Please check all that are applicable:

☐ I am an adult participant in this study.

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

****

Are you participating in any other research studies? _____ Yes _____No

You have been invited to take part in a clinical research study for people who are allergic to shrimp or cashew food. Your decision to take part in this study is voluntary.

Concise Summary

Goals of the Study

1) To learn how the shrimp and cashew food allergen affects people's immune system
2) If analyzing immune cells over time will help us predict if allergies will come back and how safe food allergy studies are.

Study Duration and Procedures

- The study will last 70 weeks and involve 21 clinic visits.
- Clinic visits include, but are not limited to, a physical examination, blood tests, lung function test, skin prick test, and food challenges.

Potential Study Risks and Benefits

- Some risks and discomforts could include itchy rash, hives, nausea, vomiting, abdominal discomfort, diarrhea, cough, stuffy, runny nose, sneezing, facial swelling, wheezing and shortness of breath. Major risks could include severe breathing difficulties and rarely anaphylaxis (severe allergic reaction).

- We cannot and do not guarantee or promise that you will receive any benefits from this study. Oral Immune Therapy (OIT _does not cure an allergy, however you may benefit from a decrease in the sensitivity to your food allergens and improve your immune protection to the offending food allergens over time.
- The knowledge obtained from this clinical study may aid in the advancement and understanding of food allergy and help in the development of new approaches for its treatment or prevention.
- The alternative to participating is to continue food avoidance, which is the standard treatment for food allergic individuals.
- 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.

PURPOSE OF RESEARCH

This is a research study for people who are allergic to either cashew or shrimp. The purpose of this study is to see how certain immune cells in your body behave when you are given the food you are allergic to as a form of treatment (often called Oral Immunotherapy or OIT). We hope to learn how the food allergen affects people's immune system differently between those people who can become able to eat the food, and those who cannot. We would like to see if checking immune cells over time will help us predict if allergies will come back and how safe food allergy studies are. We also want to develop tools to help us better understand, identify, and predict how patients will respond to OIT.

You were selected as a possible participant in this study because you have a proven allergy to either cashew or shrimp.

If you decide to terminate your participation in this study, you should notify Dr. Nadeau at (650) 724-0293.

This research study is looking for a total of 72 participants between 12 to 55 years of age, 36 participants with a proven allergy to cashew and 36 participants allergic to shrimp. Enrollment will only occur at Stanford.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and 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 70 weeks for each research participant:

- 1 to 2 days for screening (up to 6 months prior to your first food allergy treatment)
- 52 weeks of taking study provided investigational food,
- A follow-up period of 18 weeks.

PROCEDURES

If you choose to participate, Dr. Kari Nadeau and/or the research study staff will explain the study to you and ask you to read this consent form. The study personnel will answer any questions you may have about the study and what is being asked of you. If you decide to participate you will be asked to sign this consent form and a copy will be given to you. There will be at least 21 visits to the clinic throughout the study.

Screening Visit (week-24 to 0)

If you choose to participate, you will first need to go through a screening process to see if you qualify for this study. This screening process may take several visits. All the tests must be completed within 24 weeks of your first food allergy treatment.
We may ask to contact your primary provider or allergist to get a copy of any medical records pertaining to your food allergies.

At this visit, we will:

- Ask you to sign a consent or assent
- Ask you about your medical history with detailed questions about all of your food allergies and a history of reactions you have had
- Give you a physical exam
- Take your vital signs (heart rate, respiratory rate, temperature, and blood pressure)
- Review the medications you are currently taking
- Collect urine for pregnancy test, (if you are a female who has her period and could become pregnant). Your urine sample will be destroyed right after the laboratory tests are completed.
- Draw blood for (up to 70ml, about 4-5 tablespoons):
    - lab tests
    - allergy tests
    - research samples
- Perform a skin prick test to check your sensitivity to the food allergen
- Perform a lung function test called spirometry (a test that uses a hand-held instrument connected to a computer to measure how deep a breath you can take and how fast you can blow air out through your mouth).

