

## ALLERGEN IMMUNOTHERAPY INFORMATION AND CONSENT

### The Pediatric Lung and Allergy Center

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Patient name: \_\_\_\_\_ Date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_ Today's date: \_\_\_\_\_

### A SIGNED COPY OF THIS DOCUMENT MUST BE KEPT IN THE PATIENT'S MEDICAL FILE.

**WHAT IS IMMUNOTHERAPY?** Immunotherapy (allergy injections) is the process by which an "allergic" patient is made less sensitive to a specific allergy (for example, pollens, mold spores, animal dander, dust mites). This reduction in sensitivity is accomplished by repeated injections of increasing doses of extracts (mixtures) of these allergens beneath the skin of the upper arm. With reduced sensitivity, you will have fewer and less severe symptoms upon re-exposure to allergy-causing substances. This is considered a common treatment for allergic diseases.

**WHAT RESULT SHOULD I EXPECT FROM IMMUNOTHERAPY? HOW EFFECTIVE IS IMMUNOTHERAPY?** Reduction of allergen sensitivity is the goal of immunotherapy. Improvement in your symptoms will not be immediate and may take 6-18 months before any relief of allergy symptoms occurs. It may take up to 18-24 months for full benefits to be evident. Allergy medications may be continued while you are on immunotherapy. Studies with allergic rhinitis have demonstrated a 60-70% reduction in symptoms with a concomitant 70% decrease in need for medications. Venom IT reduces an individual's risk of recurrent anaphylaxis from approximately 60% down to approximately 2-3%. In allergic asthma, multiple clinic trials have demonstrated that immunotherapy reduces both symptoms and medications.

**HOW OFTEN ARE THE INJECTIONS GIVEN?** Immunotherapy injections are typically given once or twice a week beginning at a very low dose. The dose is very gradually increased at each visit. Minimum interval between injections is 48 hours. Once the highest dose, the "maintenance dose", is attained (which may be after 28 weekly or bi-weekly injections), the frequency of injections is gradually decreased to once monthly. It typically takes 7 months to reach a maintenance dose if injections are given weekly and 3 ½-4 months if injections are given bi-weekly, but this interval may be longer if there are vaccine reactions or if injections are not received on a regular basis. The total duration of immunotherapy is usually 3-5 years at which time re-evaluation is required.

**ARE THERE ANY SIDE EFFECTS TO IMMUNOTHERAPY?** Because you or your child will be receiving injections of substances to which the recipient is allergic, reactions to the injections may occur. It is not unusual for swelling and itching to occur at the site of an injection causing a local reaction. However, local reactions can involve the entire upper arm. These reactions typically occur within 30 minutes of an injection, but may occur several hours afterwards. Please notify the nurse if your local reaction exceeds two inches in diameter or lasts until the following day.

Generalized reactions rarely occur and they include generalized itching, hives, tightness in the throat or chest, coughing, wheezing, lightheadedness, faintness, nausea and vomiting, and anaphylactic shock, the last under extreme conditions. Reactions, even though unusual, can be serious and rarely, fatal. These uncommon reactions usually occur within minutes of the injection and require immediate medical attention and intervention.

To monitor for such reactions, injections must be given in a physician's office, where provisions for treating anaphylactic reactions are available. **All patients receiving immunotherapy injections must remain in the waiting room of the office for observation for 30 minutes following each injection.** If the patient is 17 years of age or younger, a parent or legal guardian must be present during the observation period. If you have a reaction, you may be advised to remain in the office longer for medical observation/treatment. **If a generalized reaction occurs after you have left the office, you should go to the nearest emergency medical facility or call 911.** While most generalized reactions are not life-threatening if treated promptly, this fact highlights the importance of remaining in the office for the required observation time of 30 minutes.

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Occasionally, side effects may occur after the thirty (30) minute waiting period. You should report any reactions to an injection to your board certified allergist so that an adjustment in the dosage of your next injection can be made.

**HOW MUCH DOES IMMUNOTHERAPY COST?** Immunotherapy extracts are prepared under controlled conditions by a trained physician or technician. Each patient’s prescription is prepared according to his or her specific sensitivities and would not be useable by any other patient. The total cost of an extract set may be requested from the billing office prior to mixing.

**ARE THERE PERSONS WHO SHOULD NOT RECEIVE IMMUNOTHERAPY?** Generally you should not receive an injection if you are having a fever, wheezing in the past 12 hours, or hives. You may receive an injection if you have a mild cold. You should avoid strenuous exercise/activity for two hours after your injection.

**ARE THERE ALTERNATIVES TO IMMUNOTHERAPY?** You should discuss with your board certified allergist the alternatives to immunotherapy which are available to you, such as avoidance and medications, before you consent to immunotherapy treatment. The allergist can explain the benefits and risks associated with these alternatives. In reality, some patients will require a combination of avoidance measures, medications, and immunotherapy to adequately control their symptoms.

**ALLERGY INJECTIONS CANNOT BE GIVEN TO PATIENTS WHO ARE CURRENTLY TAKING BETA-BLOCKER MEDICATIONS.** Examples of beta-blockers include Inderal, Atenolol, and Lopressor as well as beta-blocker eye drops, including Timolol. Consult your physician or pharmacist if you are not sure about a specific medication. Beta-blockers may be given for a variety of conditions, including hypertension (high blood pressure), angina (heart pain), thyroid disease, arrhythmias (abnormal heart beat), and certain psychiatric disorders.

**ALLERGY INJECTION SCHEDULE:** Allergy injections are offered in our office on a scheduled basis. A minimum of 48 hours is necessary between injection visits.

- Monday: 8:30 am to 4:20 pm**
- Tuesday: 8:30 am to 4:20 pm**
- Wednesday: 8:30 am to 4:20 pm**
- Thursday: 8:30 am to 4:20 pm**
- Friday: 8:30 am to 1:00 pm**

**CONSENT TO RECEIVE IMMUNOTHERAPY:** I have read (if a new patient) or re-read (if an established patient) and understand the patient information on immunotherapy. The opportunity has been provided for me to ask questions regarding the potential side effects of immunotherapy and these questions have been answered to my satisfaction. I understand that every precaution consistent with the best medical practice will be carried out to protect me against such reactions. I also agree that if I have an allergic reaction to the injections that the physician-in-charge has permission to treat said reaction.

I acknowledge the fact with my signature that I am authorizing the office to bill for the allergen vaccines, even if, for any reason, I decide not to initiate the allergen immunotherapy after the vaccine has been made. If you consent to receive, or to allow your child to receive immunotherapy, now and in the future, please sign on the line indicated below.

\_\_\_\_\_  
Signature of Patient or Legal Guardian

\_\_\_\_\_  
Date and Time of Signature

\_\_\_\_\_  
Printed Name of Patient or Legal Guardian

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date and Time of Signature

\_\_\_\_\_  
Printed Name of Witness

**ALLERGEN IMMUNOTHERAPY INFORMATION AND CONSENT**

Emergency Contact \_\_\_\_\_

Phone \_\_\_\_\_

**I certify that I and/or my staff have counseled the patient and/or legal guardian concerning the information in this Consent for Immunotherapy. I certify that the immunotherapy procedure was explained to the patient and/or legal guardian, including anticipated benefits, material risks, and alternative therapies. It appears to me that the above signee understands the nature, benefits, and risks of allergen immunotherapy.**

\_\_\_\_\_  
Anne C. Miranowski, M.D.

\_\_\_\_\_  
Date and Time of Signature