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| Information and Consent for Administration of Immunotherapy (Allergy Injections) |
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PLEASE READ AND BE CERTAIN THAT YOU UNDERSTAND THE FOLLOWING INFORMATION PRIOR TO SIGNING THIS CONSENT FOR TREATMENT

PURPOSE

The purpose of immunotherapy (allergy injections) is to decrease your sensitivity to allergy-causing substances, so that exposure to the offending allergen (pollen, mold, mites, animal danders, 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 the formation of “blocking” or protective antibodies and a gradual decrease in allergic antibody levels. These changes 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 hayfever 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.

EFFICIENCY

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.

WHAT ARE THE CHANCES OF STOPPING IMMUNOTHERAPY SUCCESSFULLY?

1. After 4-5 years of high-dose continuous immunotherapy, between 60-80% of patients should be able to stop successfully.

2. The only sure way to find out is to STOP.

If a patient stopped unsuccessfully, symptoms characteristic of returning allergy problems should not occur for at least 12 months. Between 12-24 months, 30% experience the return of allergy symptoms, and 50% the third year off immunotherapy.

NORTH TEXAS ASTHMA & ALLERGY CENTER

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PROCEDURE

Allergy injections are usually begun at a very low dose. This dosage is gradually increased on a regular basis (usually 1-2 times per week) 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 one to two weeks.

IMMUNOTHERAPY TIMELINE

| DAY ONE | 6-8 MONTHS | YEARS 2-4 (5) | END OF 4 TH (5 TH) YEAR |
|---|--|--|--|
| START | WHEN INJECTIONS ARE CRITICALLY JUDGED FOR EFFECTIVENESS | CONTINUE | |
| INJECTIONS GIVEN TWICE WEEKLY FOR 9-16 WEEKS, THEN WEEKLY | INJECTIONS GIVEN WEEKLY UNTIL THE END OF THE FIRST TWELVE MONTHS | INJECTIONS GIVEN EVERY OTHER WEEK (TWICE MONTHLY) FROM YEARS 2-4 (5) | DISCUSS STOPPING, OR CONTINUING INDEFINITELY |

DURATION OF TREATMENT

It usually takes 3 to 6 months to reach a maintenance dose. This 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. If you anticipate that regular injections cannot be maintained, immunotherapy **should not** be started. Immunotherapy may be discontinued at the discretion of Dr. Moore if the injections are frequently missed, as there is an increased risk of reactions under these circumstances. Most immunotherapy patients continue treatment for 3-5 years, after which the need for continuation is reassessed.

ALLERGY INJECTION ROOM INSTRUCTIONS

1. Patients receiving allergy injections should sign in at the injections room window immediately upon arrival at the office. The nurse uses the sign-in sheet to call you for your injection.
2. For our patients’ safety, injections cannot be given when a doctor is not available.
3. Patients receiving injections at another medical office will be responsible for their vials of extract. If you are going out of town and would like to have our injections given by another physician, please contact the injection room supervisor at least 10 working days before you plan to pick-up your injection record and extract can be prepared. **EXTRACT MUST BE REFRIGERATED.** Extract that has been allowed to remain at room temperature for long periods cannot be used again. When you return to the office, be sure to bring the extract vial and the injection record. This record is a part of your permanent medical record

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4. and must be used with each injection. Loss of this record may result in delays, as there may be no way of determining how far you have progressed.
5. If you have and questions regarding reactions to your injection, please tell the nurse before you receive your next injection so that an appropriate dosage will be given.
6. Stop by the business office to process your billing ticket before you leave the office. These copies should be retained for your insurance or for your medical expense reports at the end of the year. If you plan to pay on your account, please let the business office know before your ticket is processed. This will insure the correct amount is credited to your account.
7. All accounts shall be paid in full when you receive your last injection for the month.
8. In order for us to prepare extract refills, if you are receiving injections at another office, please contact our office at least 10 working days prior to the date you will actually need your next injection.

OTHER COMMENTS: DO NOT TAKE an allergy shot when exhausted physically or overheated. Allow 20-30 minutes to cool off before an injection. Avoid vigorous exercise for two hours following your allergy shot.

DO NOT TAKE an allergy shot if you are having an acute episode of hay fever or asthma or if you have an acute respiratory infection with fever. A mild "cold" should not prevent you from taking your allergy shot.

SEASONAL INFLUENCE – When allergy symptoms are most severe, the dose of allergy extract may be reduced by 20-30% to avoid aggravating symptoms. More commonly, taking allergy shots more frequently during this period may be more beneficial (e.g., weekly instead of twice monthly).

MEDICATIONS – Do not hesitate to use medications prescribed for allergy symptoms whenever they are needed. Medications may be taken as indicated for other illnesses while on immunotherapy.

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:

A. 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 if your local reaction exceeds two inches in diameter or lasts until the following day.

Normal Location Reaction: Redness, itching, and/or swelling may occur at the site of the allergy shot. Swelling up to one inch in diameter (size of a quarter) and lasting no more than 24 hours is considered normal.