  Or we will perform a Peak Flow Meter reading (which uses a small tube with a mouthpiece that measures how fast you can blow air out through your mouth)
- Collect a stool sample
- Give you a diary and teach you how to use it
- Give you Questionnaires to fill out
- Give you training on the following:
    - How to properly store and take your study dose

- How to recognize allergic reactions and/or other side effects
- What actions you must take should you have an allergic reaction
- How and when to use the epinephrine-containing autoinjector. You (and/or your family) will be required to have an epinephrine autoinjector with you at all times. If you do not have the auto injector, you will be given a prescription for an epinephrine-containing autoinjector (EpiPen Jr. or EpiPen) at the beginning of the study.

- Perform a food challenge called Double-Blind Placebo-Controlled Food Challenge (DBPCFC)

During the screening food challenge and all of the food challenges throughout the study:

- You will receive doses of the food allergen every 15-30 min.
- Each time, the dose will be increased until you reach the dose of 4043mg.
- You will be asked to increase your hydration during the food challenge (drink about 2 full glasses of liquid more).
- If the study team believes you are beginning to have a reaction, they may decide to increase the time between doses by 30 minutes (one hour maximum between doses).

During the other challenge you will receive a placebo material that will be given in the same way as the food allergen challenge.

- You will have a physical exam before each challenge.
- After you receive the last dose of the food challenge, you will be monitored for 2 hours and then discharged home.
- If your allergy blood test and/or skin prick test show that you are allergic to both cashew and shrimp, you will have two food challenges on different days. After those 2 challenges, only one of the food allergens will be chosen for you to continue to take at home.
- No more than 24 weeks can go by between the food challenge and the first day you begin to take the food allergen treatment.

This visit may take about 6-8 hours.

If there are any changes in your health or test results and if the investigator feels it is needed, any of the above items may be repeated within the 24 weeks before you start the study treatment.

Enrollment/Desensitization Visit (Week 0/Day 1)

If you qualify, you will be enrolled in either the cashew or the shrimp group, not both. We will choose which allergen you will receive based on your reaction and our ability to do laboratory tests.

You will come to the clinic to start your first dose of food allergen.

- The dose will start at 5mg
- After you receive the 5 mg dose, you will be observed for a minimum of 2 hours in the clinic
- If you tolerate the 5mg single dose, you will continue to take that dose at home daily for 2 weeks until your next clinic visit.
- If you do not tolerate the 5mg dose, you will be given a 3mg dose to take at home daily. You will be asked to return to the clinic in 7 days to increase the dose to 5mg.
- If you tolerate the 5mg single dose at that visit, you will continue to take that dose at home daily for 2 weeks until your next clinic visit.

At this visit, we will:

- Give you a physical exam
- Review the medications you are currently taking
- Review any reaction symptoms or health problems you have had since your last clinic visit
- Draw blood for (up to 70ml, about 4-5 tablespoons)
    - lab tests
    - research
- Perform a lung function test called spirometry or a peak flow meter reading test
- Review your diary
- Give you Questionnaires to fill out

You will be instructed to keep a daily electronic diary to record that you have taken your daily dose of food allergen and any symptoms that occur at home.

While you are on this study:

- You must continue to avoid your dietary food allergen (cashew or shrimp) the whole time.
- You are not allowed to introduce any new foods to your diet.
- You must continue to avoid any other foods you are allergic to, if any.

This visit will take about 2 hours.

Dose escalation and Build up Phase (Updosing phase) (Week 1 to Week 28)

You will come to the clinic every 2 weeks to have your daily home dose of food allergen increased to reach a maximum maintenance dose of 1000 mg at Week 28. With each new dose, you will take the first dose in the clinic followed by an observation period of a minimum of 2 hours.

You should withhold your daily home dose of food allergen and any regular doses of antihistamines on your clinic visit days, but you should take all other prescribed medications.

