

Sublingual Immunotherapy Educational Material and Consent Form

Patient name: _____

Facility name: _____

Name of provider conducting informed consent:

The facts in this form will help you learn more about the treatment your doctor has recommended. Please read it carefully. You will be asked to sign the last page of this form.

Your Health Problem

You are allergic to certain substances. This means that your body overreacts when it is exposed to them.

You can try to teach your immune system to react less to the substances. This can be done by taking small doses of the substances in the form of drops or pills under the tongue. This is called sublingual immunotherapy (or SLIT).

Your doctor thinks you should have sublingual immunotherapy to treat your allergies.

The Procedure and Follow-Up

Your doctor will give you a dose of the allergy substance. You must put the substance under your tongue.

The first dose will be given to you in your doctor's office. If you do not have any problems with the dose, then you can take it each day at home.

You must take the dose each day.

Risks and Common Problems

There are risks linked to this treatment, which include, but are not limited to:

Anaphylactic shock: Symptoms of anaphylactic shock include wheezing, shortness of breath, or low blood pressure. You could pass out or die. This can happen in minutes, but it is very rare. This can happen to anyone who has allergies. Anaphylactic shock has not happened to anyone who has had sublingual immunotherapy.

Angioedema: Symptoms include swelling in any part of the body. If too much swelling occurs in your mouth or throat, you could have breathing problems. If this happens, you need immediate medical care. This is very rare.

Hives (welts): Raised bumps may suddenly form on your skin. The bumps may be red. This may happen within minutes or hours. If this happens, you should tell your doctor.

Local reactions: Your lips, mouth, or ears may itch or swell. Your throat may feel irritated. This can happen within minutes or hours. If this happens, then you can often treat this problem with an antihistamine.

If any of the problems listed above happen to you, you may need to have more treatment.

Other Choices

If you choose not to have sublingual immunotherapy, then you have other treatment choices. You could receive shots or take medication to treat your allergies.

Shots/injections may work as well or better than sublingual immunotherapy. Shots can only be given in your doctor's office. Your doctor will talk to you about this choice.

The effectiveness of any other treatment will depend upon your specific health problem.

More Facts and Information

Sublingual immunotherapy is an off-label treatment. This means it is not approved by the Food and Drug Administration (FDA). The lack of FDA approval does not mean that it is not safe or that it will not work for you.

You may have an allergic reaction to sublingual immunotherapy. Your doctor may order an emergency epinephrine pen (also called an epi pen). You should have this with you when you take your doses.

The cost of sublingual immunotherapy may not be covered by your health plan.

Sublingual immunotherapy may not make your allergy problems go away. You may still need to take medication for your allergies.

You may need to have sublingual immunotherapy for years.

Consent for Treatment

____ Patient Initial The first two (2) pages of this form explained the risks, likely results, other choices, and problems that could happen with sublingual immunotherapy. If, after you have read and reviewed this form with your doctor, you do not believe that you really understand the risks, likely results, other choices, and possible problems of sublingual immunotherapy, do not sign the form until all your questions have been answered.

Because of my special health problem, these extra risks have also been explained to me:

None List: _____

I have the following allergies:

None List: _____

I understand all the facts given to me in the first two (2) pages of this form. I now give my consent to Dr. _____ and his/her associates to give me sublingual immunotherapy. I prove with my signature below that my doctor has discussed all of the facts in this form with me, that I have had the chance to ask questions, and that all of my questions have been answered.

Signature of Patient or Responsible Party

Date and Time

Witness

Date and Time

Physician:

I confirm with my signature that I have given the patient two (2) pages of educational material and have discussed with the above-named patient the risks, likely results, other choices, and possible problems of sublingual immunotherapy. The patient has had the chance to ask questions, all questions have been answered, and he or she has expressed understanding. Thus informed, the patient has asked that I give sublingual immunotherapy to him or her.

Physician Signature

Date and Time

Witness

Date and Time