

Single Center, Placebo Controlled Clinical Study in Desensitization vs  
Tolerance Induction in Peanut Allergy Subjects

Informed Consent Form

NCT02103270

January 9, 2019

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Kari Nadeau, MD PhD

eP 29320

*IRB Use Only*

Approval Date: January 9, 2019

Expiration Date: January 9, 2020

Protocol Title: The Peanut Oral Immunotherapy: Safety, Efficacy, and Discovery (POISED) Study

Please check one of the following:

\_\_\_\_\_ You are an adult participant in this study.

\_\_\_\_\_ You are the parent or guardian granting permission for a child in this study.

Print child's name here: \_\_\_\_\_

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

Are you participating in any other research studies? \_\_\_\_\_ Yes \_\_\_\_\_ No

**PURPOSE OF RESEARCH**

You are being asked to take part in this research study because you have peanut allergy. Peanut allergy occurs in about 2% of children and is the most common food to cause life-threatening reactions. Currently, the primary treatment for peanut allergy is a peanut-free diet and ready access to allergy medicine. The combination of avoidance diets and risks of accidental exposures and life-threatening reactions creates a tremendous burden to patients and families. Unlike food allergies to milk and egg allergy, peanut allergy tends to persist, and only 20% of children outgrow their disease.

The purpose of this study is to find out if treating children and adults with peanut allergy with an experimental treatment of peanut oral (by mouth) immunotherapy (OIT) will cause them to lose their allergy to peanuts. There are two terms that can describe losing an allergy in this way: "desensitization" and "tolerance."

A person may become desensitized to a medicine or food by giving that person small, increasing amounts of the medicine or food to help the body become used to the substance so that it no longer causes a severe allergic reaction. When a person with a food allergy is desensitized, they often have to continue to expose their immune system to the food they are allergic to in order to keep their allergy from coming back. If someone who has been desensitized to a food allergen stops eating their food allergen every day and their allergy does not come back, they are considered to have developed tolerance to that food.

By desensitizing you to peanut protein, we hope to lower the risk of life-threatening allergic reactions and cause you to have less sensitivity to peanuts. But we do not know yet whether this will happen. In addition, some food allergy

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researchers are asking the questions of how long a person who has been desensitized has to continue eating their allergic food every day and how much they have to eat in order to develop tolerance.

Right now, food allergy researchers do not know how to identify which patients will become desensitized by OIT and which will become tolerant after OIT. That is one of the major questions we want to help answer with this study.

This is a research study of an experimental treatment for peanut allergy. For this research, we will study subjects in two different groups. One group will receive the experimental treatment of peanut protein and the other group will receive placebo (oat flour) for a total of approximately 3 years. A placebo is an inactive substance given in the same form as the peanut protein that is similar to the test substance in appearance, smell, and taste but, contains no peanut protein. Neither you nor the Protocol Director will be able to choose or know the group to which you are assigned. Subjects will be randomly assigned to the groups (like flipping a coin). Out of 120 participants in this study, 95 will be randomly assigned to peanut and 25 will be randomly assigned to placebo. This means a participant in the study has a 79% chance of being assigned to peanut and a 21% chance of being assigned to placebo.

This research study is looking for 120 individuals between the ages 7 and 55 years old with an allergy to peanut. All 120 participants will be enrolled at Stanford University.

If you decide to terminate your participation in this study, you should notify the Protocol Director, Dr. Kari Nadeau (650-867-4592) or the co-Protocol Director Dr. Sharon Chinthrajah (267-235-6978).

The study stopping rules were met due to two cases of hypotension (low blood pressure) and the study was stopped on November 23, 2016. Two participants developed hypotension after they ate peanut and recovered quickly after receiving injectable epinephrine.

On November 23<sup>rd</sup>, the IRB, NIH and FDA were notified of the study stopping rules being met. On November 28<sup>th</sup>, we received notice from the FDA that the study could continue. From November 29<sup>th</sup>-December 1, the FDA reviewed the cases and determined the study may continue and that food challenges and dose escalations could continue until further information from the DSMB (data safety monitoring board) was given.