At this visit, we will:

- Perform a physical exam
- Review the medications you are currently taking
- Review any reaction symptoms or health problem you have had since your last clinic visit
- Perform a lung function test called spirometry or a peak flow meter reading test
- Review your diary
- Give you Questionnaires to fill out

Instructions for taking your daily home dose of food allergen

- It should be taken as part of a meal at the same time every day (within 2 hours of the previous day's dose).
- It is critically important to take the dose every day.
- If you miss a dose and it has been less than 12 hours from when you were supposed to take that dose, you may take the dose and resume the next dose on schedule.
- If you miss a dose and it is within 12 hours of the next dose, do not take the missed dose. Skip that dose and take the next scheduled dose at the usual time.
- Drink at least 2 glasses of water daily during your OIT
- There must be at least 1 hours between vigorous exercise and taking your dose of food allergen.
- Vigorous exercise is not permitted for at least 2 hours after you take your dose of food allergen. Allergic reactions are still possible when exercise takes place more than 2 hours after the dose.

Each of these visits will take at least 2 hours.

Maintenance phase (Week 28 to Week 52):

- If you reached a dose of 1000 mg by week 28, you will stay on that dose for 24 more weeks (until Week 52).
- If you are not able to get to a dose of 1000 mg by week 28, we will continue to increase your dose until week 52, if possible.
- If you can tolerate at least 300 mg but less than 1000 mg of food allergen protein, you will continue to take 300 mg and will be asked to come back at week 52, 58, 64 and 70 for blood and skin tests, but will not do any food challenges.
- If you cannot tolerate at least 300 mg, then you will stop treatment, no food challenges will be performed, and you will be referred to a practitioner after the week 52 visit for further follow up and clinical care. It is important for this research to be successful that you continue to come for study visits.

At week 52 (end of maintenance phase), you will come to the clinic.

At this visit, we will:

- Perform a physical exam
- Review the medications you are currently taking
- Review any reaction symptoms or health problems you have had since your last clinic visit
- Draw blood for lab tests, allergy tests and research (up to 70ml, about 4-5 tablespoons)
- Perform a lung function test called spirometry or a peak flow meter reading test
- Review your diary
- Give you Questionnaires to fill out
- Collect a stool sample
- Perform a food challenge called Double-Blind Placebo-Controlled Food Challenge (DBPCFC) for those who reached 1000mg

After the last dose of the food challenge, you will be monitored for 2 hours and then discharged home.

- If you pass your food challenge at this visit (week 52) and you are able to take 2043 mg of the food allergen with no or only mild reactions, you will be considered desensitized (able to tolerate the food with little to no allergic reaction).
- If you do not pass the food challenge at this visit (moderate or severe reaction), you will be asked to come back for visits 58, 64 and 70, but no food challenges will be done. You will restart on the highest dose that you tolerated at the food challenge.

Withdrawal/Tolerance phase (Week 52 to Week 58, Week 64 and Week 70)

During this phase you will be instructed to stop taking your daily home dose of food allergen for 18 weeks. You will have a clinic visit every 6 weeks (from week

52 to week 58, week 64 and week 70). This is to determine whether OIT has a prolonged effect to improve your food allergy.

You will return to the clinic at week 58, week 64, and at week 70 (end of study visit).

At the week 58 and 64 visit, we will:

- Perform a physical exam
- Review the medications you are currently taking
- Review any reaction symptoms or health problems you have had since you last visit
- Draw blood for lab tests and research (up to 70ml, about 4-5 tablespoons)
- Perform a skin prick test to check your sensitivity to the food allergen
- Perform a lung function test called spirometry or a peak flow meter reading test
- Collect stool sample
- Review your diary
- Give you Questionnaires to fill out
- Perform a food challenge called Double-Blind Placebo-Controlled Food Challenge (DBPCFC)
- Provide Epi injector training

After you receive the last dose of the food challenge, you will be monitored for 2 hours and then discharged home.

- If you pass your food challenge at the week 58 visit and we observe no or only mild reactions, you will be asked to undergo two more food challenges (at week 64 and at week 70) to test how long your tolerance for the food lasts when you are not eating the food.

