

Ear, Nose, and Throat Consultants Inc.

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SUBLINGUAL IMMUNOTHERAPY CONSENT FORM

We look forward to helping you treat the cause of your allergies and working toward better quality of life.

Please take a moment to read over the following background information on Allergy Drops, also known as Sublingual Immunotherapy (SLIT):

The substances that trigger a patient's allergies are called allergens. Immunotherapy is a treatment where small amounts of these allergens are delivered by injection (needle) or sublingually (under the tongue via allergy drops) to alter the patient's immunity. Some doctors call this an "allergy vaccine," and the goal is to develop tolerance to the allergens that cause your symptoms.

The allergens used for allergy drops are the same as those used for injections. However, the FDA has specifically approved the allergens for injection use. Using them for SLIT is considered an "off-label" use. Off-label use in the US healthcare delivery system is a legitimate, legal and common practice. The protocol we follow has been used in the United States for more than 40 years.

Dozens of research studies show that allergy drops are a safe, effective form of immunotherapy. Allergy drop treatment takes 3-5 years for most patients to complete, however, some patients may respond differently based upon the severity of their allergies. Like injection immunotherapy, a small percentage of patients may not respond well or at all to allergy drop treatment, or the allergy drop treatment may even worsen symptoms or cause a reaction. In order of increasing severity, the following brief descriptions explain the nature of these potential reactions:

A. LOCAL REACTIONS: Local reactions from SLIT are uncommon and are usually restricted to a mouth itching or stomach upset. These reactions are more likely to occur at the very beginning of treatment or as you reach the higher concentrations of antigens in your drops. The reactions usually occur immediately after taking a dose, but can occur hours after. Most of the time these reactions resolve themselves, or with simple dose adjustments. Antihistamine can be used as normally directed. You should notify your Provider if you have these reactions for over one hour.

B. GENERALIZED REACTIONS: Generalized reactions occur very rarely, but are the most important because of the potential danger of progression to more severe conditions. These reactions may include:

(1) Urticaria 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 typically occurs within minutes of taking a dose.

(2) Angioedema has not been reported using our protocol, but has been reported with other protocols, it is extremely rare, 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 symptom onset 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 allergy drop is taken and requires immediate medical attention.

(3) Anaphylactic shock is the rarest complication and has not been reported with our protocol, and has only been reported a small number of times using other SLIT protocols, but it is a serious event characterized by acute asthma, vascular collapse (low blood pressure), unconsciousness, and potentially death and the possibility of it happening does exist. If you have a history of these types of reactions you are required to have an epinephrine injector available to you when taking drops.

The above reactions are unpredictable and may occur with the first sublingual dose administration or after a longer time of taking the drops, with no previous warning. All generalized reactions require immediate evaluation and medical intervention. If a localized or generalized reaction occurs, the drop dosage will be adjusted for subsequent treatment.

Appropriate advice and treatment will always be available from our office staff at the time of any adverse reaction. Consult with your Provider immediately if these reactions occur, or if you decide to discontinue treatment for any reason.

Missed doses and resuming treatment: If more than one day of doses is missed, do not try to “catch up” by taking more than once daily prescribed dose. If 2 to 14 days are missed, you may resume taking your drops daily as prescribed. If more than 14 days are missed, you should contact your Provider to discuss restarting. There are typically few problems with resuming your drops after any period of time if you had been taking them successfully, but it is recommended that you check in with your Provider before resuming treatment.

_____ I understand that allergy drops are an off-label use of FDA-approved allergenic extracts, that I have read this consent form, have had opportunity to ask questions about the treatment plan, and that my questions were answered satisfactorily.

_____ I agree to contact my doctor if I miss more than 14 days of drops, or if I decide to discontinue treatment for any reason.

Patient Name/(Guardian)_____

Signature:_____ Date:_____

Witness:_____ Date:_____