The DSMB reviewed the cases and safety data from all study participants and the DSMB determined, in late December, that the study could continue. The DSMB requested that all participants be re-consented. The protocol and consent now have new rules on hydration (for both dose escalation and oral food challenge, on

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the interval between doses, and on modifying the way that the top dose of peanut is given—for oral food challenge). More details are on page 7 and 13 of this consent.

In summary, the DSMB asked for changes to be made in the oral food challenges and dose escalations to try to further improve safety. The DSMB also asked for changes in the study stopping rules. These changes have been made and the DSMB approves the changes.

**VOLUNTARY PARTICIPATION**

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on your medical care. You can decide to participate now, but withdraw your consent later and you will stop being in the study without any loss of benefits or medical care to which you are entitled.

**DURATION OF STUDY INVOLVEMENT**

This research study is expected to take approximately 3 years. After enrolling in this study, there is approximately 1 year of dose escalation visits followed by 2 years of maintenance. During the third year of the study, some subjects will be randomly assigned to a lower maintenance dose.

**PROCEDURES**

If you choose to participate, Dr. Nadeau, Dr. Chinthrajah, and/or the research study staff will ask you to sign this informed consent form.

If you agree to take part in the study, you will be assigned to one of the two different study groups. You cannot choose which study group you will be assigned. You will be assigned by chance, like flipping a coin, and will receive either the study treatment (peanut flour) or a placebo (oat flour). You will be in this study for a total of about three years.

The study includes five phases:

- Screening (3 visits)
- Initial Dose Escalation (1 visit)
- Build-Up (clinic visits every 2 weeks for approximately 1 year)
- Maintenance (clinic visits every 13 weeks for approximately 1 year)
- Tolerance Testing (clinic visits every 13 weeks for approximately 1 year)

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If you are enrolled in the study, the study staff will provide training concerning the following:

- How to properly store and administer the study dose.
- How to recognize allergic reactions and/or other adverse events.
- What actions you must take should you demonstrate an allergic reaction and/or other adverse event.

If at any time you have a question or concern, please contact the Protocol Director or other member of the study team immediately.

**Screening:**

You will be asked to come to the Stanford University Clinical Food Research Unit (CFRU) at El Camino Hospital. You will be asked to stop antihistamines (for example Benadryl, Zyrtec, Allegra, or others) for a certain amount of time before the visit in order to undergo an Allergy Skin Prick Test and Oral Food Challenge (OFC). You must be off oral corticosteroids (for example, Prednisone) at least one month before undergoing screening procedures. Before any of the OFC procedures, if your doctor thinks it is necessary, an IV catheter may be inserted into a vein in your arm in case medications are needed for treatment of a reaction. LMX cream, a medicine put on the skin to numb it, may be applied to the skin 15 minutes prior to IV placement to make it less painful.

This visit will take approximately 3 hours.

Then, the next two visits will be for double-blind placebo-controlled food challenges (DBPCFCs). These visits will be conducted on 2 separate days and will each take approximately 8 hours. On one day, you will eat peanut flour mixed in with another food, such as applesauce. The other day, you will eat the placebo, oat flour. Neither you nor the study staff working with you during the DBPCFCs will know what you are eating on that particular day.

You will eat a series of increasing doses of peanut or placebo which will be administered every 15-30 minutes until a reaction is observed or the final dose is consumed. During the peanut challenge, the total amount of allergen consumed is slightly more than 2 full peanuts. This screening challenge is being done to confirm your allergy to peanut. In order to be eligible, the study staff must see a reaction to the peanut challenge at a total dose of 500mg of peanut protein or less **AND** no reactions to the placebo challenge. If you do not have a reaction to the peanut challenge or if you have a reaction or symptoms that stop the placebo challenge, you will not be eligible to continue in the study.

If it is determined you are eligible for the study, you will be randomly assigned (like flipping a coin) to receive either peanut protein or placebo (oat flour) and you will return to the CFRU for the Initial Dose Escalation (IDE) Day. The IDE Day must take place within 300 days of the Screening Visit described above.

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Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have pregnancy tests done before beginning this research study and during the course of the study.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

Initial Dose Escalation Day:

The Initial Dose Escalation will be done to determine the starting dose for the build-up phase of the study. We will carefully feed you a small amount of peanut protein or placebo (oat protein) to observe for any reactions.

