

CONSENT FOR ORAL IMMUNOTHERAPY (OIT)

INTRODUCTION & PURPOSE

Food allergy is a potentially life-threatening condition that affects approximately 5% to 10% of people in developed countries. The prevalence of allergy and anaphylaxis is increasing. Standard management has been strict food avoidance and preparedness with an epinephrine auto-injector in the event of a reaction. Despite efforts at avoidance, severe reactions may occur in up to a third of food allergic children. Quality of life is reduced because of the likelihood of anaphylaxis, causing constant fear over food choices. Reactions to food can be triggered by milligrams of exposure and are frequently severe, and sometimes life threatening.

Oral immunotherapy (OIT) is a proven treatment of food allergy. The purpose of OIT is to increase the threshold dose of the food trigger required to cause an allergic reaction, thereby providing protection from severe reactions in case of accidental exposure.² This does not mean that OIT is a substitute for avoiding the food trigger, or for the use of allergy medications, rather it is used as a supplement to those treatment measures.

INDICATIONS

To qualify for OIT, one must have physician-confirmed history of food allergy. If the diagnosis is not clear-cut, then a supervised oral challenge may be required before one is considered for OIT.

EFFICACY

Up to 75% of patients treated on OIT achieve desensitization (hyporesponsiveness; symptoms are reduced, although not always completely eliminated), and very few may achieve something called 'sustained unresponsiveness' (cured for life). Sustained unresponsiveness is more likely to be achieved when OIT is started at a younger age and with longer duration of therapy.

PROCEDURE

OIT is usually begun at a very low dose. This dosage is gradually increased on a regular basis until a therapeutic dose (called the "maintenance dose") is reached. The maintenance dose differs from person to person and will be determined by your physician. The dose is typically increased every 2 weeks (this is known as "build-up phase"). The initial dose and dose increases are done under clinical supervision for safety reasons. This bi-weekly frequency reduces the risk of reactions and helps achieve a maintenance dose in a reasonable amount of time. After the maintenance dose is determined, the OIT is usually given daily at the same dose.

DURATION OF TREATMENT

It usually takes about 4 – 8 months to reach a maintenance dose. The time may be longer if there are adverse reactions or if the therapy is not received on a regular basis. For this reason, it is important to follow the recommended schedule. If you anticipate that regular OIT cannot be maintained, it should not be started. OIT may be discontinued at the discretion of our physician if the therapy is frequently missed, or there is an increased frequency of adverse events to the OIT.

Once you reach the maintenance dose, you will no longer need to come to the clinic for biweekly up-dosing challenge. Since there is insufficient data on the long-term protective effect of OIT after maintenance is discontinued, we encourage patients who underwent OIT to continue to consume the maintenance dose at least every other day to maintain long-term tolerance.

If you miss the maintenance dose for more than 3 days, you may lose your tolerance to the food trigger. You will need to call Dr. Leung to discuss the options at that point. Please take this into consideration prior to agreeing to the OIT, with the facts that the protective effect of OIT may not be "permanent" and you will need to continue maintenance dose at least every other day to maintain long-term tolerance.

NEW MEDICATIONS

Please notify the office staff if you start any new prescription medication, particularly medication for high blood pressure, migraine headaches, and glaucoma. "Beta blocker" medications are contraindicated while on OIT.

PREGNANCY

Females of childbearing potential: If you plan to be pregnant in the next 6 months, we do not recommend initiating OIT. If you become pregnant while on OIT, notify the office staff immediately, so that our physicians can determine an appropriate dosage schedule for the OIT during pregnancy. Doses will not be advanced during pregnancy but may be maintained at a constant level.

ADVERSE EVENTS

Oral Immunotherapy is associated with some risks, particularly during the *build-up phase* of dosing. Risk is present because you will be consuming the food trigger, for which you have a known allergy. Reactions may be life-threatening and may require *immediate medical attention*.

