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**CONSENT FOR ADMINISTRATION OF
SPECIFIC ALLERGEN IMMUNOTHERAPY
(SUBLINGUAL IMMUNOTHERAPY ■ SLIT)**

Name:
DOB:

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

PURPOSE

The purpose of sublingual immunotherapy (SLIT / allergy drops) is to decrease your sensitivity to allergy-causing substances, so that exposure to the offending allergen (pollen, mold, mites, animal danders, etc.) will result in fewer and less severe symptoms. This does not mean that sublingual 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. Sublingual immunotherapy has been identified as leading to an alteration of your immune system's response to naturally occurring allergens. These alterations 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. It is generally recognized that sublingual immunotherapy (SLIT) is less effective than subcutaneous immunotherapy (SCIT – injections), but also that it has some distinct advantages.

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 hayfever or asthma should occur upon exposure to the suspected allergen. Due to the inherent risks of immunotherapy, avoidance measures and medical management should be attempted first.

EFFICACY

Improvement in your symptoms will not be immediate and may not be complete. The most recent comprehensive literature review of efficacy was published by the AAAAI / ACAAI Joint Task Force, analyzing 43 efficacy studies using appropriate scientific methods. They reported 35% of studies resulted in significant reductions in both medication use and symptom scores; 38% of studies found no significant differences in medication use or symptom scores, and 13% of studies reported a reduction in medication use but not in symptom scores. As a comparison, greater than 50% of SCIT (injection) patients report reductions in medication use and symptom scores within one year. Analysis of efficacy studies on SLIT reveals that 2 years of SLIT may be necessary before observing benefit, as measured by a reduction in medication use and symptom scores.

PROCEDURE

Sublingual immunotherapy is usually begun at very low doses. This dosage is gradually increased on a regular basis until a therapeutic dose (often called the "Maintenance Dose") is reached. The Maintenance Dose will differ from person to person. SLIT may be given once a day, or several times per day, while the vaccine dose is being increased (Advancement Phase). This frequency reduces the chance of a reaction and permits the Maintenance Dose to be reached within a reasonable amount of time. After the Maintenance Dose is determined, SLI is usually continued on a daily basis. The specifics of your dosing regimen will be outlined by the physician.

DURATION OF TREATMENT

It usually takes several months to reach a Maintenance Dose. The time may be longer if there are vaccine reactions or if the doses are not received on a regular basis. For this reason, it is important that the recommended schedule be followed. If you anticipate that regular doses cannot be maintained, immunotherapy should not be started. Immunotherapy may be discontinued at the discretion of the doctor if the doses are frequently missed, as there is an increased risk of adverse reactions under these circumstances. Most immunotherapy patients continue treatment for 3-5 years, after which the need for continuation is reassessed.

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ADVERSE REACTIONS

Allergy immunotherapy is associated with some widely recognized risks. Risk is present because a substance to which you are known to be allergic is being administered to you. Some adverse reactions may be life-threatening and may require immediate medical attention. Potential adverse reactions include, but are not limited to, the following (listed in order of increasing severity):

A. LOCAL REACTIONS:

Local reactions are common and are usually restricted to the lips and mouth (itching, swelling). These reactions are more likely to occur as you reach the higher concentrations and higher doses. The reactions may occur several hours after the dose and can usually be treated successfully with oral antihistamines.

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 reaction may occur within minutes to hours after a dose and may involve areas in addition to the mouth and lips.
- (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 an asthma exacerbation 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 dose and requires immediate medical attention. This reaction may initially be difficult to differentiate from milder lip or tongue swelling, so every precaution should be taken if angioedema is suspected.
- (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 is rare and usually occurs within minutes of the dose; however, there are reported cases of anaphylaxis beginning as long as 2 hours after immunotherapy. At the present time, there have been no documented reports of fatalities related to SLIT, but the potential needs to be taken seriously.