The Initial Dose Escalation will start with 0.5 mg peanut protein/placebo given by mouth in a small amount of food, for example, applesauce. The amount of peanut protein or placebo given will approximately double every 15-30 minutes up to a maximum dose of 6 mg. You must tolerate a dose of at least 1.5 mg at the IDE to remain in the study. Once the maximum tolerated dose is given, you will be observed for two hours. If there is no evidence of an allergic reaction, you will be sent home. This visit may last 8 hours or longer if you have a reaction to the peanut protein or placebo.

If you do not have a current in-date epinephrine auto-injection device (for example, EpiPen, Jr™ or EpiPen™) at the beginning of the study, you will be given a prescription for one to have with you at all times. The study staff will review how to use it, with you before you are sent home. The epinephrine will be used if there are any symptoms of a life-threatening allergic reaction which may include a rash, swelling, difficulty breathing, or vomiting. You will be required to have your epinephrine auto-injection device with you at all times, including bringing it to your clinic visits.

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Again, this is a double-blind study meaning that you and the study staff will not know if you will be receiving peanut protein or placebo. However, if this information is needed for your safety in an emergency, the blind can and will be broken.

After you begin dosing with peanut or placebo, you will be trained on how to complete a daily online “diary” at home to confirm that you took your dose, whether or not you had any allergic reactions to your dose, and whether or not you had any other changes in your health that the study staff needs to know about. This diary is only available online through a secure website and must be completed every day that you are taking peanut or placebo doses as part of this study.

The table below summarizes the procedures to be done as part of Screening and the Initial Dose Escalation Day:

<b>Study Stage</b>	<b>Screening</b>	<b>IDE Day</b>
<b>Time</b>	<b>Day -300 to Day 0</b>	<b>Day 0</b>
Review of Full Allergy and Medical History	X	
Review of Allergy and Medical History Since Previous Visit		X
Physical Exam	X	X
DBPCFC to 500 mg Total	X	
Peanut/Placebo Dosing		X
Blood Draw	X	X
Pregnancy Test (if applicable)	X	
Breathing Test (Spirometry)	X	X
Skin Prick Testing	X	

**Build-Up:**

On the Initial Dose Escalation Day, you will be sent home with 2 weeks of home doses at the highest tolerated dose, which will be a minimum of 1.5 mg to maximum of 6 mg.

The daily peanut protein or placebo dose will be taken by you, at home for 2 weeks. You will then be asked to return every 2 weeks to the site to have the dose of daily peanut protein or placebo increased as appropriate.

The goal is to have you reach a daily peanut protein or placebo maintenance dose of 4,000 mg, every day without having an allergic reaction. This is the amount of peanut protein found in approximately 17 peanuts. The amount of

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time to reach this dose of peanut protein or placebo will be at least 44 weeks and may be longer.

When you reach the maximum tolerated dose (up to 4,000 mg per day) during Build-Up phase, you will enter the Maintenance phase.

The table below summarizes the procedures to be done at visits during the Build-Up Phase. Please remember that there may be visits after Week 44 (performed every 2 weeks) to increase your dose up to 4,000 mg daily.

**Changes to the Dose Escalation to try to improve safety:** During dose escalation, we will ask you to drink more (about two full glasses of liquid) and to restrict exercise for about 2 hours after dosing.

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Study Stage Time	Build-Up																					
	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44
Review of Allergy and Medical History Since Previous Visit	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Brief Physical Exam	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Breathing Test (Spirometry)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Peanut/ Placebo Dosing	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood Draw						X						X						X				
Pregnancy Test (if applicable)												X										

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**Maintenance:**

You will continue on daily peanut protein or placebo during the Maintenance phase and you will be asked to return every 13 weeks for a blood draw and skin prick test. Approximately 104 weeks following the Initial Dose Escalation Day, you will return for a visit that will include a blood draw, skin prick test, and a Double Blind Placebo Controlled Food Challenge (DBPCFCs) (one day to peanut, one day to placebo) up to 4,000 mg. A blood draw and skin prick test will be performed on the first day of the DBPCFC.

