# CONSENT FOR IMMUNOTHERAPY

**Legal name of patient undergoing immunotherapy:**_____

David Mangold or Ruth West have explained to me the procedure involved in the administration of immunotherapy (allergy injections) in a way that I understand.

1. In national studies, 70-80% of patients have reported improvement of symptoms in association with immunotherapy.
2. There may be alternative methods of treatment, which may or may not be used to control my symptoms. I understand that immunotherapy is not the only treatment available.
3. There are risks involved with immunotherapy and they have been explained to me fully. Ordinarily, local arm swelling and itching are expected after some injections. Rarely, a systemic reaction happens after an injection. Symptoms of such a reaction occur shortly after the injection and may include the following:
    a. Upper Respiratory (nasal congestion, itchy eyes, sneezing, etc.)
    b. Lower Respiratory (wheezing, coughing, short of breath, etc.)
    c. Skin (rash, hives, itching, etc.)
    d. Swelling (eyes, lips, tongue, throat, etc.)
    e. Anaphylaxis (shock, respiratory failure, death)
4. Because of these risks, I agree to wait in the office for 30 minutes after each injection or call 911 or proceed to the emergency room if any symptoms occur after I have left.
5. The costs of injections may vary depending on where you receive them. The injection costs range from $16.00 (one injection) to $34.00 (two injections). The treatment sets are $512 each and refills are $160 per set. Refills may be needed every 6-12 months. You may require 1-3 treatment sets depending on how many allergies you have.
6. Follow-up patient visits should be made ideally at 3 & 12 months after starting injections. A close provider-patient relationship is recommended so that vaccine adjustment can be made to assure the optimal safety and effectiveness of your immunotherapy.

If immunotherapy is for a child, a parent or guardian's signature is required. Parents or guardians are responsible for informing the staff of how each previous injection was tolerated. I am satisfied with the explanation that has been given and do not desire any more information. I give permission and consent for this treatment.

Signature of patient, parent, or guardian:_____ Date:_____

Printed name of person giving consent:_____

# *DEATHS ASSOCIATED WITH ALLERGENIC EXTRACTS*

FDA is concerned about reports of fatalities associated with the injections of allergenic extracts and is asking for the medical community's help in ascertaining the extent of this problem

In the U.S. population, 1.7% of those over 17 years claim to have had a severe reaction, such as itching all over, trouble breathing, flushing, hives, or angioedema at a distant site within an hours after receiving an allergy injection! From 1985 until September 1993, 35 deaths following allergen immunizations were reported to FDA or identified through a retrospective survey of member of the American Academy of Allergy and Immunology and the American College of Allergy and Immunology! No deaths were reported, however from skin testing for allergies during this same period. The majority (83%) of those patients who died from allergen immunizations had prior histories of asthma. Most of those patients with prior histories of asthma (22 of 29), Were characterized as having at least one of the following characteristics labile (12 of 22), requiring steroids. (12 of 22) prior asthma hospitalization. (10 of 22) prior asthma emergency room treatment (10 of 22) history of respiratory arrest/ intubation (4 or 22). One of the 35 deaths occurred in a non-asthmatic receiving a beta-blocker, with hay fever and coexisting hypertension and cardiovascular disease.

Other clinical factors identified in the 35 patients who died, in addition to asthma were a high degree of skin test or in vitro sensitivity (17 patients). Use of a new vial of extract for immunization (12 patients), a history of a prior systemic allergic reaction (10 patients), immunization being given during allergy season (8 patients), an immunization dosing error (7 patients), patient departing the clinic immediately after the immunization (6 patients), patient being allergy symptomatic at the time of the immunization (5 patients), immunization being done at home (2 patients).

Also, certain treatment factors were associated with the patient deaths, including 19patients were on build-up doses; 7 patients were on a maintenance dose; 21 patients were receiving grass/ ragweed extracts; 17 patients were receiving dust mite extracts; 14 patients were receiving high dosage therapy. (1:10-1:100 weight/volume); 7 patients were receiving lower dosage therapy (1:1million<1:100).

In more than half the deaths, the onset of the fatal reaction occurred in 20 minutes or less. Also, the majority of patients died in spite of administration of epinephrine. With the most common contributing cause of death being airway obstruction. The mean age for the fatalities was 39 years with 61% of the fatalities being women.

It is estimated that, during the period of the 35 reported deaths 52.3 million uses or recommendations of allergenic extracts were made. Using these data, FDA estimates that from 1985 to September 1993 the crude annual death rate for allergenic extracts is 0.7 deaths per million exposures.

The current physician labeling of allergenic extracts contains a boxed warning on the risk of life-threatening reactions that can occur with the use of these products. Additionally, that warning stresses;

- Limiting the use to physicians experienced in the use of allergenic extracts and in the emergency treatment of anaphylaxis
- The non-interchangeability of various types of extracts.
- Basing initial dosage on skin testing
- Observing the patient for at least 20 minutes following the injection
- Withholding immunotherapy when a beta blocker is used
- Instructions for treatment of adverse reactions

The reported fatalities strongly underscore the need for physicians to exercise appropriate caution in treating high-risk asthmatics with immunotherapy. Physicians who decide to initiate immunotherapy in asthmatics with significant irreversible obstruction or who require continuous systemic corticosteroids must be sure that the benefits of immunotherapy adequately outweigh the risks.

FDA is asking the help of the medical community in reporting serious adverse events (fatalities, disability, and hospitalization) associated with the se of allergenic extracts. Practitioners aware of serious adverse events following exposure to allergenic extracts can assist FDA by reporting such cases. Reports may be submitted using the Med. Watch form included in this issue of the Medical Bulletin or by calling (1-800-FDA-1088) to request a copy of the form. Those reporting are encouraged to include such pertinent information as history of asthma, clinical status of the patient before injection, degree of patient sensitivity, history of prior systemic reaction, dose of each allergen injected in comparison to the previous injected dose, and any possible predisposing factor.

Signature_____ Date:_____