- If you have a moderate or severe reaction during the food challenge at visit week 58, you will be followed until week 70 but will not have any more food challenges.

End of study Visit (Week 70)

At week 70 (end of study), you will come to the clinic. This will be your final clinic visit before exiting the study.

At this visit, we will:

- Perform a physical exam
- Review the medications you are currently taking
- Review any reaction symptoms or health problems you have had since your last visit
- Draw blood for (up to 70ml, about 4-5 tablespoons):
  - lab tests
  - allergy tests
  - research samples
- Perform a skin prick test to check your sensitivity to the food allergen
- Perform a lung function test called spirometry or a peak flow meter reading
- Review your diary
- Give you Questionnaires to fill out
- Provide Epi injector training
- Perform a food challenge called Double-Blind Placebo-Controlled Food Challenge (DBPCFC)

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What happens at the end of your participation in the study?

If you do not reach the dose of 1000 mg by week 52, but you are able to tolerate at least 300 mg of the food allergen, you will be given a powder/flour for 4 weeks at the end of the study (week 70) and referred to a practitioner for further follow-up and clinical care.

If you terminate the study early or you reach week 70, we will refer you to a practitioner for further follow up and clinical care.

Unscheduled visits

If you have any concerns or if you report a significant food allergy episode between your regularly scheduled visits, you should contact the study personnel. You may be asked to return to the clinic for an extra visit. This visit may include a physical exam, blood draw and/or skin prick test.

Throughout the study

- You will keep an electronic diary during the study to record that you have taken your dose and any symptoms that occur at home.
- You will be asked to continue to follow a food elimination diet of your food allergens. You will be continually monitored for compliance by thorough questioning and review of the electronic diaries at every study clinic visit.
- If you miss any of your food allergen doses, you will be asked to inform the study team and ask for guidance on how to proceed with dosing.
- You will be asked to bring all unused allergen dose(s) at every clinic visit.

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 potential dangers.

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 a pregnancy test done before beginning this research 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 these may result in your being withdrawn from the study.

Specimen Sampling for Research

Research using specimens (blood and stool) is an important way to try to understand human disease. You have been given this information because the investigators want to include your specimens in a research project and because they want to save the specimens for future research. There are several things you should know before allowing your specimens to be studied.

Your specimens will be stored for an indefinite period of time under a unique numbered identifier in the Nadeau Research lab. Your specimens will be sent outside of Stanford University for analysis. These research studies are very important to understand the changes in the immune system that may occur as you become desensitized to your allergens. These results may help us to design better treatments in the future for multi food allergic patients.

You have the right to refuse to allow your specimens to be saved for future study. If you do not allow us to use your specimens for the planned research now, you cannot be in the study. You may choose to allow us to do the currently planned research but not allow the specimens to be saved for future use. You may withdraw from this study at any time. The investigators might retain the identified specimens, e.g., as part of your routine clinical care, but not for additional research.

The results of the study of your specimens will be used for research purposes only and you will not be told the results of the tests.

Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of specimens do not retain any property rights

to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

_____ I consent to my specimens being saved for future research

_____ I do not consent to my specimens being saved for future research

Specimen Sampling for Genetic Testing

As part of the analysis on your specimens, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for the particular disease.

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.

The results of the study of your specimens from this project will be used for research purposes only, and you will not be told the results of the tests.

Genetic Information

Information from analyses of your coded specimens and your coded information will be put into one of the National Institutes of Health (NIH) databases along with information from the other research participants and will be used for future research. These databases will be accessible by the Internet. Only anonymous

information from the analyses will be put in a completely public database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study food allergen as instructed.
- Call the 24/7 on call number if you missed any doses or have any allergic reactions.
- 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.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study food allergen in a safe place, away from children and for your use only.
- Keep your electronic diary 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 Dr. Nadeau at (650) 724-0293.

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

- You will be asked to return to clinic for an end of study visit.
- You must return all study-related supplies, including unused study drug.

