child's personal information, study data and/or samples may be used in future research studies.

(2) The researchers can store your child's data and/or samples in one of two ways:

a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can't change your mind. So, if you wanted to have your child's data and/or samples destroyed in the future, the team could not do it as they would not know which data and/or samples were your child's.
b) Linked to your child's identity (using a code that can show the information came from your child personally). In this case you could ask for your child's data and/or samples to be destroyed in the future if you want that to happen.

How would you like your child's data and/or samples stored? Please initial **ONE** choice below:

I would like my child's data and/or samples stored anonymously _____

I would like my child's data and/or samples stored with a link to their identity through the use of a code_____

(3) Do you give the researchers permission to keep your child's data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____ No_____ _____

(4) Do you give the researchers permission to keep your child's data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____ No_____

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(4.1) From time to time, researchers outside of medicine and related sciences would like to use your child's data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your child's data and/or samples?

Please initial your choice: Yes_____ No_____

a. If the future research in a different area can be done without having to know that the data and/or samples came from your child personally, that will be done.
b. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:
   I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your child's data and/or samples is needed and what will be done with it. Your permission will be asked to use your child's data and/or samples in that research project.
   II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your child's data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your child's identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to your child or your child's privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

(5) Do you give permission to have your child's data and/or samples given **to other researchers,** including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

Please initial your choice: Yes_____ No_____

(6) Do you give permission to have portions of your child's data and/or samples deposited in large public databases (repositories) for use in research with the limits you may have chosen above? Please read the paragraphs below which explains repositories, then initial your choice:

To do more powerful research, it is helpful for researchers to share data and/or samples from the people they study. They do this by putting data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. Researchers can then use the data and/or samples from multiple studies to learn even more about health and disease. If you agree to allow your child to take part in this study, some of your child's genetic and health

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information might be placed into one or more scientific databases, but they will not share your child's direct identifiers (for example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your child's data, along with that from many other people. Researchers may use your child's samples for genetic sequencing and other experimental testing. Researchers will always have a duty to protect your child's privacy and to keep your child's information confidential, but there are always risks associated with data and/or sample collection and sharing. They are described in more detail in the Risks section.

Researchers will use a Global Unique Identifier, a computer-generated ID, which cannot be linked back to your child's identity. This is so any data collected from your child is linked to one unique ID.

Please initial your choice: Yes _____ No _____

Whether or not you have allowed us to share your child's data and/or samples with reseachers not related to the study, the researchers at Mount Sinai will keep data and/or samples collected about your child during this research study to use in future research studies consistent with the wishes you expressed above.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to allow your child to take part in this research study, you/your child will be responsible for the following things: attendance at the required visits and phone calls, avoidance or eating peanut as instructed, following study instructions, keeping a dairy, notifying the investigators/staff of allergic reactions, treating allergic reactions, avoiding peanut except as instructed. If your child is taking antihistamines, he/she will need to stop these medications for a brief time for allergy skin tests and food challenges.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to permit your child to take part in this study, you/your child will be paid $25 for time and effort.

It can take up to 6 weeks to prepare and issue a check for study participation. If you/your child does not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you/your child receives from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as

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applicable. Generally, this happens if you/your child receives payments that equal $600 or more from Mount Sinai in a calendar year. You/Your child would be responsible for the payment of any tax that may be due.

It is possible that products may someday be developed with the help of your child's data and/or samples, and there are no plans to share any profits from such products with you or your child.

POSSIBLE BENEFITS:

There is a chance this study may benefit your child, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to your child include:

The benefits of the result of the feeding test can include determining that there is low threshold allergy (sensitive to a small amount) which may prompt referral for emerging/available treatment options, or no allergy to peanut with allowing dietary inclusion of peanut. The typical instructions for people with a peanut allergy is allergen avoidance, which should pose no risk of a reaction. The benefits of the intervention may include: 1) Being able to eat a larger amount without symptoms than before after a time eating a tolerated amount, 2) ability to eat full servings of peanut even after not having a daily amount for a period of 2 months, 3) better quality of life. There may be a benefit to society to understand more about peanut allergy.

POSSIBLE RISKS AND DISCOMFORTS:

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

Insurance risks: There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against your child based on genetic information. However, it does not protect you or your child against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

There are risks associated with the different procedures that are part of this study:

Ingestion of peanut (the feeding tests and home ingestion). The potential risks are those associated with eating a food to which a person is allergic and having allergic reactions. Oral food challenges (gradual feeding of the allergic food or providing an amount somewhat higher than previously tolerated) are performed to determine if the food allergy exists or has gone away, or in this study to see how much food can be eaten before symptoms develop. Symptoms can include itchy skin rash (hives, "whelps", flare of atopic dermatitis [eczema], swelling), nausea, stomach pain, vomiting, and/or diarrhea, rhinitis (stuffy "runny" nose and sneezing) and/or wheezing/trouble breathing. The major risks involved include severe breathing difficulties and rarely a drop in blood pressure/trouble with blood circulation. There is a single reported death. Over 30,000 oral food challenges have been performed at Mount Sinai with no deaths. The procedure is performed under direct medical supervision according to guidelines.

