VIRGINIA
EAR NOSE & THROAT
The Choice is Clear

Date: _____

Physician Name: _____

Fax #: _____

Patient: _____ DOB: _____

Some patients undergoing immunotherapy (allergy injections) request that their injections be administered in another physician's office. Guidelines for the administration of allergy injections now recommend that the prescribing physician confirms that the designated provider is able and willing to administer the allergy injections.

The above-referenced patient has been evaluated in our office and has been prescribed allergen immunotherapy as a part of the treatment plan for an allergic disorder. The patient (or parent/legal guardian) has requested that I forward the allergen extract (along with detailed treatment instructions) to you for administration in your office. The patient will be required to receive the first injection out of each new vial in our office. All other injections may be administered at an outside facility.

This letter is to confirm your participation in the administration of specific allergen immunotherapy to this patient. Following is an **Acknowledgement and Consent** form for you to complete Upon return receipt of the executed document we will proceed with having the patient receive immunotherapy injections at your facility.

After reviewing the **Acknowledgement and Consent** form below, please record your signature, printed name, the date and the address to which the extracts should be sent.

Thank you for your help in this matter. We look forward to working with you on the management of our patient's allergic disorder.

Sincerely,

Emily Kane, FNP-BC
Virginia Ear, Nose & Throat

Virginia Ear, Nose & Throat

ACKNOWLEGEMENT AND CONSENT.

Patient Name: _____ DOB: _____

My signature below acknowledges that my staff and I will administer specific allergen immunotherapy injections for the above referenced patient in a supervised medical setting. Furthermore, I acknowledge the following facts:

1. My staff and I are trained in the recognition and management of both local and systemic reactions to allergen immunotherapy;

2. My staff and I understand that Virginia Ear, Nose & Throat and their staff will be available for phone consultation as needed, but cannot be responsible for the training or supervision of my office personnel, for procedures performed within my office, or for any quality control measures within my office; and

3. I understand that the patient may return to Virginia Ear, Nose & Throat Associates at any time for continuation of immunotherapy, if so requested by me or by the patient.

Please send extracts and instructions to the following address:

_____

_____

_____

Acknowledged and agreed to by:

_____ _____

Physician/NP/PA's Signature Printed Name

_____/_____/_____

Date

Please fax this page back to Virginia Ear, Nose & Throat at 804-272-6900

Thank You.

Virginia Ear, Nose & Throat
EXTRACT TRANSFER - ACKNOWLEDGEMENT AND CONSENT

To be completed by the patient when allergy injections will be administered at a facility other than the offices of Virginia Ear, Nose & Throat (Virginia ENT).

Patient Name: _____ **Date of Birth:** _____

Special instructions: _____

I, _____, have read and signed the **"What You Should Know About Immunotherapy Consent Form."** However, I wish to have my injections administered at another medical facility (designated below), and I request that Virginia ENT transfer my extract vial(s), along with instructions for administration of the injections, to the designated physician/facility.

- I understand that Virginia ENT has no legal or financial arrangement with the designated facility.
- I understand and agree that I will receive the first shot from each new immunotherapy vial at a Virginia ENT facility.
- I understand that Virginia ENT cannot assume responsibility for my medical treatment within the designated facility.
- I understand that it is my responsibility to make certain that the facility and its staff are willing and able to provide allergen immunotherapy, as well as the management of any immediate or delayed adverse reactions that may result from the immunotherapy.
- I agree that I will not attempt to administer my allergy injections to myself nor will I permit anyone who is not a licensed health care provider, or under the direct supervision of a licensed physician, to administer the injections.
- I agree to notify Virginia ENT of my intent before I transfer my extract vial(s) to any physician/facility other than the one designated below.
- I understand that I may call Virginia ENT at any time (804-484-3700) if questions or problems develop and that I may also return at any time to Virginia ENT for continued administration of my injections.

