

## Virginia Ear, Nose & Throat

### SUBLINGUAL IMMUNOTHERAPY CONSENT FORM

Sublingual (under the tongue) immunotherapy (SLIT) is given as a 50% glycerin solution containing up to 11 of the most reactive allergens as determined by prick, intradermal or blood testing methods. Patients receive increasing doses (escalation) from 1 to 5 drops of the solution over 10 days. The drops are given under the tongue and held for 2 minutes. Dosing is daily and done at home. There have been no episodes of anaphylaxis or severe allergic reactions in over 40 years of experience in Europe and this country, mainly the Midwest. The worst reactions have been swelling under the tongue or mild stomach upset, easily corrected with dose adjustment. SLIT therefore avoids patients having to come to the office weekly for immunotherapy and it allows a greater number of patients to utilize immunotherapy in the treatment of their allergies. It also allows us to treat patients who are not good candidates for shots (e.g., children and adults with multiple medical problems) because of its safety profile.

Although more routinely used in Europe, SLIT is considered an experimental therapy in the U.S. and is being studied by multiple Allergy societies. The use of the standardized allergy serums typically administered via shots (i.e., subcutaneous immunotherapy) as of today is an off-label use in SLIT. Therefore, the preparation of the allergen therapy vial is not covered by any insurance company. A charge for the mixing of the SLIT treatment vial is equal to the charge for mixing 2 vials for shot therapy since the vial volume for SLIT is 2X the vial volume of SCIT. Each vial should last for 7 weeks.

The treatment period is the same for subcutaneous therapy (shots) as it is for sublingual therapy. Treatment will extend for 3-5 years. Patients will be required to have routine follow up visits to evaluate the effectiveness of treatment as well as to determine if any changes in their therapy need to be made.

#### Patient Consent

I have been instructed in the use of sublingual therapy. All of my questions and/or concerns have been addressed. I understand that I am financially responsible for the cost of the vial (which is \$220.00) and payment in full is due at the time that I take it from the allergy office. I understand that new vials are made prior to the end of the current vial thus it is required that I give at least 2 weeks' written notice of my intent to discontinue immunotherapy. Virginia Ear, Nose & Throat has a form that I must sign stating my intention to discontinue immunotherapy. I understand that if I fail to give such notice and new vials are prepared, I will be responsible for all charges associated with that service.

**Patient Name:** \_\_\_\_\_

**D.O.B.:** \_\_\_\_\_

**Patient Acct #:** \_\_\_\_\_

**Patient signature/Responsible Party:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Witness' signature:** \_\_\_\_\_