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Consent for Administration of Sublingual Immunotherapy (SLIT)

Purpose – The purpose of sublingual immunotherapy (allergy drops or SLIT) is to decrease your sensitivity to allergy-causing substances so that exposure to the offending allergen will result in fewer and less severe symptoms. It is not a substitute for avoidance of known allergens or for the use of allergy medications but rather a supplement to these treatment measures.

Efficacy – Allergy drops have been shown to lead to an alteration of your immune system’s response to naturally occurring allergens which allow you to tolerate exposure to the allergen with fewer symptoms. The amount of immunization is different for each person. Improvement in symptoms will not be immediate. It usually requires 3 – 6 months before any relief of allergy symptoms is noted. About 80 – 90% of patients on immunotherapy note significant improvement in their symptoms.

Procedure – Allergy drops are usually begun at a lower dose and gradually increased on a regular basis until a therapeutic dose is reached. Drops are administered by you at home daily. The first dose will be administered in our office. Immunotherapy may be discontinued at the discretion of your doctor. Most immunotherapy patients continue treatment for 3 – 5 years.

Background on SLIT – The allergens used for allergy drops are the same as those used for injections. However, the FDA specifically approved the allergens for injection use. Using them for SLIT is considered “off-label” use. Off-label use in the US healthcare delivery system is a legitimate, legal, and common practice. The protocol we use is endorsed by the American Academy of Otolaryngic Allergy. Dozens of research studies show that allergy drops are a safe, effective form of immunotherapy.

Adverse Reactions – Immunotherapy is associated with some widely recognized risks. There are NO reports of death associated with sublingual therapy.

1. Local reactions – Local reactions are uncommon and usually restricted to itching of the mouth or upset stomach. These reactions usually occur immediately after taking a dose but can occur hours afterwards. Most reactions resolve themselves or are mitigated with dose adjustments. An antihistamine can be used as normally directed. You should notify your doctor immediately if you have any reactions.
2. Generalized reactions – These reactions occur very rarely but are the most important because of the potential danger of progression to more severe conditions. These reactions include:
 - a. Urticarial reactions (hives) – rash, swelling, and/or itching of more than one part of the body. This occurs within minutes of taking a dose.
 - b. Angioedema – This is an extremely rare reaction to SLIT characterized by swelling of any part of the body, inside and out, such as the ears, tongue, lips, throat, intestine, hands or feet, alone or in any combination. This may be accompanied by asthma and may progress to the most severe reaction, anaphylactic shock.

- c. Anaphylactic shock is the rarest complication and has only been reported a few number of times. It is a serious event characterized by acute asthma, vascular collapse (low blood pressure), unconsciousness and, potentially, death.

Missed Doses – If more than one day is missed, do not try to “catch up.” Contact the office.

Pregnancy – If you become pregnant while on immunotherapy, notify our office immediately so that the doctor can determine an appropriate dosage schedule for the drops during pregnancy.

New Medications – Please notify the office if you are starting any new medications, particularly medications for high blood pressure, migraines, and glaucoma. “Beta-blocker” medications may be contraindicated while on immunotherapy and your drops will need to be discontinued.

I acknowledge that I have been given a prescription for an epinephrine injector and have been instructed on when to use it and have demonstrated how to properly use it.

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 sublingual 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 sublingual immunotherapy over an extended period of time as prescribed by my doctor. I further hereby give authorization and consent for treatment by my doctor and staff for any reactions that may occur as a result of immunotherapy drops.

Printed name of patient

Patient signature (or parent / legal guardian)

Date

Witness signature