

IMMUNOTHERAPY

Consent Form

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

Purpose

The purpose of immunotherapy (allergy injections) is to decrease your sensitivity to allergy-causing substances, so that exposure to the offending allergens (pollen, animals, mites, insects, etc.) will result in fewer and less-severe symptoms. This does not mean that immunotherapy is a substitute for avoidance of known allergens or for allergy medications.

Indications

To qualify for immunotherapy, you must be allergic to one or more environmental substances that you cannot avoid. You may have hay fever or asthma that occurs upon exposure to suspected allergens or you may have a history of severe reaction to an insect sting. Because of risks associated with immunotherapy, avoidance measures and medical management usually should be attempted first.

Efficacy

Improvement in your symptoms will not be immediate. It usually requires *three to six months* before any relief of allergy symptoms is noted, and it may take 12 to 24 months for full benefits to be evident. Usually 85% to 90% of allergic patients on immunotherapy note significant improvement of their symptoms. This means that symptoms are reduced, although not always eliminated.

Procedure

Allergy injections usually are begun at a very low dose. This dosage is gradually increased on a regular (usually weekly) basis until a therapeutic dose (often called the “maintenance dose”) is reached. The maintenance dose will differ from person to person. Injections typically are given once or twice a week while the allergen dose is being increased. This frequency reduces the chances of a reaction and permits the maintenance dose to be reached within a reasonable amount of time. After the maintenance dose is determined, the injections may be given every one to four weeks.

Duration of Treatment

It usually takes three to six months to reach a maintenance dose. The time may be longer if there are allergy shot reactions or if the injections are not received on a regular basis. For this reason, it is important that the recommended schedule of injections be followed. If you know that you cannot receive regular injections, immunotherapy should not be started. Allergy injections may be discontinued at the discretion of your physician if injections are frequently missed, as there is an increased risk of reactions under these circumstances. Most immunotherapy patients continue treatment for three to five years, after which the need for continuation is reassessed.

Adverse Reactions

Allergy injections are associated with some widely recognized risks. The risk is present because a substance to which you are known to be allergic is being injected into you. Some adverse reactions to allergy injections are potentially life threatening and may require *immediate medical attention*. Here are brief descriptions of the kinds of possible reactions, listed in order of increasing severity:

A. Local Reactions

Local reactions are common and usually are 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 nurse if your local reaction exceeds two inches in diameter or lasts until the following day.

B. Generalized Reactions

Generalized reactions occur rarely, but are the most important because of the potential danger of progression to low blood pressure and death if not treated. All generalized reactions require immediate evaluation and medical intervention. Generalized reactions may be of one or more types:

1. **Urticarial reactions (hives)** include rash, swelling and itch of more than one part of the body. There may be mild-to-moderate discomfort, primarily from the itching. This uncommon reaction may occur within minutes to hours after an injection.
2. **Angioedema** is swelling of any part of the body, inside or out, such as the ears, tongue, lips, throat, intestine, hands or feet, alone or in any combination. This occasionally may be accompanied by asthma or difficulty with breathing and may progress to the most severe reaction, anaphylactic shock. In the absence of shock, the principal danger lies in suffocation resulting from swelling of the airway. Angioedema may occur within minutes after the injection and requires immediate medical attention.
3. **Anaphylactic shock** is acute asthma, vascular collapse (low blood pressure), unconsciousness and potentially death. This reaction usually occurs within minutes of the injection and is extremely rare.

The above generalized 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 immunotherapy dosage will be adjusted. Appropriate advice and treatment will always be available from our office staff at the time of any adverse reaction.

Observation Period Following Injections

All patients receiving immunotherapy injections should wait in the physician's office **for 30 minutes after each injection**. If you have a reaction, you may be advised to remain longer for medical observation and treatment. If a generalized reaction occurs after you have left the physician's office, you should **immediately** return to the office, go to the nearest emergency medical facility, or call **911**. If you cannot wait the 30 minutes after your injection, you should not receive an immunotherapy injection.

There are several allergy shot-related deaths each year in the United States. Most generalized reactions are not life threatening if treated promptly. You should wait in your doctor's office for the suggested observation time to be close to emergency treatment if needed. If you do not remain in the office for the designated time, your doctor may recommend that you discontinue immunotherapy.

Under no circumstances will injections be given without the immediate availability of emergency medical treatment. If the prescribed injections are to be given elsewhere, you must provide 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 Allergy Injections at an Outside Medical Facility."

Pregnancy

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately so that the physician 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 or glaucoma. "Beta blocker" medications, often prescribed for heart diseases, are usually not allowed while on immunotherapy. Your injections may have to be discontinued if you take a beta blocker. Your physician will have to evaluate the risk/benefit in these circumstances.

Questions

If you have questions concerning anything in this consent for immunotherapy, please direct the questions to the nurses or to the physician. If you wish to begin immunotherapy, please sign the *Authorization for Treatment* (Page 4).

**Consent for 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 every precaution consistent with the best medical practice will be carried out to protect me from adverse reactions to immunotherapy. I do hereby give consent for the patient designated below to be given immunotherapy (allergy injections) over an extended period of time and at specified intervals, as prescribed. I hereby give authorization and consent for treatment by Bonnie B. Baswell, M.D., Eric L. Caplan, M.D., and staff, including authorization and consent for treatment of any reactions that may occur as a result of an immunotherapy injection.

If my insurance plan does not pay for the antigen or injections, I will be responsible for the payments myself. I understand that I am responsible for any co-pays or the portion of charges not covered by insurance.

Patient Signature (or Legal Guardian)

Date Signed

Printed Name of Immunotherapy Patient

Date of Birth

Witness

Date Signed

I will be receiving my allergy injections at the following location:

Audubon

Northcare

Monument

Lake Plaza (South)

Other: _____

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

_____, M.D.

Date Signed