ELPIS HEALTHCARE

Informed Consent–Allergy Testing and Immunotherapy Treatment

Please sign this form once you have read in its entirety and fully understand its contents.

This consent form is intended to educate patients and improve communication between the medical provider and said patients regarding the procedures described herein. The following is to be explained:

1. **Allergic Rhinitis is the diagnosis requiring this procedure**
2. **Hypo-sensitization (to make one less sensitive to allergic responses) is the nature of this procedure, which also includes a skin prick test used to evaluate the severity of potential allergic responses.**
3. **These procedures are for the purpose of: Testing for allergic responses and to ultimately help relieve allergic symptoms.**
4. **Possible Risks: To list all possible complications that may occur, as with any procedure, would be impossible. However, we have been diligent in the consideration of these potential risks. Possible risks involved in these procedures including, but not limited to are as follows:**

   Reaction locally at testing site: Itching, redness of skin, burning, bleeding, swelling and/or hives, skin blistering/sloughing, possible infection at the injection/skin prick site.

   Reaction Systemic- (Mild): Allergy Symptoms, i.e.: "runny nose" and/or nasal congestion and/or sneezing, itching of ears, nose, throat, diarrhea, headache, itchy and/or watery or red eyes may also occur within two hours of the injection/skin prick procedure.

   Reactions potentially Severe: Coughing, wheezing, or shortness of breath: bronchial asthma, swelling of tissue around the eyes, tongue or throat; generalized hives (welts); stomach or uterine (menstrual type) cramps, if pregnant; possible miscarriage.

   Rare complications: Arrhythmias or abnormalities of the heartbeat, loss of ability to maintain blood pressure or pulse, delayed response,
   anaphylactic shock, death.

   Severe complications: If unrecognized or untreated, could possibly involve a severe reaction involving the heart, lungs and blood vessels, could potential be fatal.
5. **Precautions to be taken: Our experience and research has shown that the majority of reactions that require emergency treatment due to allergy testing/and or immunotherapy administration occur within 30 minutes of the procedure. It is our policy that; All patients receiving testing and/or immunotherapy treatment remain in our offices under the supervision of medical personnel for no less than 30 minutes or until released by one of our Allergy technicians. You may choose to leave prior to the 30-minute observation policy, but do so against medical advice and therefore accept all responsibility and liability for any subsequent reaction(s) from the above-described procedures.**

Patients will be educated on how to self-administer their immunotherapy injections. Once a patient who has received skin testing and /or immunotherapy injections leaves our facilities, there is a possibility of a reaction occurring. It is of the upmost importance that any such reaction be reported immediately to the Allergy Team as well as our Physician prior to receiving the next injection. Upon leaving our offices, if for any reason you are concerned about a reaction, you should, if possible, return to our office or go to your local urgent care facility or Emergency room for treatment.

In the event you are experiencin g a life-threatening emergency, immediately Call 911

6. Duration of Treatment: Allergy Immunotherapy shots for the average patient generally last for approximately two (2) years. Depending on what your allergies are, the severities of your allergies and how well you tolerate treatment, this schedule will differ from patient to patient. Consistency is key to successful treatment and in minimizing potential risk factors. Consistency is best achieved by strictly adhering to your dosage log provided by and communicated to you by our allergy staff. Note: Arriving at the appointed time(s) for your allergy shots and/or immunotherapy medication follow up appointments is paramount in the success of your treatment. It also greatly reduces your risk of having an adverse reaction(s) to your immunotherapy, including but not limited to anaphylactic shock. If you cannot be consistent in arriving at the appointed time(s) to receive your allergy shots and/or immunotherapy medication, you will be asked, for your own protection, to find alternative methods for your allergy treatment. At the discretion of our Physician and/or our Allergy Department, repeat offenders who are unable to adhere to the guidelines of allergy treatment may be prevented from continued allergy shots and/or immunotherapy, for their own protection and the program discontinued.

With up to an 85% success rate, Immunotherapy treatment is a viable alternative to the continued; long term use of chemical Allergy medications that merely treat symptoms verses the patient. Practical Alternatives may include such medical treatments as the prescription of antihistamines, allergy medications, and potential surgical procedures. Prognosis: The patient's prognosis (future medical condition) is unknown if the patient chooses not to have the above procedures.

It has been explained to me that the physician, medical personal, allergy technicians, or other assistants will rely on statements made by me, the patient, and the patients' medical history prior to determining whether to perform the procedures or in determining and/or recommending the course of treatment pertaining the patient's condition.

No guarantees or assurances have been made to me concerning the results or outcomes of these procedures. I understand the practice of medicine is not an exact science.

I consent to and authorize the person described herein to make the decision concerning any additional procedures which may be deemed necessary or appropriate, which may however, be unforeseen and not known to be needed at the time this consent is given.

I consent to and authorize the possible taking and publication of any photographs or videotapes taken during the patient's procedure, which may be used for educational, medical, or scientific purposes as approved by my physician. I also consent, for educational purposes the presence of any observers in the allergy lab, which have been approved by my physician.

By signing this form, I acknowledge that I have read, or have had read to me, the contents of this form and that I fully understand that which is contained within. I understand that I will be given the opportunity to ask questions regarding the procedure prior to its completion and that all my questions will be answered satisfactorily.

I have been made aware that taking beta-blockers can greatly increase the risk of severe reactions, asthma, anaphylaxis, and possible death while taking allergy shots or skin tests. I agree that I will inform the allergy technician at any time that a physician prescribes or places me on a beta-blocker.

