Revere Health
Allergy & Immunology

Henry Yeates, MD • Tammy Jacobs, MD

(Office Only) MRN: _____

PATIENT NAME: _____

DOB: ____/____/_____ **AGE:** _____ **SEX: M / F**

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make a decision whether or not to undergo the procedure 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 procedure.

1. I voluntarily request Dr. HENRY YEATES and/or Dr. TAMMY JACOBS as my physician(s), and such associates, technical assistants, and other health care providers as necessary, to treat my condition which on the basis of my allergy history and allergy tests has been explained to me as allergic rhinitis, allergic conjunctivitis and/or asthma which is triggered by allergy.
2. I understand the following medical procedure is planned for me and I voluntarily consent and authorize: **sublingual immunotherapy**, also known as **allergy drops**. Allergy drops utilize the same allergen extracts with which skin testing and allergy shots are performed. However, it is important that you realize that while the allergen extracts used in the allergy drops are approved by the Food and Drug Administration (FDA) for allergy testing and allergy shots, they are currently **not FDA approved for the use as allergy drops,** and are therefore considered an **"off-label"** form of treatment**.** While widely used in Europe and other countries safely and effectively, allergy drops are considered by the FDA to be an "**investigational therapy"** at the present time.
    a. How do allergy drops work? Research has shown that allergy drops decrease allergic reactions by stimulating the formation of protective "blocking antibodies", by decreasing the production of "allergic antibodies", and by altering other immune cell function in a beneficial way. Allergy drops likely work in much the same way as allergy shots.
    b. How often and how long must I receive allergy drops? Allergy drops are generally self-administered at home once-daily in increasing doses until a maintenance (constant level) dose is achieved. This process takes about 2 weeks, although may take longer in certain people. A maintenance (or constant) dose is then taken every day. The duration of treatment with allergy drops will depend on how well you tolerate them and how well you respond to treatment. In general, a 12-month trial is given, and if benefit is realized, the drops are continued for 3-5 years with frequent follow-up appointments with your allergy doctor.
3. I understand that no warranty or guarantee has been made to me as to clinical result, benefit or cure. Allergy drops, similar to allergy shots, may not work for all people with allergic diseases.
4. There are risks and hazards related to the performance of sublingual immunotherapy. I realize that risks that may occur in connection with sublingual immunotherapy include, but are not limited to:
    a. **Local reactions** with itching of the lips, tongue or throat are very common. You may have a sense of mild swelling under/around your tongue or lips. It is also possible that you may have a mild upset stomach or mild diarrhea as a result of your allergy drops. Mild itching of the eyes and nose may also occur. In general, these reactions tend to go away after you've been taking the allergy drops for a few weeks. See ***Attachment 2*** for more information on these reactions.
    b. **Generalized reactions** (sometimes called "anaphylaxis"), which may include hives, itching of the eyes, nose, or skin, severe swelling of the throat or tongue, wheezing, coughing, difficulty breathing, abdominal cramps, rapid heart rate, sudden drop in blood pressure, and rare potentially life-threatening reactions that could include death. These reactions are extremely rare with allergy drops, and no deaths have ever been reported from taking allergy drops. For this reason, allergy drops can be safely administered at home, unlike allergy shots.
        i. Should these reactions occur, refer to ***Attachment 2***, treatment of reactions to allergy drops. If these reactions are frequent, severe or are otherwise bothersome, please stop taking your allergy drops and contact our office.
        ii. If you become pregnant, or think you are pregnant, stop taking your allergy drops and contact our office. You may be able to continue your allergy drops if you become pregnant, although this should be discussed with your allergist and obstetrician/primary care doctor before doing so.
        iii. Notify your allergist if you are started on a beta-blocker (some common examples of beta-blockers include Toprol, Lopressor, Metoprolol, Inderal, Propanolol, Atenolol, Bisoprolol, etc) or other high blood pressure medication. Allergy drops must be stopped if you are taking a beta-blocker, as