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Local Allergic Reaction: Excessive swelling (larger than a quarter) with itching, redness, and pain may occasionally occur. If this occurs within the first 20 minutes, report immediately to the nurse or doctor.

Delayed Allergic Reaction: An excessive local reaction may occur up to 12 hours after an allergy shot. Taking an antihistamine and applying ice to your arm will usually relieve any discomfort.

B. 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.

Note: An increase in allergy symptoms may occur on the evening after an allergy shot. Nasal congestion, sneezing, itching of the nose and eyes, hives, coughing or wheezing may occur. You may experience a headache or may “just not feel well”. Take your usual antihistamine and/or anti-asthma medication as previously described. Contact your physician if the symptoms do not improve promptly.

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.

REPORT ANY IMMEDIATE OR DELAYED ALLERGIC REACTION BEFORE YOU RECEIVE YOUR NEXT ALLERGY SHOT SO THAT THE PROPER ADJUSTMENT CAN BE MADE.

Mild reactions – We will repeat the same dose until it no longer occurs.

Moderate reactions – We will reduce the amount injected by 1 or 2 doses.

Severe reactions – Handled individually.

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OBSERVATION PERIOD FOLLOWING INJECTIONS

All patients receiving immunotherapy injections should wait in the clinic area **for 20 minutes following each injection**. If you have a reaction, you may be advised to remain in the clinic longer for medical observation and treatment. If a generalized reaction occurs after you have left the clinic area, you should **immediately return to the clinic or go to the nearest emergency medical facility**. If you cannot wait the 20 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 clinic for the suggested observation time. If you do not remain in the clinic area for the designated time, the doctor may recommend discontinuation of immunotherapy.

Under no circumstances will injections be permitted without immediate availability of emergency medical treatment. If the prescribed injections are to be given elsewhere, our 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 4 to 8 months, but still carry a 12 month expiration period.

PREGNANCY

Females of childbearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately, so that Dr. Moore 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.

NEW MEDICATIONS

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.

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ALLERGY INJECTION SCHEDULE

Allergy injections are offered in our clinic on a “walk-in” basis during the following hours. No appointment is necessary; simply scan your card at the front counter during the designated hours. A minimum of 48-hour interval is necessary between injection visits. *A parent or legal guardian must be present before an injection will be given to a minor.* Please be prepared to wait in the clinic area for 20 minutes following each injection.

| | | | |
|------------|-------------------------|-----|------------------------|
| Monday: | 9:00 a.m. to 12:30 p.m. | and | 2:00 p.m. to 4:45 p.m. |
| Tuesday: | 9:00 a.m. to 12:30 p.m. | and | 2:00 p.m. to 6:45 p.m. |
| Wednesday: | 9:00 a.m. to 12:30 p.m. | and | 2:00 p.m. to 4:45 p.m. |
| Thursday: | 9:00 p.m. to 12:30 p.m. | and | 2:00 p.m. to 4:45 p.m. |
| Friday: | 7:00 a.m. to 11:45 a.m. | | |

(Any temporary exceptions to these hours will be posted in the shot clinic.)

PAYMENT OBLIGATION

It is important for you to understand that **we cannot** guarantee payment for these services, which include both the administration of allergy injections and the serum used for this method of treatment. As our patient, you are obligated and responsible for full payment for the serum and the routine injections, which take place. **As a courtesy**, we will file a claim to your insurance provider for the total amount of serum ordered and for routine injections. It is important for you to understand that **you are responsible for full payment** of both the serum and the injections if your insurance fails or denies paying for the above services. You may have a **deductible that you are obligated to pay in advance** of insurance payment. You may also have a **co-pay that is also required before each shot is administered**, and for the mixing of the shot serum. It is your responsibility to understand what is covered and not covered under your insurance plan. We will be happy to assist you in this process if requested.

If you have questions concerning anything in this *Consent for Immunotherapy*, please direct the questions to the nurses or to Dr. Moore. If you wish to begin immunotherapy, please initial each of the first four pages, then sign the *Authorization for Treatment* (next page) and return it to our front desk.

Thank you,

Gerald C. Moore, M.D.

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Consent for Administration of Immunotherapy (Allergy Injections)

Authorization for Treatment

I have read and discussed the above information on immunotherapy and understand it. I have been given the opportunity to ask any and all questions that I may have and am satisfied that they have been fully answered. I understand fully the risks involved with this method of therapy and agree to abide by and follow the medical directions given to me by the members of North Texas Asthma & Allergy Center. I do hereby give consent for the patient described below to be given immunotherapy (allergy injections) over an extended period of time and at specified intervals as prescribed by my doctor. I hereby give authorization and consent for treatment by Dr. Moore and his staff, of any reaction that may occur as a result of an immunotherapy injection.

Printed Name of Immunotherapy Patient

____ Plano
____ Frisco

Patient Signature (or Legal Guardian)

Date Signed

Witness

Date Signed

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.

Gerald C. Moore, M.D.

Date Signed