The table below summarizes the procedures to be done at visits during the Maintenance Phase.

<b>Study Stage</b>	<b>Maintenance (Week #)</b>				
	<b>52</b>	<b>65</b>	<b>78</b>	<b>91</b>	<b>104</b>
<b>Time</b>					
Physical Exam	X	X	X	X	X
Review of Allergy and Medical History Since Previous Visit	X	X	X	X	X
Blood Draw	X	X	X	X	X
Pregnancy Test (if applicable)	X		X		X
Breathing Test (Spirometry)	X	X	X	X	X
DBPCFC to 4,000 mg					X
Skin Prick Testing	X	X	X	X	X

**Tolerance Testing:**

After the DPBCFCs at Week 104, if you meet certain criteria, you will reduce your daily dosing either to 300 mg of peanut protein OR to 600 mg of placebo. During this stage, you will return every 13 weeks for 4 more timepoints (until Week 156) for a blood draw, skin prick test, and DBPCFCs to 4,000 mg. Each DBPCFC visit entails 2 in-person visits that are 5-7 days apart; one day will be a placebo challenge and the other, peanut.

If you do not meet the protocol specific criteria at Week 104, you will be considered a desensitization failure and may continue in the study or you will be offered a follow-up protocol at week 117 that is separate from this protocol.

The table below summarizes the procedures to be done at visits during the Tolerance Testing Phase.

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Study Stage	Tolerance Testing (Week #)				Tolerance Testing (Week #)			
	117	117	130	130	143	143	156	156
<i>Time</i>								
Physical Exam	X	X	X	X	X	X	X	X
Review of Allergy and Medical History Since Previous Visit	X	X	X	X	X	X	X	X
Blood Draw	X		X		X		X	
Pregnancy Test (if applicable)			X				X	
Breathing Test (Spirometry)	X	X	X	X	X	X	X	X
DBPCFC to 4,000 mg*	X	X	X	X	X	X	X	X
Skin Prick Testing	X		X		X	X	X	X

Note: these DBPCFC\* might or might not be performed.

### **Description of Procedures**

**Allergy Skin Prick Testing:** Skin testing involves putting drops of allergy extracts to food and environmental allergens on the forearm or back and lightly pricking the skin with a sterile lancet. If you are allergic to the allergy extracts, the results could be an itchy, raised bump and are usually apparent within 15 minutes.

**Blood samples for research markers:** You will have blood drawn approximately every 12-13 weeks throughout the study. Some tests will be done for safety and some tests will be done to look at how your immune system changes during the study. Each time blood is drawn, we will collect blood according to weight-based safety guidelines established by the National Institutes of Health (NIH). When blood is collected, the minimum volume collected will be approximately 30 mL (2 tablespoons). For children younger than 13, the maximum volume drawn could be up to 5 mL/kg. For adults, the maximum amount will not exceed 500 mL.

Research tests help us learn more about your disease, the immune system (the body's natural defense system against illness), and response to drugs or treatment. The results of the research tests will not be shared with you. These research samples will not identify you by name, but will have a code.

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Research tests will include genetic tests. These laboratory tests study your inherited (present from birth) characteristics which are present in each of your cells.

Genetic testing may help researchers learn more about allergic disease, or help to find treatments for allergy. As with all research tests, these results will not be shared with you.

Some of your blood samples may be sent outside of Stanford for analysis.

**Diet and Allergy Assessment:** During the study you will be asked to answer questions about your medical history, diet, and allergy symptoms you have experienced.

**IV Catheter Insertion:** For your safety, an IV catheter needle may be inserted into a vein in your arm before some visits in case medications are needed for treatment of a reaction. LMX cream, a medicine put on the skin to numb it, may be applied to the skin 15 minutes prior to IV placement to make it less painful.

**Initial Dose Escalation:** The initial dose escalation procedure begins with a very small amount of peanut protein or placebo (0.1 mg) given by mouth in a small amount of food. The amount of peanut protein or placebo given to you will approximately double every 15-30 minutes until 6 mg is given. Once the 6 mg dose is given, you will be observed for two hours. If there is no evidence of an allergic reaction, you will be sent home. This visit may last 8 hours or longer if you have a reaction to the peanut protein or placebo.