The Protocol Director may also withdraw you from the study and the study medication/food allergen may be stopped 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.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.
The potential discomforts with the desensitization procedure, food challenge and OIT may include an itchy rash, hives, nausea, abdominal discomfort, vomiting, diarrhea, facial swelling, cough, stuffy, runny nose, sneezing, wheezing, and shortness of breath. The major risks involved include severe breathing difficulties and rarely anaphylactic shock (severe allergic reaction involving many of the above symptoms plus sudden drop in blood pressure and loss of consciousness).

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A severe allergic reaction would require immediate medical treatment and could result in permanent disability or death. Medication, personnel, and equipment will be immediately available to treat allergic reactions at the clinic. You will also be provided a prescription for an Epinephrine autoinjector to have with you at all times and to use in case of an allergic reaction.

The other major concern besides anaphylaxis is eosinophilic esophagitis (EoE). EoE is a condition where a type of white blood cell (eosinophil) builds up in the tube that connects your mouth to your stomach (esophagus). This can cause stomach/chest pain, vomiting, regurgitation, and/or difficulty swallowing. It is possible that EoE may be reversed upon stopping the food allergen, but this is not certain.

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. You may be given topical steroid creams for application to the affected areas if needed.

Risks with blood draws include 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.

The risk of a lung function test is the discomfort of exhaling forcefully. This may be associated with mild shortness of breath, slight dizziness, temporary cough and/or chest discomfort. Most patients do not have any symptoms.

POTENTIAL BENEFITS

We cannot and do not guarantee or promise that you will receive any benefits from this study. You may benefit from a decrease in the sensitivity to your allergens and improve your immune protection to the offending food allergens. The knowledge gained from this study may aid in the advancement and understanding of food allergy and help in the development of new approaches for its treatment or prevention.

ALTERNATIVES

The alternative to participating is to continue food avoidance, which is the standard treatment for food allergic individuals.

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

CONFIDENTIALITY

Identifiers might be removed from identifiable private information or identifiable specimens and, after such removal, the information or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

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.

The purpose of this research study is to obtain data or information on the safety and effectiveness of cashew and shrimp oral immunotherapy; the results will be

provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as your information related to this study.

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?

The purpose of this study is to characterize the immune response in food allergic participants undergoing oral immunotherapy (OIT) with shrimp and cashew. The study doctor, Dr. Kari Nadeau, will use your personal health information to complete this research. Regulatory authorities such as the FDA and the IRB may also review or copy your information to make sure that the study is done properly or for other purposes required by law. The results of this study may be published in a medical journal and shown at medical meetings. You will not be identified (by name or any other means) in any of these publications.

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: Dr. Kari Nadeau, 269 Campus Drive, CCSR Building, Room 3215, Stanford, CA 94305.

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, your demographic information (including date of birth, gender, race/ethnicity, and medical record number), medical history, history of allergies, physical examinations, lab test results.

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 Dr. Kari Nadeau
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

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 National Institutes of health (NIH)
- The Food and Drug Administration
- Research collaborators outside of Stanford

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 December 31, 2100 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 (LAR) Date
(e.g., parent, guardian or conservator)

_____

Print Name of LAR

_____

LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

IRB Use Only
Approval Date: June 12, 2019
Expiration Date: June 12, 2020

FINANCIAL CONSIDERATIONS

Payment/Reimbursement
You will not be paid to participate in this research study.

Costs
There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.

Sponsor
The National Institutes of Health (NIH) and the Sean N. Parker Center for Allergy and Asthma Research are providing financial support and/or material for this study.

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.**

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 at (650) 724-0293. 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.

Appointment Contact: If you need to change your appointment, please contact snpcenterallergy.scheduler@stanford.edu

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;
- 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 will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Print Name of Other Parent or Guardian

_____
Authority to Act for Participant

The panel determined that this study falls under 21 CFR 50.53 and therefore two parent signatures are required.

The permission of the second 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

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

Participant ID:

STUDY