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INTEGREVIEW IRB
DECEMBER 24, 2018

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR:	Christopher Thompson, MD
PROTOCOL NUMBER AND TITLE OF STUDY:	TASC-ILIT-MC-2018; "**T**e**X**an Allergy & **S**inus Center **M**ountain Cedar **I**ntra-**L**ymphatic Immunoth**E**rapy Study (TX-SMILE)"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR /INVESTIGATOR):	Christopher Thompson, MD
TELEPHONE NUMBER(S), DAYTIME:	(512) 994-1002
AFTER HOURS:	(512) 799-4110

INTRODUCTION

You are deciding if you would like to volunteer for a medical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

The investigator is the sponsor, and is paying for this study.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

PURPOSE OF THE STUDY

This study will investigate a alternate route of administration for injecting a commercially-available, approved allergenic extract to treat allergies to Texas Mountain Cedar pollen. This route of administration in investigational.

"Investigational" means the allergenic extract being tested is not approved by the FDA for injection directly into a lymph node. The purpose of this study is to to evaluate whether injecting an allergenic extract, called allergen immunotherapy, into a lymph node is safe and effective for treating allergies to Texas Mountain Cedar.

In this document, you may see the terms "medication", "treatment", and "treatment period"; these are terms used in research studies as mentioned above. These terms apply to the investigational study drug and parts of the study where you will be receiving this investigational product.

If you qualify for the study, you will receive

- Three (3) injections of 0.1 mL (about 2 drops) of study medication into a lymph node just under the skin, near your groin.
- These injections will be in the doctors office and spaced out by about four weeks

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Half of the subjects in this study will receive placebo during the study. Placebo contains no active ingredient.

This is a double-blind study, which means that neither you nor the investigator will know which drug you are taking. The study staff can get this information if needed.

The drug you receive will be assigned by chance, like the flip of a coin.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The study will last about 7 months and involve up to 5 visits plus daily diary questions during the allergy season. About 96 healthy men and women, ages 18 and older, are expected to be in this study.

TO BE IN THIS STUDY

You cannot be in this study if you are in another research study or if you have been in any other research study in the last 30 days.

Subject Responsibilities:

While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study.
- Answer questions about:
    - Your allergy symptoms
    - Your use of allergy medications
    - Being in the study

WHAT WILL HAPPEN DURING THE STUDY

Screening:

Before the study starts, you will be asked to sign this consent form, give your health history, and tell study staff if you take any over-the-counter or prescription medicines, vitamins or herbs.

The investigator will do some tests to find out if you can be in the study. These tests include:

- Ask you questions about your health, including your allergies and any medicines that you take
- Perform a physical exam
- Check your vital signs (blood pressure, temperature, heart and breathing rates)
- Skin testing for allergies to Mountain Cedar pollen
- Blood test for allergies to Mountain Cedar pollen
- Urine pregnancy tests for women who may become pregnant

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Study Procedures:

If you are eligible for the study, you will have four more study visits.

Treatment Visit 1

- Ask you questions about any changes to your health or the medicines that you take
- Check your vital signs (blood pressure, temperature, heart and breathing rates)
- Urine pregnancy tests for women who may become pregnant
- Perform an injection of about two drops of study medication into a lymph node near your groin
- Re-check your vital signs for one hour
- Ask you some questions about how painful the injection was and if you feel any side effects

Treatment Visit 2 (About four weeks after Treatment Visit 1)

- Ask you questions about any changes to your health or the medicines that you take
- Check your vital signs (blood pressure, temperature, heart and breathing rates)
- Urine pregnancy tests for women who may become pregnant
- Perform an injection of about two drops of study medication into a lymph node near your groin
- Re-check your vital signs for one hour
- Ask you some questions about how painful the injection was and if you feel any side effects
- Administer medications for allergic reactions to study medication if necessary

Treatment Visit 3 (About four weeks after Treatment Visit 2)

- Ask you questions about any changes to your health or the medicines that you take
- Check your vital signs (blood pressure, temperature, heart and breathing rates)
- Urine pregnancy tests for women who may become pregnant
- Perform an injection of about two drops of study medication into a lymph node near your groin
- Re-check your vital signs for one hour
- Ask you some questions about how painful the injection was and if you feel any side effects
- Administer medications for allergic reactions to study medication if necessary
- Review your contact information and review the procedures for completing your diary

Daily Diary Questions (During Allergy Season)

- You will receive text or email with a link to questions about your allergies. You will be asked to rate your allergy symptoms for that day on the following scale:

  no symptoms = 0
  mild symptoms = 1
  moderate symptoms = 2
  severe symptoms = 3

You will answer be asked to rate your symptoms from 0 to 3 for each of the following:

1. runny nose
2. stuffy nose
3. sneezing

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4. itchy nose
5. gritty/itchy eyes
6. watery eyes

- You will also be asked to answer "yes" or "no" about whether you used any allergy medicines on that day:

  Did you use an oral antihistamine (Zyrtec) today?
  Did you use antihistamine eye drops (olopatadine) today?
  Did you use a nasal corticosteroid (Flonase) today?

- If you have asthma, you will also be asked if you used your inhaler on that day.

End of Study Visit (After allergy season is over)

- Ask you questions about any changes to your health or the medicines that you take
- Review your symptom and medication diary
- Ask you questions about your health, including your allergies and any medicines that you take
- Perform a physical exam
- Repeat the blood test for allergies to Mountain Cedar pollen
- Ask you some questions about how your experience was with the study

Blood Samples:

Blood samples will be taken by single needle-sticks.