Financial arrangements for purchase of the extract vials will be made through Virginia ENT Associates. Financial arrangements for the administration of the allergy injections, as well as for the treatment of adverse reactions to the injections, will be made with the facility where the injections are administered.

_____ _____
Patient Signature (or Legal Guardian's Signature) **Date Signed**

_____ _____
Witness **Date Signed**

Transfer Extract To:

Physician Name: _____

Address: _____

_____

Phone Number: _____ **Fax Number:** _____

Virginia Ear, Nose and Throat Associates

ESCALATION & DOSE ADJUSTMENT PROTOCOL FOR ALLERGY INJECTIONS (SCIT)

Contraindications for giving an injection:

1. Allergy injections are not to be given if the patient has a temperature of 100 degrees or more, current or recent wheezing (within 48 hours, or use of albuterol w/in 48 hours), rash, or hives.

2. Peak flow monitoring will be performed before SCIT administration on patients that have been designated at risk for reactive airway symptoms or with a known h/o asthma. Do not give shot if patient is not able to blow their pre-determined peak flow number, as indicated on the injection record.

3. Patients who have upper respiratory infections should wait until symptoms are improving to get their allergy injections.

4. Allergy injections should be held until the following day on patients who have had a vaccine such as MMR, DPT, tetanus, pneumovax, hepatitis or flu shot.

5. Patients taking beta blockers must hold this medication for 24 hours prior to injections, unless cleared by the doctor.

Considerations related to giving injections:

1. TECHNIQUE: Extracts should always be kept refrigerated (4 degrees C). Use a 1cc syringe with a 26 to 27 gauge (3/8 inch) needle. Carefully withdraw proper amount from appropriate vial. Inject subcutaneously in the posterior aspect of the middle third of the upper arm. Aspirate prior to injecting to avoid intravenous administration. Swab but do not massage area after injection. Gentle pressure may be applied. Give multiple injections in different arms. If giving 2 injections in one arm, separate injection sites by about 2 inches.

2. MEDICAL SUPERVISION AND WAIT: Allergy injections must always be given in a medical facility equipped to recognize and treat anaphylaxis and only when a physician/nurse practitioner/physician assistant is available. All patients must wait 20 minutes after injections so that he or she can be checked for local and/or systemic reactions.

3. Immunotherapy will begin escalating doses from 0.05cc to 0.50cc in incremental increases one to two times per week.

4. Injections will be administered on a weekly basis for the first year.

5. Shots will be given every 2 weeks for the second year as long as the patient has been at maintenance for 6 months, and every 3 weeks for the third year. At three years, the patient may or may not continue injections once a month.

6. Patients who are not adhering to their shot schedule (routinely skipping shots) should be reported to the allergy office to determine if immunotherapy should be continued.

7. If more than 12 months elapse between shots, the patient will be retested.

8. After every injection, the patient is to wait in the allergy observation area[1] for 20 minutes.

9. Patients will be required to bring and show a current Epipen prior to receiving their shot(s).

10. During the 20 minute observation period, if the patient exhibits signs/symptoms of anaphylaxis the clinical staff observing the patient shall immediately administer epinephrine, bring a physician to examine the patient and call 911.

11. Before leaving the patient must report any local reactions and have the injection site examined by a clinical staff member.

12. Local reactions will be recorded on the flow sheet in the EMR. The clinical staff member observing the reaction should give the patient instructions for caring for a local reaction (cold compress, hydrocortisone/Benadryl cream, oral antihistamine, NSAID, other).

    Patients who have a localized or "site reaction" greater then 25mm, about the size of a quarter that does not resolve in 24 hours, will repeat the previous dose (last tolerated dose). The patient should not be escalated until the site reactions are less than 25mm and resolving in 24 hours. If site reactions are repeatedly 25mm or significantly larger, they should be reported to our office to determine the course of action and if shots should be allowed to be given off site. Make 2 attempts to increase the dose. If the patient is not tolerating, make the highest tolerated dose the maintenance dose and inform the allergy provider. If swelling is very large (joint to joint), inform the allergy provider and follow their recommendations.

