



CONSENT FOR ADMINISTRATION OF CONVENTIONAL IMMUNOTHERAPY

PLEASE READ AND BE CERTAIN THAT YOU UNDERSTAND THE FOLLOWING INFORMATION PRIOR TO SIGNING THIS CONSENT FOR TREATMENT.

PURPOSE

The purpose of allergen immunotherapy (“allergy shots”) is to decrease your sensitivity to allergens to which you are allergic, so future exposures to those substances will result in fewer and less severe symptoms. The best treatment of an allergy is to avoid a known allergen, and allergy shots do not substitute for avoidance. Allergy shots are used for supplemental treatment of allergies, along with allergy medications.

Allergy shots have been shown to result in the formation of “blocking” (also known as protective) antibodies, and a gradual decrease in allergic antibody levels. These changes in your immune system may allow you to tolerate exposure to the allergen with fewer symptoms. The end result of this change is that you become more “tolerant” of the offending allergen(s). This effect is different in each person and is therefore unpredictable.

INDICATIONS

It has been determined that you are a candidate for allergy shots. To qualify, you must have documented sensitivity to an allergic substance. This may be documented through allergy skin testing or allergy blood tests. In addition, you should have symptoms, whether they are nasal, eye, respiratory, or a reaction to an insect sting, upon exposure to the substance to which you are allergic. Due to the risks involved in immunotherapy, avoidance measures and medicines are usually attempted first.

EFFECTIVENESS

Improvement in your allergy symptoms is not immediate, and your allergies may in fact worsen initially while starting your allergy injections. Patients may not begin to see improvement in symptoms for 3-6 months, and full benefits may not be evident for 12-24 months. A majority of patients improve while on allergy shots, which means that symptoms are reduced, but not necessarily completely eliminated.

PROCEDURE

The allergy shot is a mixture of the allergens to which you are allergic. When you begin receiving your allergy shot, this mixture is diluted so that your body will be less likely to react to the shot. Your allergens may be divided into one, two, or three shots. The dose is increased regularly, usually once or twice a week, until your full strength shot (“maintenance dose”) is achieved. The maintenance dose will differ from person to person. Once you achieve your maintenance dose, you will receive this dose every 1-6 weeks, depending on your individual circumstance.

DURATION OF TREATMENT

The time it takes you to achieve a maintenance dose will vary, but usually it takes 6-9 months. Factors that influence the time it takes you to reach your maintenance dose include missed shots or reactions to your shots. For this reason, it is recommended that the immunotherapy schedule be followed. If you anticipate that it will be difficult for you to get your allergy shot on a routine basis, immunotherapy should not be started. Immunotherapy may be discontinued at the discretion of your doctor if injections are frequently missed, as there is an increased risk of reactions under these circumstances. It is currently recommended that immunotherapy be continued for a period of 3-5 years, at which point the need for further allergy shots is reassessed.

ADVERSE REACTIONS

Immunotherapy is a treatment that may be used to treat both non-life threatening medical conditions (e.g. allergic rhinitis, allergic conjunctivitis), as well as a potentially life threatening medical conditions (e.g. asthma, venom sensitivity). As such, immunotherapy is associated with some widely recognized risks. Risk is present because a substance to which you are known to be allergic is being injected into you. Some adverse reactions may be life-threatening and may require immediate medical attention. Some of these potential adverse reactions are the following:

- A. **LOCAL REACTIONS:** Local reactions are common and are usually restricted to a small area around the site of the injection. However, they may involve the entire upper arm, with varying degrees of redness, swelling, pain, and itching. These reactions are more likely to occur as you reach the higher concentrations and higher volume injections. The reactions may occur several hours after the injection. You should notify the medical staff if your local reaction is uncomfortable or exceeds two inches in diameter or lasts until the following day.

