



PRINCETON ALLERGY AND ASTHMA ASSOCIATES **CONSENT FOR IMMUNOTHERAPY**

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

PURPOSE

The purpose of subcutaneous immunotherapy (allergy injections) is to decrease your sensitivity to allergy-causing substances, so that exposure to the offending allergen (pollen, mold, mites, animal dander, stinging insects, etc.) will result in fewer and less severe symptoms. This does not mean that 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.

Allergy injections have been shown to lead 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.

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 hay fever or asthma should occur upon exposure to the suspected allergen, or you may have a history of a severe reaction to an insect sting. Due to the inherent risks of immunotherapy, avoidance measures and medical management should usually be attempted first.

EFFICACY

Improvement in your symptoms will not be immediate. It usually requires 3 to 6 months before any relief of allergy symptoms is noted, and it may take 12-24 months for full benefits to be evident. About 85-90% of allergic patients on immunotherapy note significant improvement of their symptoms. This means that symptoms are reduced, although not always completely eliminated.

PROCEDURE

Allergy injections are usually begun at a very low dose. 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. Injections typically are given once or twice per week while the vaccine dose is being increased. This frequency reduces the chances of a reaction and permits the maintenance dose to be reached within a reasonable amount of time. After the maintenance dose is determined, the injections can usually be given every two to four weeks.

DURATION OF TREATMENT

It usually takes approximately 6 months to reach a maintenance dose. The time may be longer if there are vaccine reactions or if the injections are not received on a regular basis. For this reason, it is important that the recommended schedule be followed. Additionally, when you are late for your injections, the risk of a systemic reaction increases, and for your safety we will either not increase or may lower the doses from the last injection. This will delay your improvement, and you may then need to come more frequently to catch up. Immunotherapy may be discontinued at the discretion of your physician if the injections are frequently missed. If you anticipate that regular injections cannot be maintained, immunotherapy should not be started. When there are holidays, our injection hours may be extended to make it easier for you not to be late, so please look for notices in the waiting room. Most immunotherapy patients continue treatment for 3-5 years, after which the need for continuation is reassessed.

ADVERSE REACTIONS

Immunotherapy is associated with some widely recognized risks. Risk is present because a substance to which you are known to be allergic is being injected into you. Some adverse reactions may be life threatening and may require immediate medical attention. In order of increasing severity, the following brief descriptions explain the nature of these potential reactions:

LOCAL REACTIONS

Local reactions are common and are usually restricted to a small area around the site of the injection. However, they may involve the entire upper arm, with varying degrees of redness, swelling, pain, and itching. These reactions are more likely to occur as you reach the higher concentrations and higher volume injections. The reactions may occur several hours after the injection. You should notify the nurse, when you come for your next injection, if your local reaction exceeds two inches in diameter or lasts more than 24 hours.

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 uncommon reaction may occur within minutes to hours after an injection.
- 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 asthma 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 injection and requires immediate medical attention.
- (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 usually occurs within minutes of the injection and is extremely rare.

The above reactions are unpredictable and may occur with the first injection or after a long series of injections, 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 injections. Appropriate advice and treatment will always be available from our office staff at the time of any adverse reaction.

OBSERVATION PERIOD FOLLOWING INJECTIONS

All patients receiving immunotherapy injections should wait in the office for 30 minutes following each injection. If you have a reaction, you may be advised to remain in the office longer for medical observation and treatment. If a generalized reaction occurs after you have left the office, you should immediately return to the office or go to the nearest emergency medical facility. If you cannot wait the 30 minutes after your injection, you should not receive an immunotherapy injection. There are several allergy vaccine-related deaths each year in the United States. While most systemic reactions are not life threatening if treated promptly, this fact does stress the importance of remaining in the office for the suggested observation time. If you do not remain in the office for the designated time, the doctor may recommend discontinuation of immunotherapy.

Under no circumstances will injections be permitted without the immediate availability of emergency medical treatment. If the prescribed injections are to be given elsewhere, this office must be provided with the name and address of the physician who will assume the responsibility for your injections. You will be asked to complete the "Request for Administration of Immunotherapy at an Outside Medical Facility." Our office will then contact the designated facility and confirm their availability for administration of your immunotherapy injections.

INITIAL EXTRACT PRESCRIPTION

Your initial prescription includes all vaccine vials that are required to reach a "maintenance" dose. In order to utilize these vials prior to their expiration date (6 months from date of preparation), you will need to receive injections at least once or twice per week on a regular basis. Taking injections twice per week will allow you to reach maintenance earlier, well before expiration. If you take injections once per week regularly, you will reach maintenance level at about the same time as the expiration date. When you receive regular maintenance injections, the renewal vials generally last 2 to 3 months, but still carry a 6-month expiration period.

PREGNANCY/MEDICATIONS

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately, so we can determine an appropriate dosage schedule for the injections during pregnancy. Immunotherapy doses will not be advanced during pregnancy, but may be maintained at a constant level.

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 injections will need to be discontinued while you are taking a beta-blocker.