The above reactions are unpredictable and may occur with the first dose or after a long series of doses, 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 doses. Appropriate advice and treatment will always be available from our office staff at the time of any adverse reaction. As an additional precaution, the doctor recommends that all immunotherapy patients carry an emergency epinephrine autoinjector (Twinject® or EpiPen®) with them on the days that they receive immunotherapy.

OBSERVATION PERIOD FOLLOWING INJECTIONS

All patients receiving allergen immunotherapy should be observed **for 30 minutes following each dose**. The ideal locale for immunotherapy administration is under direct medical supervision (i.e., the doctor's office), but home administration of SLIT may also be recommended. In either setting, the observing personnel ("physician surrogate") should be trained in the recognition and management of potential adverse reactions, including anaphylaxis. If home administration is recommended, you will be asked to complete the **"Request for Home Administration of SLIT."** Our office will then arrange for training of you and your physician surrogate in the details of SLIT administration, dose adjustments, and management of potential adverse reactions.

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ALTERNATIVES TO SCIT:

Patients have three alternative approaches to their allergy treatment: (1) avoidance of recognized environmental allergens, (2) medications for symptom control, and (3) subcutaneous immunotherapy (injections – SCIT). The discussion with your physician has outlined the “pros and cons” of each approach, as well as the option of no specific treatment.

IMPORTANT INFORMATION CONCERNING YOUR SLIT EXTRACT PRESCRIPTION

The acquisition and use of your specific SLIT extract prescription vials will be discussed with you by our staff. Currently, no U.S. Food and Drug Administration (FDA)-licensed extracts or American Medical Association Current Procedural Terminology (CPT) codes are available for sublingual immunotherapy (SLIT) use in patients in the United States. In addition, this treatment is considered to be investigational and off-label in the United States for the products being used, and, although SLIT is considered much safer than SCIT, the doses required for efficacy are much higher than when employing injection therapy. As a result, it is unlikely that any U.S. health insurance policy will cover the expenses related to SLIT. Each allergen vaccine vial carries an expiration date; doses should not be administered from expired vials.

PREGNANCY

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately, so that the doctor can determine an appropriate dosage schedule 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, and glaucoma. “Beta blocker” medications are contraindicated while on immunotherapy, and your immunotherapy will need to be discontinued while you are taking a beta blocker.

ATTACHMENTS

I acknowledge that I have received the four attachments on immunotherapy: (*suggested topics / titles*)

- Immunotherapy I: General Information About Sublingual Immunotherapy (SLIT)
- Immunotherapy II: Common Questions (And Answers) Concerning Immunotherapy (SLIT)
- Immunotherapy III: Medications To Be Avoided While On Immunotherapy (SLIT)
- Immunotherapy IV: Initial Sublingual Immunotherapy Dosing Schedule (SLIT)



ADMINISTRATION OF IMMUNOTHERAPY (SLIT)

If dosing is to be done at home, it is recommended that you do so during our usual office hours, so that our staff will be immediately available by phone for questions or emergencies. If you call our office with questions concerning your immunotherapy, please ask for Malorie Alderson at extension 432-653-1484 or state that you need to speak to someone immediately. **Our routine office hours are as follows:**

Monday through Fri: 8:30 AM to 5PM
After hours: Go to your nearest emergency room

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If you have questions concerning anything in this *Consent for Administration of Specific Allergen Immunotherapy (SLIT)*, please direct the questions to the nurses or the doctor. Once your questions have been answered and you have made the decision to begin allergen immunotherapy, please initial and date each of the first three pages of this document, then sign the *Authorization for Treatment* (below) in the presence of a witness and return it to our front desk. Thank you.

**CONSENT FOR ADMINISTRATION OF SPECIFIC ALLERGEN IMMUNOTHERAPY (SUBLINGUAL - SLIT)
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 allergen 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 specific allergen immunotherapy (SLIT) over an extended period of time and at specified intervals, as prescribed by Raphael Nwojo, M.D.

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 Specific Allergen Immunotherapy (SLIT)* and that it is my opinion that the signee understands the nature, risks, and benefits of the proposed treatment plan.

Prescribing Physician's Signature

Date Signed

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