- B. **SYSTEMIC REACTIONS:** Systemic reactions occur rarely, but are the most significant adverse reaction because of the potential danger of progression to collapse and death if not treated. Although it is the rarest of the recognized complications, death has occurred as a result of allergen immunotherapy. Systemic reactions may include:
 - a. **Rhinoconjunctivitis** or an increase in your nasal/eye allergy symptoms.
 - b. **Urticarial reactions (hives)** include varying degrees of rash, flushing, swelling, and/or itching of more than one part of the body. There may be mild to moderate discomfort, primarily from the itching. This reaction may occur within minutes to hours after an injection.
 - c. **Angioedema** is rare and is characterized by swelling of any part of the body, inside or out, such as the ears, tongue, lips, throat, intestine, hands or feet, alone or in combination. This may occasionally be accompanied by asthma and may progress to the most severe reaction, anaphylactic shock. In the absence of shock, the principal danger lies in suffocation due to swelling of the airway. Angioedema may occur within minutes after the injection and requires immediate medical attention.
 - d. **Anaphylactic shock** is a very rare complication, but is a serious event characterized by acute asthma, vascular collapse (low blood pressure), unconsciousness, and potentially death, usually occurring minutes after a shot.

The previously listed reactions are unpredictable and may occur with the first injection or after a long series of injections, with no previous warning. *All generalized reactions require immediate evaluation and medical intervention.* If a localized or generalized reaction occurs, the vaccine dosage may be adjusted for subsequent injections. Appropriate advice and treatment will be available from our office staff after a reaction.

OBSERVATION PERIOD FOLLOWING INJECTIONS

All patients receiving immunotherapy injections should wait in the clinic area *at least 30 minutes following each injection.* If you have a reaction, you may be advised to remain in the clinic longer for medical observation and treatment, and your future waiting times may lengthen. 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 injection, you should not receive an injection.* There have been allergen immunotherapy related deaths in the United States, and this fact does stress the importance of remaining in the clinic for the suggested observation time. Most systemic reactions are not life-threatening if treated promptly. If you do not remain in the clinic area for the designated time, the doctor may recommend the discontinuation of immunotherapy.

Under no circumstances will injections be permitted without the immediate availability of emergency medical treatment. If the prescribed injections are given elsewhere, our clinic must be provided with the name and address of the physician who will assume the responsibility for your injections. You will be asked to complete the *“Request for Administration of Immunotherapy at an Outside Medical Facility.”* Our office will then contact the designated facility and confirm their availability for administration of your immunotherapy injections.

INITIAL EXTRACT PRESCRIPTION

Your initial prescription includes all vaccine vials that are required to reach a “maintenance” dose. In order to utilize these vials prior to their expiration date, you will need to receive injections at least once a week on a regular basis. Taking injections twice per week will allow you to reach maintenance earlier, well before the expiration date of your extract.

PREGNANCY

Females of child-bearing potential: If you become pregnant while on immunotherapy, please notify the office staff immediately, so your doctor can determine an appropriate dosage schedule for the injections during pregnancy. Immunotherapy doses will not be advanced during pregnancy, but may be maintained at a constant level.

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” and “ACE Inhibitor” medications are relatively contraindicated while on immunotherapy, and your injections may need to be discontinued if you are taking, or begin taking, a beta-blocker or ACE Inhibitor.

ACKNOWLEDGEMENT

I acknowledge that I have discussed with my physician the benefits and risks of allergen immunotherapy and that my questions have been answered.

In addition, you may receive: *Information/consent form for RUSH immunotherapy.*

If you have any questions concerning anything in this Consent for Immunotherapy, please direct the questions to one of the medical personnel in the office. If you wish to begin immunotherapy, please initial each of the first two pages and sign the Authorization for Treatment below and return it to the front desk. Thank you.

**CONSENT FOR ADMINISTRATION OF CONVENTIONAL IMMUNOTHERAPY (ALLERGY INJECTIONS)
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 immunotherapy and these questions have been answered to my satisfaction. I understand that precautions consistent with the usual medical practice will be carried out to protect me from adverse reactions to immunotherapy. I do hereby consent for the patient designated below to be given immunotherapy (allergy injections) over an extended period of time and at specified intervals, as prescribed by the physician. I further hereby give authorization and consent for treatment, by the physicians and their staff, of any reactions that may occur as a result of an immunotherapy injection.

Printed name of Immunotherapy Patient

DOB

Patient signature (or Legal guardian)

Date signed

For office use only:

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

Physician

Date signed