THE ALLERGY AND ASTHMA GROUP OF

ALLERGEN VACCINE TREATMENT CONSENT FORM (IMMUNOTHERAPY OR ALLERGY SHOTS)

Allergy shots are given to reduce sensitivity to airborne substances that cannot be adequately avoided (allergens/antigens).

The allergen vaccine contains the airborne allergens that were found positive on skin testing and which provoke respiratory symptoms. Initially, the vaccine concentration is very weak; then the vaccine gradually increases in dose and concentration. By increasing, we can usually build up a tolerance, so your body can withstand larger and longer exposures to the allergen without producing undesirable symptoms or requiring as much medication to control symptoms. At no time should the allergen vaccine cause a flare-up of the underlying disorder.

Adverse reactions to allergen vaccines are rarely a serious problem. Mild local reactions at the site of the injection are fairly common and may consist of itching, redness, swelling, or soreness. The presence of a mild local reaction is not necessarily a problem. However, if there is more than minor disturbance, then the dosage, concentration, content, or technique should be reassessed.

Rarely, an allergic patient could experience symptoms from their allergen vaccine which are similar to the systemic reaction known as **anaphylaxis** (including hives, swelling, nasal symptoms, itching, coughing, throat irritation, difficulty breathing, fainting). Anaphylaxis can occur in patients allergic to stinging insects. Symptoms begin in 15-20 minutes in most cases and can be serious. Allergen vaccines are generally viewed as a safe and effective form of therapy with a low incidence of systemic allergic reaction and almost negligible incidence of anaphylaxis with hypotension (shock). For example, the risk of anaphylaxis is significantly higher with a penicillin shot. Among the millions of patients treated in the United States with immunotherapy during the past 50 years, there have been 24 documented fatalities. Most had an identifiable risk factor, such as use of beta blocker drugs or unstable asthma. Allergic patients with asthma should check their peak expiratory flow value prior to allergen vaccine.

Although the risk of systemic reaction is quite small, it is the primary reason all injections should be given in a physician's office, followed by a 30-minute observation period. The use of medications containing beta blocking agents is contraindicated during allergen vaccine treatment since such medications increase the risk of a more serious systemic reaction. These medications are present in some of the preparations for heart conditions, blood pressure control, eye drops for glaucoma, and migraine prevention.

An average course of allergen vaccine treatment will utilize a weekly schedule for the first year, progress to every two weeks the second 12-18 months, and move to every three to four weeks for 18-24 months. It takes six months to a year to experience a substantial relief from allergen vaccine treatment. Thereafter, progressive improvement is expected, and most patients are gradually weaned from their vaccine treatment. If improvement is not seen within 18-24 months, then a decision must be reached as to whether further allergen vaccine is indicated.

The following information is provided to summarize how charges related to your immunotherapy are assessed.

<u>New Vial Charge</u>

The charge for vials is for the cost for the antigen that makes up your "Allergy Shots." The cost is based on a unit basis or per-dose fee related to the number of units you are to receive. *These charges will be billed when a New Vial is mixed*. An initial series can consist of up to 72 units or more. Maintenance vials will vary from 10-32 units when a new set of vials are mixed, and charges will be based on that number of units. Most insurances have a maximum number of units that can be billed per year and any units after the maximum will be the patients out of pocket responsibility.

Injection Charge

Allergy and venom injections require a separate administration charge, which will be applied when the shots are given. This cost is determined by the number of injections given (single or multiple injections).

Rush Immunotherapy

Rush Immunotherapy injections are charged by *units of time*, based on a per-hour rate. Insurance fees differ based on plan and could be more out of pocket than injection charges. Injections are given in 30-minute intervals, and vital signs are monitored before each shot. Two options of Rush Immunotherapy are available. 1) A one-hour series (two sets of injections) available without an appointment as long as your physician has approved the option. 2) A series of four or more sequential injections which requires an appointment.

My signature below acknowledges that:

- 1. I have reviewed my skin tests with my provider and understand the treatment what is being prescribed for me including what allergies I am being treated for, dosing, length of treatment, and schedule.
- 2. I agree that if I feel that my allergy shots are not working for me that I will schedule an appointment with my provider and discuss alternative options.
- 3. I understand that there is a schedule that has to be maintained in order to receive all doses of my antigen before it expires. If I fail to maintain the schedule for any reason (non-compliance, illnesses, etc.) I will be charged for any remix of antigen.
- 4. I understand that each vial has an expiration date and that I will not receive any expired antigen. Expired antigen will be discarded according to the manufacturers expiration dates.
- 5. I am authorizing the office to bill my insurance and myself for allergen vaccines, even if, for any reason, I decide not to initiate the allergen immunotherapy program after the antigen has been made.

- 6. I am not taking any beta blocker medications (including eye drops) and will notify staff if I begin any beta blocker medications while receiving immunotherapy. For Example: Betapace, Brevibloc, Bystolic, Byvalson, Coreg, Corgard, Hemangeol, Inderal, InnoPran, Kerlone, Lopressor, Sectral, Sorine, Sotylize, Tenormin, Toprol, Trandate, Zebeta, acebutolol, atenolol, betaxolol, bisoprolol, carvedilol, esmolol, labetalol, metoprolol, nadolol, propranolol, sotalol, timolol.
- 7. I am not currently pregnant and will notify staff if I become pregnant while receiving immunotherapy.
- 8. If the patient is a minor, I understand that a parent or guardian must be present for each allergy injection.
- 9. I am required to wait in the medical facility in which you receive the injections for 30 minutes after each injection. If I leave prior to the 30 minutes I will assume all risks and responsibilities.

I have requested that The Allergy & Asthma Group of Galen start Allergy Immunotherapy Treatment and intend for this consent to be continuing in nature. The consent will remain in full force until revoked in writing. I certify that I have read and fully understand the above statements and consent fully and voluntarily to all of them.

Signature	Date			Relationship to Patient			
Witness		Date					
	I would like to receive my injections at (circle):						
	Gunbarrel	Dalton	Cleve	eland	Hixso	n Ba	attlefiel