NEW Serum Immunotherapy Work-up Schedule

GREEN - 1st Set of Vials	
1	0.05 ml
2	0.10 ml
3	0.30 ml
4	0.50 ml

BLUE - 2nd Set of Vials	
1	0.05 ml
2	0.10 ml
3	0.20 ml
4	0.30 ml
5	0.40 ml
6	0.50 ml

YELLOW - 3rd Set of Vials	
1	0.05 ml
2	0.10 ml
3	0.20 ml
4	0.30 ml
5	0.35 ml
6	0.40 ml
7	0.45 ml
8	0.50 ml

RED - 4th Set of Vials	
1	0.05 ml
2	0.10 ml
3	0.15 ml
4	0.20 ml
5	0.25 ml
6	0.30 ml
7	0.35 ml
8	0.40 ml
9	0.45 ml
10	0.50 ml

Each year when your extract expires and we remake new serum for you, we will be decreasing your dose by 50% and have you come in weekly for five (5) weeks to get back to your maintenance dose. This is recommended by the American Academy of Allergy, Asthma and Immunology (AAAAI).

Please make an appointment with your physician if you have any questions. As a reminder, you should see your physician every six (6) months while on immunotherapy.

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ALLERGY INJECTION INFORMATION

- It is your responsibility to verify your referral status.
- A parent or adult needs to accompany a minor at all times.
- Minors sent without a parent, need permission in writing.
- Injections are given weekly. The maximum number of days between injections is 10 days. If longer, a decreased dose must be given for safety reasons.
- It is recommended that on injection days, especially during the pollen season, you keep your home and car windows closed. This will help to reduce increased exposure to pollens and risk of a reaction.
- After your injection you are required to:
 1. Wait in the office for 30 minutes. This is in accordance with the American Academy of Allergy & Immunology.
 2. Parents of minors (or an adult) need to be in the office with the minor for 30 minutes.
 3. Have your arms checked by the nurses before leaving the office.
 4. **NOT EXERCISE** 1 hour before or 2 hours after an injection.
- Personal serum cannot be taken from one office to another.
- Each office does injections on different days and times. Please check the schedule.
- You must have your Epi-Pen or Auvi Q with you at the time of your injection. If directed by your doctor, please take your allergy medication at least 1 hour before your injection.
- Allergy injections are considered medications; please list them as such.
- Some blood pressure medications (Beta-Blockers) cannot be taken with allergy injections; please check with your family physician before starting injections.
- If you begin taking chronic medication, please inform the nurse.
- If you are pregnant or planning to get pregnant, please discuss this with your physician.

Patient Name _____

Signature _____ Date _____ → over

9/10/19

ALLERGY INJECTIONS WILL NOT BE GIVEN:

- 1. If you have had an allergic reaction; also, you must see the doctor before getting your next injection. It is your responsibility to make an appointment with your physician.**
- 2. If you are sick.**
- 3. If allergy symptoms are severe.**
- 4. If you have a fever.**
- 5. If you have exercised within the last hour. This can cause a severe allergic reaction.**

Patient Name _____

Signature _____ **Date** _____



CONSENT FOR ADMINISTRATION OF IMMUNOTHERAPY

Authorization of 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 subcutaneous 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 immunotherapy (allergy injections) over an extended period of time and at specified intervals, as prescribed by Princeton Allergy and Asthma.

I further hereby give authorization and consent for treatment, from Princeton Allergy and Asthma and the staff, of any reactions that may occur as a result of an immunotherapy injection.

Printed Name of Patient: _____ Date: _____

Patient/Parent Signature: _____ Date: _____

Witness: _____ Date: _____

FOR OFFICE USE ONLY:

I certify that I have counseled this patient and/or authorized legal guardian concerning the information in this Consent for Immunotherapy and that it appears to me that the signee understands the nature, risks, and benefits of the proposed treatment plan.

Physician _____ Date: _____

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Allergy Immunotherapy Serum Agreement

I, _____, or guardian, elect to start immunotherapy. I have been informed and agree that my insurance company or I will be billed at the time the serum is made. The serum will automatically be renewed as needed. I am aware that a referral will be needed at the time the serum is billed. If I elect after the serum has been compounded not to institute immunotherapy, I will still be responsible for the cost of the serum.

_____ (Initial) Non-compliant patients may be subject to additional out of pocket expenses due to re-dilution of allergy serum per insurance guidelines.

_____ (Initial) **Please be aware that due to insurance restrictions, your serum may take 2 weeks or more to be prepared. You will receive a text or call when it is ready.**

Printed Name of Patient: _____ Date: _____

Patient/Parent Signature: _____ Date: _____

Witness: _____ Date: _____

Princeton Allergy & Asthma Associates, P.A.

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Beginning 7/1/22

D. Loren Southern, MD
Andrew J. Pedinoff, MD
Julie A. Caucino, D.O.
Helen S. Skolnick, M.D.
Kristen M. Sikorski, M.D.
Shaili N. Shah, M.D.

Monday	8:30 - 12:00	Princeton Office
	1:30 - 6:45	Princeton Office
	8:30 - 12:00	Hamilton Office
	1:30 - 6:45	Hamilton Office
	12:45 - 5:45	Plainsboro Office
Tuesday	1:15 - 4:00	Princeton Office
	8:30 - 12:00	Hamilton Office
	1:30 - 5:00	Hamilton Office
	9:30 - 11:30	Flemington Office
	1:00 - 5:00	Flemington Office
Wednesday	8:45 - 11:45	Plainsboro Office
	1:00 - 6:45	Plainsboro Office
	1:00 - 6:45	Flemington Office
Thursday	8:30 - 12:00	Princeton Office
	1:30 - 5:45	Princeton Office

6/9/22