**Double Blinded Placebo Controlled Food Challenge (500 mg and 4,000 mg):** A DBPCFC consists of you eating both a food to which you may be allergic (peanut) and eating a placebo at different times. The peanut or placebo will be given in a "double-blinded" fashion under observation in the hospital clinic. "Double-blinding" means that neither the Protocol Director, nor the research team, nor you will know whether you are receiving peanut protein or placebo. However, in the case of an emergency, the study staff can quickly locate the information.

You will be given peanut protein or placebo at about 15-45 minute intervals up to a maximum single dose of 125 mg or 1,050 mg, for a total cumulative dose of 500 mg or 4,000 mg respectively, if you complete all of the doses and do not have an allergic reaction to one of the doses. If you have a reaction to one of the doses, the dosing of peanut protein or placebo will be stopped and the allergic reaction will be treated with appropriate medications to stop the reaction. The food challenge (500 mg and 4,000 mg) will happen over the course of 2 days.

**Changes to the Oral Food Challenge to try to improve safety:** During oral food challenge, you will be asked to drink about two glasses of liquid, the interval

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between higher doses has been increased from 15-30 min to 45 min or longer and the last dose has now been split into two smaller doses (i.e. 2,100 mg is now given as 1,050mg and 1,050 mg).

**PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug (daily peanut or placebo) as instructed
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

**WITHDRAWAL FROM STUDY**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify the Protocol Director, Dr. Kari Nadeau (650-867-4592) or the co-Protocol Director Dr. Sharon Chinthrajah (267-235-6978).

If you withdraw from the study, or the study medication is stopped for any reason,

- You will stop taking the study administered peanut/placebo
- Return to the research center for a final blood draw
- The Protocol Director may ask you to come back for the visits until the study is over, even if you have stopped taking the study drug (peanut or placebo flour)

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.

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- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

**POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES**

**Risk of allergic reactions:** The daily peanut oral immunotherapy may cause allergic symptoms. Potential symptoms may include some or all of the following symptoms: sneezing, runny nose, flushing, swelling of the tongue/throat or lips, flares of eczema, nausea, vomiting, abdominal discomfort, itching, rash/hives, swelling, wheezing or difficulty breathing, fainting or becoming lethargic or weak. Allergic reactions are usually mild but may occasionally be moderate or severe.

A very serious allergic reaction called anaphylaxis has been known to occur with rapid flushing/itching, more severe wheezing or difficulty breathing, swelling of the throat, and/or drop in blood pressure. Sometimes, this reaction can result in death. In order to lessen the likelihood of you experiencing any allergic symptoms, dosing of peanut protein will be initiated at extremely small amounts. Participants will be closely observed in the clinic for at least 2 hours, before being discharged to watch for these signs or symptoms. Doctors and nurses trained in these kinds of reactions will be present and emergency equipment will be available if treatment is necessary.

There may be an increased risk of developing Eosinophilic esophagitis (EoE), which is an immune-mediated disease as a result of inflammation of the esophagus. Symptoms range by age, with children potentially presenting with feeding difficulties, abdominal pain, and/or vomiting and adults may experience chest pain, food getting “stuck”, and/or abdominal pain. If these symptoms present, an endoscopy will be needed to confirm diagnosis, which may be performed by a gastroenterologist.

Vigorous exercise is not permitted for at least 2 hours after the dose of oral allergen immunotherapy. Also, there must be at least 1 hour between vigorous exercise and taking a dose of oral allergen immunotherapy. Allergic reactions are still possible when exercise takes place more than 2 hours after the dose.

**Allergy Skin Prick Testing:** The risk involved with skin testing includes discomfort from the needle prick, along with itching and swelling at the skin test site in positive responses. Less common side effects include severe allergic reactions, as described above.

**Blood Tests/IV Catheter Insertion:** This study includes the following risk or discomforts associated with blood draws including the risk of fainting, local pain, stinging, bleeding, or bruising at the site where the needle is inserted into the vein. On rare occasions infection at the needle stick site may occur. Insertion of

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an IV can cause a temporary burning feeling, bruising, or, on rare occasions, infection at the needle stick site.