Reaction	Symptoms	Frequency	Note
Oral and gastrointestinal side effects	You may experience oral swelling and itchiness, abdominal pain and vomiting.	Most common (up to 50%)	These reactions are more likely to occur as you reach the larger doses
Lower Respiratory symptoms	Cough, wheezing, shortness of breath.	2 nd most common (1/3)	
Hives	It may be generalized (on the whole body) or only to a specific location.	Around 24% experience this on their first day, and around 3% experience hives on home-dosing	Hives may occur within minutes to hours after introduction of a dose
Eosinophilic Esophagitis	Difficult and/or painful swallowing, heartburn, nausea & vomiting.	Reported in 3-8% of patients	Symptoms resolve with discontinuation of therapy
Angioedema	Swelling of any part of the body (ears, tongues, lips, throat, etc). May progress to suffocation due to swelling of airway.	Rare	May occur within minutes of administering OIT. It requires immediate medical attention and may require the use of epinephrine in case of anaphylaxis.
Anaphylaxis	Acute asthma, very low blood pressure, unconsciousness and potential death.	Rarest	

The above reactions are unpredictable and may occur with the first dose or after serial escalations in the dose, with no previous warning or reliable predictive factors. All generalized reactions require *immediate evaluation and medical intervention*. It is the very reason why the biweekly up-dosing needs to be performed at our center under Dr. Leung's supervision. If a localized or generalized reaction occurs, the OIT dosage will be adjusted for subsequent administrations based on Dr. Leung's recommendation. Dr. Leung's team have performed over 2000 supervised oral challenges over the years and are prepared and equipped to treat any allergic reactions.

MINIMIZING RISKS

It is recommended that OIT doses be administered following a meal or large snack, and physical activity should be restricted for one to two hours after dosing. In addition, dosing is suspended during active illness. Dosing is either resumed at the same dose, at home or under supervision in the office, or the dose is reduced and gradually escalated to pre-illness level, depending upon the number of missed doses. The doctor will prescribe an epinephrine autoinjector, instruct its directions for use, and give a detailed emergency anaphylaxis treatment plan. In addition, we suggest avoiding exercise 4 hours after the up-dosing challenge in the office to reduce the risk of delayed allergic reactions.

OBSERVATION PERIOD FOLLOWING THERAPY ADMINISTRATION

All patients receiving oral immunotherapy in the clinic should wait in the clinic area **for 30 minutes following each dose**. If you have a reaction, you may be advised to remain in the clinic longer for medical observation and treatment. If a generalized reaction occurs after you have left the clinic area, you should **immediately return to the clinic or go to the nearest emergency medical facility**. If you cannot wait the 30 minutes after your therapy, you should not receive oral immunotherapy. If you do not remain in the clinic area for the designated time, Dr. Leung will discontinue the oral immunotherapy.

FINANCIAL CONSIDERATION

OIT is very expensive but it may be covered by your insurance. We suggest you call your insurance before agreeing to proceed with OIT. Below are the CPT (billing codes) we will use to bill for the OIT.

On day 1 of OIT, we will charge you a level 4 follow-up visit (CPT 99214) with dose escalation over 6-8 hours (CPT 95180 times 6-8 units). On the biweekly up-dosing visit, we charge level 3 visit (CPT 99213) with a supervised oral challenge (CPT 95076). Treatment of allergic reaction, if any, will be charged extra and the billing depends on severity (whether you need epinephrine, oxygen, nebulizer and etc.). To clearly understand your financial responsibility, please also ask if you have any "deductible" or "co-insurance" and if you have any "co-pay" associated with follow up visits.

If you do not have insurance, we charge a **non-refundable and non-negotiable \$8000** for the OIT. The fee covers the first visit, serial up-dosing visits (up to 20 visits if needed) and professional fees for all in-clinic treatment of OIT-related allergic reactions. Medication fee (such as epinephrine, albuterol and etc.) is not included.

AGREEMENT

If you have questions concerning anything in this *Consent for Oral Immunotherapy*, please direct the questions to our staff. If you wish to begin oral immunotherapy, please initial and date each of the first three pages of this document, then sign the *Authorization for Treatment* (below) in the presence of a witness and return it to our front desk. Thank YOU.

**CONSENT FOR ADMINISTRATION OF ORAL IMMUNOTHERAPY
 AUTHORIZATION FOR TREATMENT**

I have read the information in this consent form and understand it. The opportunity has been provided for me to ask questions regarding the potential risks of oral immunotherapy, and these questions have been answered to my satisfaction. I understand that precautions consistent with the best medical practice will be carried out to protect me from adverse reactions to oral immunotherapy. I do hereby give consent for the patient designated below to be given oral immunotherapy over an extended period of time and at specified intervals, as prescribed. I further hereby give authorization and consent for treatment of any reactions that may occur as a result of oral immunotherapy.

