

**ALLERGY, ASTHMA AND IMMUNOLOGY
PAUL D. NIOLET, MD**

**CONSENT FOR ADMINISTRATION OF ALLERGEN IMMUNOTHERAPY
(ALLERGY INJECTIONS)**

**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 allergen (pollen, mold, mites, animal dander, stinging 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 the use of allergy medications, but rather is a supplement to those treatment measures.

Allergy injections have been shown to lead to the formation of “blocking” or protective antibodies and a gradual decrease in allergic antibody levels. These changes may permit you to tolerate exposure to the allergen with fewer symptoms. You, in effect, become “immune” to the allergen. The amount of this immunization is different for each person and is, therefore, somewhat unpredictable.

INDICATIONS

To qualify for immunotherapy, there must be documented allergy to substances in the environment that cannot be avoided. Documentation of allergy can be either in the form of a positive skin test or a positive blood test. In addition to demonstrable allergy by one of the above tests, problems such as hay fever or asthma should occur upon exposure to the suspected allergen, or you may have a history of a severe reaction to an insect sting. Due to the inherent risks of immunotherapy, avoidance measures and medical management should usually be attempted first.

EFFICACY

Improvement in your symptoms will not be immediate. It usually requires 3 to 6 *months* before any relief of allergy symptoms is noted, and it may take 12 to 24 months for full benefits to be evident. About 85-90% of allergic patients on immunotherapy note significant improvement of their symptoms. This means that symptoms are reduced, although not always completely eliminated.

PROCEDURE

Allergy injections are usually begun at a very low dose. The dosage is gradually increased on a regular basis (usually 1-2 times per week) 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 per week while the vaccine 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 can usually be given every one to three weeks.

DURATION OF TREATMENT

It usually takes 3 to 6 months to reach a maintenance dose. The time may be longer if there are vaccine reactions or if the injections are not received on a regular basis. For this reason, it is important that the recommended schedule be followed. If you anticipate that regular injections cannot be maintained, immunotherapy should not be started.

Immunotherapy may be discontinued at the discretion of Dr. Niolet if the injections are frequently missed, as there is an increased risk of reactions under these circumstances. Most immunotherapy patients continue treatment for 3-5 years, after which the need for continuation is reassessed.

ADVERSE REACTIONS

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 in you. Some adverse reactions may be life threatening and may require *immediate medical attention*. In order of increasing severity, the following brief descriptions explain the nature of these potential reactions:

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 of 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 collapse and death if not treated. These reactions may include:

(1) Urticarial reactions (hives) include varying degrees of rash, swelling, and/or itching 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 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 any combination. This may occasionally be accompanied by wheezing and may progress to the most severe reaction, anaphylactic shock. In the absence of shock, the principle danger lies in suffocation due to swelling of the airway. Angioedema may occur within minutes after the injection and requires immediate medical attention.

(3) Anaphylactic shock is the rarest complication, but is a serious event characterized by acute asthma, vascular collapse (low blood pressure), unconsciousness, and potentially death. This reaction usually occurs within minutes of the injection and is extremely rare.

Early symptoms may include eye itching/tearing, runny nose, vocal changes, such as hoarseness, nausea, vomiting, diarrhea, and stomach or menstrual cramping.

The above reactions are unpredictable and may occur with the 1st 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 will be adjusted for subsequent injections. 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 inside the clinic area **for 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. 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 are several allergy vaccine-related deaths each year in the United States. While most generalized reactions are not life-threatening if treated promptly, this fact does stress the importance of remaining in the clinic for the suggested observation time. If you do not remain in the clinic area for the designated time, the doctor may recommend discontinuation of immunotherapy.

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 per week on a regular basis*. If you take injections once per week regularly, you will reach maintenance level at about the same time as the expiration date. When you receive regular maintenance injections, the renewal vials generally last 3-4 months.

PREGNANCY

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately, so that Dr. Niolet 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 are contraindicated while on immunotherapy, and your injections will need to be discontinued while you are taking a beta-blocker.

MINORS

Patients that are less than 18 years of age must be accompanied by a parent or legal guardian for all injections. The parent or legal guardian must remain with the patient.

**CONSENT FOR ADMINISTRATION OF 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 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 by Paul D. Niolet, MD. I further hereby give authorization and consent for treatment, by Dr. Niolet and his staff, of any reactions that may occur as a result of an immunotherapy injection.

Printed Name of Immunotherapy Patient

Medical Record Number

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.

Paul D. Niolet, M.D.

Date Signed