**Oral Food Challenges**

Again, as described above, a potential risk associated with oral food challenge is the risk of a severe allergic reaction, called anaphylaxis. Symptoms of anaphylaxis (severe allergic reaction) may include itchy rash, hives, facial swelling, swelling of throat, wheezing, cough, shortness of breath, vomiting, diarrhea, and in severe cases low blood pressure, loss of consciousness, hospitalization, and, rarely, death. After the tolerance testing period of the protocol, there is a risk of reacting to the food challenge. As stated above, medication, personnel, and equipment are immediately available in the event of an anaphylactic reaction.

**POTENTIAL BENEFITS**

If you agree to take part in this study, there may be no direct medical benefit to you. It is hoped that the results of this study will help the investigators plan future studies in individuals that have allergy to peanut or other common allergies (egg, milk, wheat, etc.).

**We cannot and do not guarantee or promise that you will receive any benefits from this study.**

**ALTERNATIVES**

The alternative to participating is to continue with routine medical care for your peanut allergy.

**PARTICIPANT'S RIGHTS**

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

**ClinicalTrials.gov**

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

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identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**CONFIDENTIALITY**

Your identity will be kept as confidential as possible as required by law. Your personal health information related to this study may be disclosed as authorized by you. Your research records may be disclosed outside of Stanford, but in this case, they will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

You will be identified by a study code, not your name. The key to the code is kept in a secured file at the study site. Personal data from your records will not be released without your written permission. You will not be named in any publication about this study. After the study is completed, the study data may be placed in a central storage location. The purpose is to make study data available to other researchers who must request permission from National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). This data does not include names of any of the participants and your privacy is protected whenever this data is used.

Medical and research records from this study will be reviewed by the United States agency funding this study (the National Institute of Allergy and Infectious Diseases), including its, representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring or analyzing the study. In addition, the U.S. Food and Drug Administration (FDA), or other health authorities, and pharmaceutical or device sponsor(s) and their commercial partners may review your medical and research records for regulatory purposes.

The purpose of this research study is to obtain data or information on the safety and effectiveness of Peanut Flour. The results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Participant ID:



STUDY

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Kari Nadeau, MD PhD

eP 29320

*IRB Use Only*

Approval Date: November 27, 2018

Expiration Date: January 10, 2019

Protocol Title: The Peanut Oral Immunotherapy: Safety, Efficacy, and Discovery (POISED) Study

Stored Samples and Information:

If you agree, we will store your remaining samples and information in a central location. The purpose is to make these samples and information available for future research which is not yet planned.

Your decision to allow your remaining samples and data to be stored is separate from your decision to participate in this study. If you decide to allow storage, your samples and data may be stored for an indefinite length of time. No additional samples for storage are taken. Remaining samples are stored when all other study required tests are completed. Your samples may be sent outside of Stanford for analysis.

The results of tests done on your stored samples will not be given to you or your doctor. The results will not be put in your records and will not change your medical care. There will be no benefits to you from the storage of these samples and information. However, the use of your samples and information may help researchers learn more about your disease or help study the genetics related to your disease.

There may be risks in allowing the storage or analysis of samples and information. For example, if future research is for genetic testing and because genetic information is unique to you there is a risk that someone could trace it back to you. Researchers are required to protect your privacy and to keep you and your information private to the extent permitted by the law.

The samples and information will not be sold; however, the results of the tests could lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

You can change your mind at any time during the study and ask to have your samples destroyed. This request should be made in writing to the Protocol Director. If your samples have not been used, they will be destroyed. If your samples have already been tested before your request, the information from these tests will be used and cannot be destroyed.

Participant ID:



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Choose yes or no to allow the storage of your remaining samples (blood) and information for genetic tests.

Yes     No

\_\_\_\_\_   
Initials of Adult Participant or LAR

Choose yes or no to allow the storage for future use of remaining samples (blood) and information for other research tests (not genetic).