Printed Name of Immunotherapy Patient	Date of birth
_____	_____

Patient Signature (or Legal Guardian)	Date Signed
_____	_____

Witness	Date Signed
_____	_____

FOR OFFICE USE ONLY:
 I certify that I have counseled this patient and/or authorized legal guardian concerning the information in this Consent for Immunotherapy and that it appears to me that the signee understands the nature, risks, and benefits of the proposed treatment plan.

Name	Date Signed
_____	_____

Instructions for Oral Immunotherapy (OIT)

Pre-therapy instructions

- 1. If you have asthma, please continue your daily inhaled steroid medications for asthma** (Flovent, Advair, Pulmicort, Symbicort, Asmanex) and/or Singular.
- 2. If you use albuterol, Xopenex or any bronchodilator medication more than two times (except prior to exercise) in the week before the oral immunotherapy, please contact our clinic.**
- 3. You can continue inhaled steroid nasal sprays** (Flonase, Nasonex, Rhinocort)
4. To minimize reactions to oral immunotherapy, please take an antihistamine the night before and the morning of Day#1, #2 and each 2-week visit.
5. Please inform the nursing staff if you have recent illness prior to the OIT. We might need to put the OIT on hold for safety reason.

What can you expect on your first day of the Oral Immunotherapy (OIT)?

The first day is called the “**dose-escalation day**”. Therapy can last for up to 8 hours. Please bring something to occupy yourself such as a laptop, book, tablet, etc. We request you arrive at our clinic on time at 8 am.

It is recommended that you do not have an empty stomach during the OIT. Bring plenty of healthy snacks throughout the day. Drink plenty of water and avoid dehydration.

Every 15 min you will have your vitals retaken and escalating doses will be given according to pre-determined protocol. We will also ask you to note any symptoms that you observe and report them immediately to us.

You will be carefully monitored for potential reactions. Your vital signs, oxygen saturation, breath sounds, and skin will be continuously monitored.

Please bring your auto-injectable epinephrine (Epi-Pen, Auvi-Q, or Twinject) to the appointment, to have it available after you have left the clinic. This is a precaution in case a delayed reaction occurs after leaving the clinic.

What to do after Day #1?

You will be given specific individualized recommendations depending on the outcome of day 1 treatment. If day 1 goes well, you will be asked to come back on the following day for 1 more oral challenge. The day 2 visit usually last 2 hours.

What to do after Day #2?

The dose you have tolerated on Day #2 without any symptoms will be the dose you go home with and take *every day* until your next visit with us in 2 weeks. Every 24hrs (range 22-26hrs), the daily dose needs to be consumed. You do not need to take antihistamines for this 2 week.

Do not consume any other brand of protein other than what we prescribe!

Dose Escalations: What to expect in subsequent visits?

1. Every 2 weeks, you will return to the clinic for elevation of the dose. Dose escalation must only be performed and supervised by Dr. Leung. It is too dangerous to do it at home without medical supervision. **Please take a dose of antihistamine the night before and the morning of the visit.**
2. In the clinic the next escalated dose will be given. You will then be monitored for one hour. You can expect to stay in the clinic for a total of about 2 hours. If you are asymptomatic then you will go home on the daily dosing of the new amount of peanut.
3. Please bring your auto-injectable epinephrine (Epi-Pen, Auvi-Q, or Twinject) to the appointment, to have it available after you have left the clinic. This is a precaution in case a delayed reaction occurs after leaving the clinic.
4. If you develop any reactions to the escalated dose, we will hold the dose, and continue the dose previously tolerated for 2 weeks at home. We will again give you the escalated dose after 2 weeks.
5. **No escalations are to be undertaken at home, for any reason!**
6. If you are symptomatic at home, please notify us immediately. Administer epinephrine for anaphylaxis as indicated. Do not wait for call back from Dr. Leung's office in case of medical emergency and call 911.

Maintenance

After serial dosing elevations in the build-up phase (usually takes 18-34 weeks), maintenance dose will be reached. Dr. Leung will determine the optimal maintenance dose on a case to case basis. You will need to continue taking the daily maintenance dose for at least 3-5 years or may be longer. Research Studies have suggested that patients on a longer duration of OIT are more likely to achieve sustained unresponsiveness,



which is a state of permanent tolerance to peanuts, i.e., no recurrence of clinical allergy upon reintroduction of peanuts in a person not on the maintenance dose.

Please do not hesitate to call our clinic for any questions or concerns: 617-804-6767.