| **CONSENT FOR ADMINISTRATION OF SPECIFIC ALLERGEN IMMUNOTHERAPY**<br>**( SUBLINGUAL IMMUNOTHERAPY ■ SLIT )** | Name<br>Clinic # / DOB |
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**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, dust 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 degree of this immunization is different for each person and is, therefore, somewhat unpredictable.

## INDICATIONS

To qualify for sublingual immunotherapy, there must be documented allergy to substances in the environment that cannot be avoided. Documentation of allergy can be 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 rhinitis 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. Although sublingual immunotherapy has been shown to be quite effective, it is perhaps not as effective as the traditional injection protocols for some allergens (e.g., venoms). Various studies have shown symptom reduction from sublingual to range from 30% to 70%, whereas similarly designed studies with injection immunotherapy show symptom reduction scores of 40%-80%. Of course, each individual patient's response will vary, but improvement should be evident within the first few months of treatment. Dr. Park will periodically review your treatment plan with you to be certain that you are achieving maximum efficacy with your particular prescription.

## PROCEDURE

Sublingual immunotherapy is usually begun at very low doses. This dosage is gradually increased on a regular basis until a therapeutic dose (called the "Maintenance Dose") is reached. SLIT should be given once a day while the vaccine dose is being increased (Build-up Phase). This frequency reduces the chance of a reaction and permits the Maintenance Dose to be reached within a reasonable amount of time ( about 30 days ). After the Maintenance Dose is determined, SLIT is continued on a daily basis, at a stable dose ( usually 5 drops from each maintenance vial ). The specifics of your dosing regimen will be outlined by Dr. Park at the start of your treatment.

## DURATION OF TREATMENT

It usually takes 30 days 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, sublingual 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 5 years, after which the need for continuation is reassessed.

## 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 appear to be more common early in treatment, but usually subside in severity as treatment doses are advanced. The reactions may occur minutes to hours after the dose and can usually be treated successfully with oral antihistamines.

### B. GENERALIZED REACTIONS:

Generalized reactions occur very rarely, but are the most important because of the *potential danger* of progression to collapse and death if not treated. These reactions may include any or all of the following:

**(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 will 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 extremely rare and usually occurs within minutes of the dose. 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 should 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, Dr. Park recommends that all immunotherapy patients have an emergency epinephrine autoinjector (EpiPen® or Auvi-Q®) immediately available whenever immunotherapy is administered.***

## ALTERNATIVES TO SUBLINGUAL IMMUNOTHERAPY

Patients have three alternative approaches to their sublingual allergy treatment: (1) avoidance of recognized environmental allergens, (2) medications for symptom control, and (3) subcutaneous immunotherapy ( injections – SCIT ). Your discussion with the 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) 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 cumulative doses required for efficacy are 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 should not be advanced during pregnancy, but may be maintained at a constant level, at the physician's discretion.

## 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 immunotherapy will need to be discontinued while you are taking a beta blocker.

## ATTACHMENTS

Your signature below acknowledges that you have received the four (4) handouts on sublingual immunotherapy entitled:

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| Immunotherapy I: | General Information About Sublingual Immunotherapy (SLIT) |
| Immunotherapy II: | Frequently Asked Questions Concerning Sublingual Immunotherapy (SLIT) |
| Immunotherapy III: | Medications To Be Avoided While On Immunotherapy (SLIT) |
| Immunotherapy IV: | Initial Immunotherapy Dosing Schedule (SLIT) |

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 two 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 practices 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 sublingual immunotherapy (SLIT) over an extended period of time and at specified intervals, as prescribed by Dr. Park.

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| **Printed Name of Immunotherapy Patient** | **Medical Record Number** |
| **Patient Signature (or Legal Guardian)** | **Date Signed** |
| **Witness** | **Date Signed** |



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