

## **Consent for Administration of Immunotherapy and Testing (Allergy Injections)**

**Please read and be certain that you understand the following information prior to signing this form**

### **Purpose:**

The purpose of immunotherapy (allergy injections) is to decrease your sensitivity to allergy causing substances, so that exposure to the offending allergens (pollens, mold, mites, animal dander, stinging, insects, etc) will result in fewer and less severe symptoms. This does not mean that immunotherapy is a substitution for avoidance of known allergens or 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 allergens with fewer symptoms. You, in effect, become "immune" to the allergens. The amount of this immunization is different for each person and is, therefore, somewhat unpredictable.

### **Indications:**

For quality immunotherapy, there must be documented allergy to substances in the environment that cannot be avoided. Documentations of allergy can be either in the form of a positive skin test or a positive blood test (RAST/ELISA). In addition to demonstrable allergy by one of the above test, problems such as hay fever or asthma should occur upon exposure to the suspected allergens, or you may have a history of a severe reaction to an insect sting. Due to the inherent risk of immunotherapy, avoidance measures and medical management should usually be attempted first.

### **Efficacy:**

Improvements 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 12-24 months for full benefits to be evident. About 85-90% of allergic patients on high-dose immunotherapy note significant improvement of their symptoms. This means that symptoms are reduced, although not always completely eliminated.

### **Procedures:**

Allergy injections are usually begun at a very low dose following your skin test. This dosage is gradually increased on a regular basis (1-2 times per week) until the therapeutic dose (often called the "maintenance" dose) is reached. The maintenance dose will differ from person to person. Injections typically are given once to twice per week while the vaccine dose is being increased. The frequency reduces a chance of reaction and permits the maintenance dose to be reached within a reasonable amount of time.

### **Duration of Treatment:**

It usually takes 3-6 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 the physician if the injections are frequently missed, as there is an increased risk of reactions under these circumstances. Most immunotherapy patients continue treatment for 3 to 5 years, after which the need for continuation is reassessed.

### **Adverse Reactions:**

Immunotherapy is associated with some widely recognized risks. Risk is present because the substance to which you are known to be allergic, is injected into 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* are common and are usually restricted to a small area around the site of the injection. However, they may involve the entire upper area, with varying degrees of redness, swelling, pain, and itching. These reactions are more likely to 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* 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:
  - \* **Urticarial reactions (hives)** including 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 reaction may occur within minutes to hours after an injection.
  - \* **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 asthma 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 airways. Angioedema may occur within minutes after the injections and requires medical immediate attention.
  - \* **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.

The above reactions are unpredictable and may occur with the first injections or after a long series of injections with no previous warning. All generalized reactions require immediate evaluations and medical interventions. If a localized or generalized reaction occurs, the vaccine dosage will be adjusted for subsequent injections. Appropriate advice and treatment will always be from our office staff at the time of any adverse reaction

**Observation Period Following Injection**

All patients receiving immunotherapy injections should wait in the clinic area for 30 minutes following the first three injections, then as determined by physician/nurse. 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 medical facility. If you cannot wait the 30 minutes after your injection, you should not receive an immunotherapy injection. There are several allergy vaccine related deaths each year in the United States. While most systemic reactions are not life threatening if treated promptly, the 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 (6 months from date of preparation), you will need to receive injections at least once per week on a regular basis. Taking injections twice per week will allow you to reach the maintenance level sooner (at around 3 months). When you receive regular maintenance injections, the renewal vials generally lasts 2-3 months.

**Pregnancy**

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

I have read the information in this consent form and understand it. I have had ample opportunity to ask questions regarding the potential risk 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 reactions to allergy injections over an extended period of time and specified intervals. I further hereby give authorizations and consent for treatment of any reactions that may occur as a result of an immunotherapy reaction.

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Print Name of patient

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Date of Birth

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Patient signature (or legal Guardian)

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Today's Date