13. During the pollen season, some patients experience large local reactions to previously tolerated (even maintenance) doses. During this period, the dose may be reduced and then increased again after the pollen season is over, per protocol.

14. Also during the pollen season, a patient on maintenance (every 2-3 weeks) may experience more symptoms. In this case, the patient can receive the maintenance injection once a week if requested while the pollen is high. Once the symptoms are alleviated, resume the regular 2-4 week maintenance schedule.

15. Patients should not exercise within 2 hours of injections.

16. If patient becomes pregnant, she will require an appointment before additional shots are given. Generally, she can maintain at the current dose of SCIT but may not escalate until after delivery.

Patients will need to have a follow up appointment 3 months after starting immunotherapy, then as determined by the practitioner.

STANDARD injection schedule:

Escalating Vials

Week 1	0.05ml
Week 2	0.10ml
Week 3	0.15ml
Week 4	0.20ml
Week 5	0.25ml
Week 6	0.30ml
Week 7	0.35ml
Week 8	0.40ml
Week 9	0.45ml
Week 10	0.50ml

Amended / Accelerated Schedule

Week 1	0.05ml
Week 2	0.10ml
Week 3	0.20ml
Week 4	0.30ml
Week 5	0.40ml
Week 6	0.50ml

As long as the patient is stable and it has been at least 72 hrs. from their last shots, the amended schedule can be used.

New Maintenance Vials will start at 0.40ml for patient safety.

- **Doses start at 0.05ml and continue to increase until a dose of 0.50ml is reached**. At this point a new vial will be made if the patient is still escalating. The 0.05ml dose will be given from the new vial after an appropriate vial test. This same escalation will continue until maintenance is reached. Then the 0.50ml dose is continued until the vial has expired or is empty. A vial may be used up to 7 days beyond its expiration date.

- Injections are given with an allergy treatment syringe (grey) which has a subcutaneous needle. Subcutaneous injections are given straight into the tissue **not** on a 45 degree angle as previously taught. Typical sites would be the "flabby" part of the upper arm or less commonly the thigh.

- Patients should be given their injections in the same site each time to facilitate identification of the serum should there be a local reaction. On each visit, two shots may be given in one arm if there are three shots to be given. However if only two shots are given they should be placed in separate arms.

MANAGEMENT OF MISSED INJECTIONS (ACCORDING TO # OF DAYS FROM LAST INJECTION)

During build-up phase:

- Up to 11 days- continue as scheduled
- 12-18 days- repeat previous dose
- 19-25 days- reduce previous dose by 25%
- 26-32 days- reduce dose by 50%
- Over 32 days- contact office for instructions
  (After dose adjustment, resume with next higher dose on the schedule)

  **Once reaching maintenance, patient should maintain weekly injections for 6 months for optimal effectiveness (de-sensitization) of shots. Then, can go to every 2 weeks.

During the 6 month weekly maintenance schedule after initially reaching maintenance:

- < 2 weeks, keep shot at same dose
- 2-4 weeks, reduce to 0.4ml
- >4 weeks, reduce to 0.1ml from same vial, rebuild in 0.1ml increments 1-2X weekly 72 hours apart
- >6 weeks- contact office

After reaching Maintenance (Every 2 week schedule/year 2 SCIT):

- < 4 weeks, give same dose
- > 4 weeks, reduce to 0.4ml
- > 6 weeks, reduce to 0.1ml from the maintenance vial; rebuild by 0.1ml increments 1-2X weekly 72 hours apart
- > 8 weeks - contact office

After reaching Maintenance (every 3 week schedule/years 3+ SCIT):

-Up to 4 weeks – give same maintenance dose
-5-6 weeks – reduce maintenance dose by 25%; resume maintenance dose within 7 days
-7-8 weeks – reduce dose by 50%
-over 8 weeks – contact office for instructions (typically decrease by whole dilution)
(Always return to top dose by weekly incremental increases)