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these medications may make generalized reactions more severe and difficult to treat. If you are not sure what medication has been prescribed to you, please contact our office to be sure that your new medication is not a beta-blocker.

iv. You should not take your allergy drops if you are ill or have a fever, such as from a cold, flu or gastrointestinal illness (nausea, vomiting, abdominal pain or diarrhea). Wait until you are **completely better for at least 24 hours** before taking your next dose of allergy drops. If more than 7 days has passed since your last dose, see ***Attachment 1*** for dosing instructions. If you are not sure if you should take your allergy drops, call our office.

v. You should not take your allergy drops if your asthma symptoms have worsened. If you have asthma, you should **always check your peak flow right *before* taking your allergy drops**. If your peak flow is less than 80% of your best value, do not take your allergy drops that day. If your asthma continues to be a problem for more than a day (increased symptoms or low peak flows), please call us for an appointment as soon as possible.

vi. You should not take your allergy drops if you have had recent dental surgery, lost a tooth, have open sores (canker sores) or cuts in the mouth or have any injury to the inside of the mouth. In addition, if you are going to the dentist for any reason, do not take your allergy drops on the morning of your dental appointment. If no surgery is performed and no teeth are extracted, and only a cleaning and/or routine exam is performed, you may re-start your allergy drops the following day. If dental surgery or tooth extractions were performed, please **wait for 3-5 days** for your mouth to heal before re-starting your allergy drops, or contact our office for more information if you are not sure.

5. I understand that there are alternatives to allergy drops. These include, but are not limited to, the following choices: tolerate/ignore the allergy symptoms, avoid exposure to things to which I am allergic, and/or take allergy/asthma medications on an as needed or daily preventative basis and/or traditional 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, as well as side effects from medication use.
6. Since **traditional allergy shots are an FDA-approved therapy, these are considered to be a preferred method of treatment** over allergy drops. However, there may be reasons that you may choose allergy drops over allergy shots; these may include: the ability to administer at home, fear of needles, decreased time and travel commitment (not having to come into our office as frequently), and possible better safety profile.
7. I have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of non-treatment, the methods of to how to use allergy drops, and the risks and hazards involved, and I have sufficient information to give this informed consent.
8. I understand that allergy drops, while studied extensively in Europe and other parts of the world and found to be safe and efficacious, are **not approved by the FDA** in the United States and therefore considered to be an **"investigational"** and/or **"off-label"** form of allergy treatment at the present time.
9. I have been given a prescription for injectable epinephrine (such as an epinephrine autoinjector), and understand that I will need to **obtain this device and have it readily available** for use if a severe allergic reaction should occur as a result of taking sublingual immunotherapy.
10. I certify this form has been fully explained to me, and I have either read it or had it read to me, and I understand the contents.

Date: _____ Time: _____

Signature of patient/other legally responsible person: _____

Name of Patient: _____ Date of Birth: _____

Signature of counseling physician: _____ Henry Yeates, MD Tammy Jacobs, MD

I understand that because allergy drops are an **"off-label"** therapy, my insurance does not cover this form of treatment, and therefore cannot be billed for the cost. Therefore, I understand that the cost of allergy drops will be incurred completely by me. It is my responsibility to determine if these costs can be covered and/or reimbursed by any health savings account (HSA) or other similar account that I may have. Insurance coverage for routine office visits related to your allergies should remain unaffected.

I understand that it is my responsibility to notify the office **one to two weeks** prior to needing refill serum of my sublingual immunotherapy (allergy drops). I will be charged for this either in person or by phone at the time of order. I may pay up to 6 months in advance for the allergy drops to be **refilled and picked up monthly** or mailed out monthly with **$10.00 USD per S&H charge**. If I have paid in advance, I may call 1-2 weeks prior to monthly refilling to delay a month if needed. I understand that there are no refunds if I do not pick up the serum after they have been made. I will be notified by phone when my refill is ready for me to pick up.

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