There will be 2 blood draws. The total amount of blood drawn will be about 1 mL. For comparison, the standard blood donation is about 480 mL (two cups).

HIV AND HEPATITIS TESTING

If any person is exposed to your blood, you must have your blood tested for the hepatitis viruses and for HIV. HIV is the virus that causes AIDS. If you have a positive HIV or hepatitis test you cannot be in the study.

If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be told in private and you will also be told about counseling.

It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

Positive test results are required to be reported to the Texas State Department of Health. If you have any questions about what information is required to be reported please ask the investigator or study staff.

Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

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POSSIBLE SIDE EFFECTS AND RISKS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because this procedure is investigational, all of the side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Below is a list of the most common side effects of skin testing and immunotherapy treatment for allergies. Where the study doctor injects you or pricks your skin, you may have:

- Redness
- Itching
- Swelling
- Pain

You should tell the study team if you have these side effects, especially if you have a lot of swelling or pain.

It is also possible that the injections or skin testing can cause a serious allergic reaction. This is very rare. The symptoms or a serious allergic reaction include:

- Coughing
- Wheezing
- Runny nose
- Watery eyes
- Fainting
- Slow heart beat
- Low blood pressure
- Hives
- Swelling of the face, tongue, or throat

These symptoms are serious and you must tell your doctor if you experience any of them. Your study doctor is trained to treat these side effects and you may require treatment for them.

There is a very low risk of:

- **Death** from a serious allergic reaction

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ADDITIONAL RISKS OR DISCOMFORTS

Blood Samples (taken by single needle-sticks at the beginning and end of the study):

There may be side effects of having blood drawn such as:

- Fainting
- Redness
- Pain
- Bruising
- Bleeding
- Infection
- Nerve damage
- Blood clots, which may cause inflammation, swelling and pain

If you feel faint tell the study staff right away.

Injections (needle-sticks during the treatment visits):

There may be side-effects of having an injection into a lymph node near your groin such as:

- You might feel nervous or anxious about the procedure
- Your blood pressure may go up
- Your heart rate might speed up

For patients that experienced these side-effects, the side-effects have gone away shortly after the procedure.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you should not get pregnant while in this study. If you are trying to get pregnant, you cannot be in the study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control listed below.

Methods of birth control for this study include:

- Hormonal contraceptives
- Barrier methods

Even if you use birth control during the study, there is a chance you or your partner could become pregnant. If you are pregnant or become pregnant during the study, it is not known whether allergenic extract used for treatment or skin testing can cause harm to your unborn baby. Studies have not demonstrated any risk, but one of the drugs used during skin testing can cause contractions. So, allergen testing and immunotherapy is not recommended for pregnant women unless clearly needed Because of this, if you are or become pregnant in this study you will not be able to continue study treatments. A pregnancy test is not always right, especially in the early stages of pregnancy.

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You cannot be in the study if you are breastfeeding. It is not known what effect allergen immunotherapy has during breastfeeding. Therefore, if you are breastfeeding a child you should not participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You may benefit from free medical tests. You will receive and be instructed to take medicine for your allergy symptoms.

There is no promise that your condition will get better as a result of the study treatment. It might stay the same or it might get worse, especially if you get the placebo.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

If you are not in this study you can still receive allergen immunotherapy or other treatments for your allergy symptoms. Allergen immunotherapy is proven to reduce the severity of allergies but takes 30 to 70 injections into your arm. This process takes at least 3 years, but benefits begin to show in 1 to 2 years.

If you choose not to be in this study, you can still get treatments for your allergy symptoms, including:

- An oral antihistamine, such as Zyrtec
- A prescription for eye drops called olopatadine
- A nasal corticosteroid, such as Flonase

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The sponsor-investigator, Dr. Thompson
- People appointed by Dr. Thompson to monitor or audit the study data
- Employees of Texan Allergy & Sinus Center
- The United States Food and Drug Administration (FDA)
- IntegReview IRB

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will **not** include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

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IN CASE OF STUDY RELATED INJURY

If you experience a serious allergic reaction during the study, the study doctor and his team will provide necessary medical treatments up to transferring you by ambulance to a hospital.

These treatments may include:

- One or more shots of epinephrine into your thigh
- Oxygen given by a mask
- A breathing tube to ensure that your airway is clear
- Other medicines to help you breathe
- If you faint, medicines to help support your blood pressure
- Other medicines to help control the allergic reaction
- You may receive emergency treatments, if your heart or breathing stop

If you are injured or experience a side effect during this study, no other form of compensation is offered aside from the listed medical treatments. If you are transferred by ambulance to a hospital, you may be responsible for the ambulance and hospital costs.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Dr. Christopher Thompson
(512) 994-1002 (day time)
(512) 799-4110 (after hours)

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please call 911 or go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. You can still get healthcare in the future.

Employees of Texan Allergy & Sinus Center:

Employees of Texan Allergy & Sinus Center are allowed to participate in this study. If you are an employee:

- The decision to participate or not will not affect your performance evaluation.
- The decision to participate or not will not affect possible promotions.
- The decision to participate or not will not affect your pay.

The sponsor-investigator, IntegReview, or the FDA may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health
- If you become pregnant
- If you do not complete the study treatments
- If you do not routinely complete the patient diary
- If you are going to leave central Texas for a large part of the allergy season

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

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NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Latin America and Japan.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will receive a signed and dated copy of this consent form to keep.