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Home ingestion of an allergenic food that has been ingested safely under supervision during food challenges could cause an allergic response as well. To minimize risk of allergic reaction to home ingestion, specific instructions are provided, e.g., eating the measured amount of peanut at the same time of the day following or with a full meal, avoidance of exercise for 2 hours following ingestion and temporary suspension of eating peanut during fevers, illnesses, or asthma flares. Written emergency plans will be given to use to use at home and include instructions on initial emergency treatment and calling 911 in the event of a serious allergic reaction. You must also have a prescribed epinephrine auto injectors to use in an emergency and be trained how to use it.

Having food allergy is a risk for a problem called eosinophilic esophagitis (EoE), an allergic problem in the gut, affecting the tube going from the mouth to the stomach that makes it difficult for food to go down. Eating an allergen could trigger EoE. The risk that home ingestion of small amounts of an allergen can trigger EoE has been estimated at about 3 in 100 people. If EoE is suspected, you may be asked to see a doctor outside of the study to find out if there is EoE. If there is EoE you will be instructed to stop eating peanut. Stopping peanut is expected to result in the EoE going away if peanut is really the trigger. However, people with food allergies can develop EoE even if they did not start eating a new food allergen, and so EoE diagnosed during the study may or may not go away with stopping peanut.

Collection of stool and saliva: There are no anticipated risks from collecting stool and saliva.

Blood draw: The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw. Blood drawing may aggravate a pre-existing anemic condition, but this risk is low since the amount of blood to be drawn will be minimized according to government standards.

Prick skin test: Skin prick tests will be performed by scratching a liquid containing peanut, saltwater, and histamine (a chemical that should cause an itchy bump) on the surface of the arm. This should cause minimal discomfort (the sensation of a prick and an itchy bump (hive) that will go away quickly. Such tests could theoretically cause a stronger allergic reaction, but this is exceedingly rare (under one in one thousand)

Questionnaires: You will complete various surveys about your child's health, symptoms surveys, dietary and quality of life questionnaires. There should be no significant risk.

In addition to these risks, this research may hurt your child in ways that are not known. The unknown risks may be minor or may be major (death).

If your child is or becomes pregnant, this research may hurt the baby or the pregnancy in ways that are unknown. The unknown risks may be minor or may be major (death). Your child should not become pregnant while on this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.

- The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

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- In addition to these risks, this research study may hurt your child in ways that are not known. The unknown risks could be minor or major (death).
- If your child is pregnant or becomes pregnant, this research may hurt your child's baby or your child's pregnancy in ways that are unknown. The unknown risks could be minor or major (death) for the pregnancy. Your child should not become pregnant or get someone pregnant while taking part in this study. Please read the acceptable methods of birth control found under the Description of What Is Involved section of this document.
    - Group Risks - Although your child's name will not be given to researchers, basic information such as your child's race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as your child. However, they could also be used to support harmful stereotypes or discrimination.
    - Privacy Risks - Your child's name and other information that could directly identify your child (such as an address, date of birth, or social security number) will never be placed into a database. However, because your child's genetic information is unique to your child, there is a small chance that someone could trace it back to your child. The risk of this happening is very small, but may grow in the future. Since the database contains genetic information, a break in security may also pose a potential risk to blood relatives as well as your child. For example, it could be used to make it harder for your child (or a relative) to get or keep a job or insurance. If your child's private information was misused, it is possible your child would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.
    - Insurance Risks - There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against your child based on their genetic information. However, it does not protect your child against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

OTHER OPTIONS TO CONSIDER:

You may decide not to allow your child to take part in this research study. If you decide not to allow your child to take part, this will not affect the clinical care your child receives at Mount Sinai. The choice is totally up to you.

Instead of being in this research study, your choices may include:

Avoiding peanut, following your allergist's advice about management, pursuing other studies about peanut allergy, or using FDA-approved therapies as they become available.

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IN CASE OF INJURY DURING THIS RESEARCH STUDY

If your child is injured or made sick from taking part in this research study, medical care will be provided. Generally, this medical care will be billed to you and/or your child's health care insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your child's insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop your child's participation in this study at any time. No matter what you choose, your child's care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop your child from being in the study, please contact the Lead Researcher or the research staff. Banked samples will be maintained for research purposes unless you request in writing that they be destroyed or made anonymous (if they were already anonymous, they cannot be retrieved or destroyed).

You may also withdraw your permission for the researchers to use and share any of your child's protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your child's health information may still be used or shared after you withdraw your authorization if your child has an adverse event (a bad effect) from taking part in the research study.

If you stop your child from being in the research study, the research team may not remove information they have already placed in the study database, and may continue to use that data as part of this study. The research team may ask you whether they can continue to collect information from your child's medical record.

If you decide you don't want your child's data and/or samples to be used for research anymore, you can contact the researcher and ask to have your child's data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your child's data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your child's identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your child's data and/or samples have already been deposited in an external repository, the study team will request that your child's data and/or samples be removed.

