## ALLERGEN IMMUNOTHERAPY – DISCLOSURE AND CONSENT THE TANKERSLEY CLINIC ALLERGY, RESPIRATORY AND SKIN CARE

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You have the right, as a patient, to be informed about your condition and the recommended allergen immunotherapy (allergy shots) to be used so that you may decide whether to undergo the allergy shots after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the allergy shots.

- 1. I voluntarily request Dr. Mike Tankersley, as my Allergist, and such associates, technical assistants, and other health care providers as necessary, to treat my condition which, based on my allergy evaluation, has been explained to me as one or more of the following: allergic rhinitis with or without conjunctivitis, asthma which is triggered by allergy, atopic dermatitis, and/or venom allergy.
- 2. I understand the following medical procedure is planned for me, and I voluntarily consent and authorize allergen immunotherapy, also known as allergy shots or subcutaneous immunotherapy (SCIT).
  - a. **How do allergy shots work?** Research has shown that allergy shots decrease allergic reactions by stimulating the formation of protective "blocking antibodies," by decreasing the production of "allergic antibodies," and by altering other immune cell functions in a beneficial way.
  - How often and how long must I receive allergy shots? Allergy shots are given once or twice a week, but not two days in a row, in increasing doses typically over 40 visits (10 shots from each of the 4 build-up vials) until a maintenance dose is reached. Cluster visits will allow you to reach maintenance sooner and are an option for all patients. Once reaching maintenance, shots are generally given once a month. However, allergy shot maintenance intervals are individualized and can vary between 2-6 weeks. The vials have expiration dates. The first two vials (green and blue) have 6-month expiration dates and the last two vials (vellow and red) have 12-month expiration dates. Once a year a new maintenance vial will be made, and the maintenance dose will be decreased 50% with a build-up for five visits required back to maintenance. After being on shots for two years, each annual new vial maintenance dose thereafter will be decreased 50% with the other 50% given 30 minutes later so that no further build-up is required. The duration of treatment with allergy shots will depend on how well you tolerate them and how well you respond to treatment. In general, an 18-month trial is given, and if benefit is realized, the shots are continued for 3-5 years after reaching maintenance with follow-up appointments 1 month after starting shots, 2 months after the 1<sup>st</sup> appointment, 4 months after the 2<sup>nd</sup> appointment then every 6 months. All allergy shots are done on a walk-in basis between the hours of 8 am and 4 pm. We do not close for lunch. We have a late clinic on Thursdays till 4:30 pm. If you are doing cluster, you would need to back up the time to account for the cluster injections.
- 4. I understand that no warranty or guarantee has been made to me as to result or cure.
- 5. Just as there are risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of allergy shots. I realize that common to allergy shots is the potential for allergic reactions and even death. I also realize the risks which may occur in connection with allergy shots include but are not limited to the following reactions:
  - a. Local reactions with itching, redness, warmth, swelling and tenderness at the injection site. Swelling may at times extend down to the elbow. If this is bothersome, use a cold pack at site, take Tylenol or Motrin and/or take another dose of your antihistamine if the site itches. It is

- acceptable to double dose your antihistamine. Allergy shot doses are generally not adjusted for local reactions unless they are bothersome to the patient and then other measures can be taken.
- b. Generalized reactions may include hives; eye/nose/skin itching; swelling of face, throat, hands and/or feet; wheezing/difficulty breathing; nausea, vomiting, diarrhea and/or abdominal cramps; lightheadedness and/or sudden drop in blood pressure; and rarely death. Historically, there are two deaths/year in the US related to allergy shots. These generalized reactions can usually be easily reversed if treated early but can be life-threatening without immediate medical attention. For this reason, we ask you to remember and adhere to the following:
  - i. Administration at a medical facility capable of treating an allergic reaction with supervision by either a physician or advanced practice provider (NP or PA).
  - ii. Remain for 30 minutes in the designated waiting area following each shot visit.
  - iii. Report any symptoms immediately and/or report any reaction from prior visit, local or generalized, before you receive your next shot.
  - iv. Notify Dr. Tankersley if you become pregnant. With few exceptions allergy shots can be continued (not increased) during pregnancy (discuss with Dr. Tankersley).
  - v. Notify us if you are started on any new medications, especially a beta-blocker medication (used for high blood pressure and migraine headaches). With very few exceptions allergy shots cannot be started and must be stopped if you are on a beta-blocker.
  - vi. Do not receive an allergy shot if you have active asthma symptoms in the last 24 hours.
  - vii. Take an oral antihistamine (e.g., Allegra, Claritin, Clarinex, Zyrtec or Xyzal) in the morning or evening before you receive your allergy shot. We do not recommend ever taking Benadryl due to its short duration and high sedation properties.
- 6. I understand there may be alternatives to the allergen immunotherapy. Alternatives include but are not limited to the following: tolerate/ignore the allergy symptoms, environmental control measures to avoid exposure to things to which I am allergic, oral medication such as antihistamines and decongestants taken as needed or daily, anti-allergy eye drops, anti-allergy nose sprays, anti-asthma inhalers and/or sublingual immunotherapy (SLIT) for Timothy grass, ragweed, or house dust mite.
- 7. Just as there may be risks and hazards to allergy shots, I also realize that risks and hazards may occur in connection with the alternatives and include, but are not limited to, ongoing allergy and/or asthma symptoms, missed school/work due to symptoms, diminished quality of life and/or work performance, and/or side effects from medications.
- 8. I have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of non-treatment, the procedures to use, and the risks and hazards involved, and I have sufficient information to give this informed consent.
- 9. I understand that my extract, the mixture of allergens with which I will be treated, will be made in the next few weeks, and once made, cannot be used for any other patient. Therefore, I will be billed for this extract even if I should decide not to take the injection treatment. If I am nonadherent in the first two vials (green and blue), I understand there will be additional charges to remake either of these vials.
- 10. I certify both pages of this two-page form have been fully explained to me, the blank spaces here have been filled in, and I have either read it or had it read to me, and I understand the contents.

Name of Patient:	Date:	 /	/	_
Date of Patient Birth:				
Signature of patient (or other legally responsible person if patient <18 years):		 		
Name of legally responsible person if patient <18 years:		 		
Signature of counseling physician: <i>Mike Tankersley</i> ,				

Name of counseling physician: Mike Tankersley, MD, MBA