Female Patients: If at any time during the course of allergy immunotherapy treatment I learn that I have become pregnant, I agree to notify my physician and the lab technician immediately.

I voluntarily consent to allow all medical personnel under the supervision and control of Our medical provider, as well as the designated acting physician, to perform all procedures described or otherwise referred to herein.

Please answer the following questions by circling YES or NO:

Have you read the above Informed Consent document? **YES / NO**

Do you understand the risks, expected benefits, and the nature of the above-described testing/treatment procedures as well as options of alternative treatment? **YES / NO**

Do you understand that to the outcomes of testing and/or treatment there is no guarantees? **YES / NO**

Do you understand that any patient under the age of 18 must have a parent or guardian present to receive a consultation and/or testing and/or treatment of any kind? **YES / NO**

Do you understand that all patients receiving injections must remain in the office for observation for no less than 30 minutes after their injection(s), until released by an allergy technician. And that anyone doing so, does so against medical advice and thus accepts all liability for subsequent reaction(s)? **YES / NO**
Do you understand that any reaction(s) to your allergy injections or to the skin prick test must be reported, and that you are responsible for reporting any reaction(s) to our allergy department in a timely manner. If you are at any time concerned about your reaction(s), you are encouraged to return to our allergy department or go to the local emergency room or immediate care facility for treatment? **YES / NO**

Do you understand that if you are not able to consistently arrive for injections or to "pick-up" immunotherapy medications as scheduled, you greatly increase your risk of having an adverse reaction to Immunotherapy treatment? **YES / NO**

Do you understand that if you fail to consistently arrive/document your injection(s) in accordance with your dosage log, our office may discontinue, for your own safety, your immunotherapy treatment?
YES / NO

We may choose to communicate with patients' personal medical information via email. By allowing your physician to utilize this method of communication, you may receive appointment alerts as well as Immunotherapy updates. All such information will be kept confidential. By filing out your email address below you are giving us authorization to send your medical information via email.

Patient E-Mail Address: _____

I, the undersigned , hav e read all four (4) pages of this form in its entirety a n d /or have had this form explained to me and fully understand the content of this authorization.

I consent to have allergy Immunotherapy medication vials prepared for me, under the supervision of the Medical Director, upon receipt of my lab results and/or allergy skin test results so that I may begin my Immunotherapy medication/treatment as soon as possible.

Signature:_____ **Printed Name:**_____ **Date:**_____

Witness:_____ **Printed Name:**_____ **Date:**_____

This form will be used to help guide you along your immunotherapy treatment plan, this will also help you stay up to date with your prescription and prescheduled injections.

Before starting your immunotherapy treatment plan, it is important that you bring in all of your prescription items to each office visit, this will include:

1. EPI-Pen (Adult/Jr.)
2. Allergy Syringes 28Gx1/2” 1CC 3. OTC Liquid Benadryl
3. Immunotherapy Vials (This will be required when moving up in strength o f medications)

First Injection training by the MT will include:

1. Verification of prescription
2. Office visit with your physician
3. How to take your Immunotherapy 4. How to Draw up your medications
4. How to clean and prepare injection-site 6. How to administer your injection

Safety procedures training:

1. Emergency Instructions
2. How to administer your EPI-Pen 3. How to read Dosage log
3. Functions of the syringe

During your first allergy injection, a Medical Technician will educate you on all your Immunotherapy procedures. We understand you may not be ready to perform these procedures on your own. However, if you need additional visits with your Medical Technician to help ensure you feel comfortable as a patient

administering your own injections in the comfort of your own home, they are available. **If you still feel uncomfortable with your procedures, additional office visits can be scheduled as needed for your convenience.**

First Injection reminder date & time:_____/_____

Date of medication completion:_____/_____

Date scheduled for first immunotherapy injection: _____

I fully understand and agree to bring the following materials to every allergy appointment that has been scheduled.

1. EPI-Pen (Adult/Jr.)
2. syringes (28Gx1/2" 1CC)
3. Liquid Benadryl (OTC Children's Benadryl)
4. Immunotherapy vials (if required)

Patient Signature:_____**Date:** _____

IMPORTANT: I fully understand that at any time I forget my EPI-Pen, I will not receive an injection and must be rescheduled.

Patient Signature:_____**Date:** _____

IMPORTANT: I fully understand not to expose my EPI-Pen and or Immunotherapy to extreme heat/cold conditions and will follow appropriate storage requirements as per packaging directions for all the above.

Patient Signature:_____**Date:** _____

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Pre-testing Criteria - READ CAREFULLY to allow accurate & timely testing.

For Allergy testing:

1. Please do not take ANY antihistamines 72 hours prior to testing. (Benadryl, Claritin, Allegra, Zyrtec, Xyzal, ZzzQuil, and Tylenol PM)

2. No oral steroids allowed one week prior to testing. (ex..... Medrol dos e pack, prednisone)

3. No Nasal or inhaled steroids 48 hours prior to testing. (ex ..... Advair, Nasonex, Flonase)

4. If taking Beta Blocker as listed below for HTN or migraines, you CAN Not be tested:

Acebutolol (Sectral®)
Atenolol (Tenormin®)
Betaxolol (Kerlone®, Betoptic®)
Bisoprolol (Zebeta®)
Esmolol (Brevi bloc®)
Nebivolol (Systolic®)
Metoprolol (Lopressor®, Toproi-XL ®).