Yes     No

\_\_\_\_\_   
Initials of Adult Participant or LAR

Participant ID: \_\_\_\_\_



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**Authorization To Use Your Health Information For Research Purposes**

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

**What is the purpose of this research study and how will my health information be utilized in the study?**

This is a research study to learn about the medical effects, the safety, and the immunologic effects of Peanut Oral Immunotherapy (OIT) treatment. A total of 120 people between the ages of 7 and 55 years old will be asked to take part in this study at Stanford University. The goal of the study is to find out whether subjects can develop the ability to eat peanut (the food allergen) regularly without allergic symptoms after stopping the study therapy.

**Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke it or withdraw from the research later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Kari Nadeau, MD PhD or

Participant ID:



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Dr. Sharon Chinthrajah at Stanford University, 269 Campus Drive,  
CCSR Building, Room 3215, Stanford, California 94305-5164.

**What Personal Information Will Be Obtained, Used or Disclosed?**

Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to demographics (including date of birth, name, address, and phone number), medical history, allergy history, and blood samples.

**Who May Use or Disclose the Information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Kari Nadeau, MD PhD, and the co-Protocol Director Sharon Chinthrajah, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff at the Sean N Parker Center for Allergy Research at Stanford University
- Other collaborators involved in this study at Stanford University

**Who May Receive or Use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Sponsor, the National Institutes of Health
- Collaborators conducting this type of research at other universities or hospitals outside of Stanford (if you have allowed future use of your samples)
- Ukko
- AllerGenis
- The Food and Drug Administration

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Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will end on January 1, 2063 or when the research project ends, whichever is earlier.

**Will access to my medical record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Adult Participant

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Legally Authorized Representative

\_\_\_\_\_  
Description of Representative's Authority to Act for Subject

Participant ID: \_\_\_\_\_



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**FINANCIAL CONSIDERATIONS****Payment**

Every 3 months after the IDE, your compliance with timely completion of the daily dosing diaries will be reviewed by study staff. Each time your compliance is evaluated as timely for >80% of daily entries for the preceding 3 months, at your next regularly scheduled study visit you will receive a \$30 gift card. Each 3-month period will be evaluated separately.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

**Costs**

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance.

**Sponsor**

This study is funded by the National Institute of Allergy and Infectious Diseases (NIAID) part of the National Institutes of Health (NIH), Ukko, and AllerGenis.

**COMPENSATION for Research-Related Injury**

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

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If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

**CONTACT INFORMATION**

**Questions, Concerns, or Complaints:** If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Kari Nadeau (650-867-4592) or the co-Protocol Director Dr. Sharon Chinthrajah (267-235-6978). You should also contact her at any time if you feel you have been hurt by being a part of this study.

**Independent Contact:** If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

**Alternate Contact:** If you cannot reach Dr. Nadeau, the Protocol Director, or the co-Protocol Director Dr. Sharon Chinthrajah, please contact the Sean N Parker Center for Allergy Research team at (650) 724-0293.

**EXPERIMENTAL SUBJECT'S BILL OF RIGHTS**

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;

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- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

**May we contact you about future studies that may be of interest to you?**

Yes  No

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

\_\_\_\_\_  
Printed Name of Adult Participant

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of LAR (Parent, Guardian or Conservator)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of LAR

\_\_\_\_\_  
Authority to act for participant

\_\_\_\_\_  
Signature of Other Parent or Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Other Parent or Guardian

\_\_\_\_\_  
Authority to act for participant

Participant ID: \_\_\_\_\_



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The permission of the other parent was not obtained because:

This parent is deceased

This parent is unknown

This parent is incompetent

This parent is not reasonably available\*

One parent has legal responsibility for the care and custody of the child

\*Not reasonably available

Means the other parent is not contactable by phone, mail, email or fax or the other parent's whereabouts are unknown.

Does not mean the other parent is at work, at home, lives in another city, state or country, but is contactable by phone, mail, email or fax

Examples of not reasonably available:

- The other parent is on active military duty and is not contactable by phone, mail, email or fax.
- The other parent is incarcerated and is not contactable by phone, mail, email or fax.
- The whereabouts of the other parent are unknown

**Person Obtaining Consent**

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

Participant ID:



STUDY