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Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your child's involvement in this research study at any time without your permission. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your child's best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your permission.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed your child, please contact the office of the research team and/or the Lead Researcher at phone number 212-241-5548

If there is an emergency, please call 212-241-5548 or call 911 or go to the emergency room. Let the emergency room staff know that your child is in a research study so they can contact the Lead Researcher if needed.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

Dr. Hugh Sampson (a Co-Investigator in this study) is a paid consultant and equity owner in N-Fold Therapeutics, LLC, a developer of peanut allergy treatments. Dr. Sampson is a named co-inventor on an issued patent titled, "microbial delivery system." This is licensed to N-Fold Therapeutics. Dr. Sampson also receives financial compensation as a paid consultant equity owner in DBV Technologies. DBV Technologies is a company developing skin patch treatments for food allergies and other disorders. In addition, Dr. Sampson receives financial compensation as a consultant for Siolta Therapeutics, a developer of allergy treatments. Dr. Mayte Suarez-Farinas (a Co-Investigator in this study) is a paid consultant for DBV Technologies.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your child's private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

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1. PHI contains information that identifies your child. It will be used to contact you and link your child to their health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your child's mental and physical health from your child's visits to doctors or hospitals, or from study visits.

Every time your child visits a hospital or their doctor, PHI is created and recorded in your child's medical record by their healthcare providers. In the same way, the PHI created as part of this study will be linked to who your child is and your child's medical information.

What PHI is collected and used in this research study, and might also be shared with others?

During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent

During the study, the researchers will gather information by:

- Reviewing and/or taking your child's medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature.
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your child's PHI being used?

Researchers need the information that identifies your child so they can contact you during the study. They need your child's health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who your child is or that your child took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who your child is, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your child's care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may

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use and share your child's information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your child's information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your child's name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your child's PHI?

As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your child's PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings: Mount Sinai's InCHOIR office
- The sponsoring government agency and/or their representatives who need to confirm the accuracy of the results submitted to the government or the use of government funds: The National Institute of Allergy and Infectious Diseases.
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety. The United States Food and Drug Administration.

In all disclosures outside of Mount Sinai, your child will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to your child without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your child's privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your child's records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your child's medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your child's name and other identifying information will be kept confidential.

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For how long will Mount Sinai be able to use or disclose your child's PHI? Your authorization for use of your child's PHI for this specific study does not expire.

Will you be able to access your records?
During your child's participation in this study, you will not be able to access your child's medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your child's information will be available should an emergency arise that would require your child's treating physician to know this information to best treat your child. You will have access to your child's medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your child's medical record.

Do you need to give the researchers permission to obtain, use or share your child's PHI?
NO! If you decide not to let the research team obtain, use or share your child's PHI, you should not sign this form, and your child will not be allowed to participate in the research study. If you do not sign, it will not affect your child's treatment, payment, or enrollment in any health plans or affect your child's eligibility for benefits.

Can you change your mind?
If you withdraw your permission for your child to be in the study, please contact the Lead Researcher or the research staff.

The research team may ask you whether they can continue to collect information from your child's medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your child's protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your child's health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your child's PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your child's information to continue to protect your confidentiality.

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If researchers are reviewing your child's medical records or asking questions about your child's medical history or conditions, it is possible that they may learn information related to your child's HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your child's medical records or asking questions about your child's medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of your child's HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your child's HIV-related information without authorization. If you or your child experiences discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your child's rights.

Certificate of Confidentiality: To further protect your child's privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your child's identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your child's personal information, study data and/or samples with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that your child or someone else is threatened with serious harm, such as a child or an elderly person being abused, the research team may notify the appropriate authorities if necessary to protect your child or others. A Certificate of Confidentiality does not prevent you, your child or a member of your family from voluntarily releasing information about your child or their involvement in this research. This means that you, your child and your family must also actively protect your child's privacy. If an insurer or employer learns about your child's research participation, and you agree that they can have your child's research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.

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- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your child's rights as a research participant.
- You want to get information or provide input about this research

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ADULT PARTICIPANT:

Your signature below documents your permission for the child named below to take part in this research study and to the use and disclosure of this child's protected health information. A signed and dated copy will be given to you.

Printed Name of Child: _____

Signature of Parent/Guardian	Printed Name of Parent/Guardian	Date	Time

❑ Parent
❑ Guardian (May provide permission only if legally authorized to consent to the child's general medical care.)

Signature of second Parent/Guardian	Printed Name of second Parent/Guardian	Date	Time

Note on Second Parent: *If the IRB determined both parents must give permission unless an exception below applies, and if documented permission of the second parent of this child is not obtained, indicate the reason: (select one)*

❑ *Second parent is deceased*
❑ *Second parent is unknown*
❑ *Second parent is incompetent*
❑ *Second parent is not reasonably available*
❑ *Only one parent has legal responsibility for the care and custody of the child*

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the parent(s)/guardian(s), and that permission was freely given by the parent(s)/guardian(s).

Signature of Witness	Printed Name of Witness	Date	Time

Assent
❑ Obtained
❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

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