INFORMATION AND CONSENT FORM

Study Title: A Study of ATI-50002 Topical Solution for the Treatment of Vitiligo

Study #: ATI-50002-VITI-201

Sponsor: Aclaris Therapeutics, Inc.

Study Doctor: <<investigator>>
<<firm name>>
<<street address>>, <<city>>, <<state>> <<zip>>

Telephone Number: <<000-000-0000>>

After Office Hours: <<000-000-0000>>

The study doctor wants to know if you would like to be part of a research study.

If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

WHAT IS THIS STUDY ABOUT?

Researchers want to find out more about an investigational drug called ATI-50002 Topical Solution. An “investigational” drug is a drug that is being tested as a potential treatment and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).

Vitiligo is a disorder in which white patches of skin appear on different parts of the body. The white patches appear because the cells that make the pigment (color) in the skin are destroyed. Vitiligo may spread to other areas of the body. There is no way to tell if vitiligo will spread to other areas. For some people, vitiligo spreads slowly and for others spreading occurs quickly.

Vitiligo may be an autoimmune disease. Your body’s immune system protects you from disease and infection, but if you have an autoimmune condition or disease, your immune system attacks healthy cells in your body by mistake. In vitiligo, the immune system attacks the melanocytes (melanin-forming cells).

Current treatment options for vitiligo include medical treatments that you put on your skin or take by mouth, treatments that use a topical medicine plus ultraviolet light A (UVA) light (PUVA), lasers, removing the color from other areas to match the white patches, surgical options such as a skin graft or tattooing small areas of skin, and other treatments such as cosmetics to cover the white areas.

Treatments that restore the color to the skin may take 2 to 3 months before small areas of color can be seen and 6 to 9 months before more color fills in the areas of white skin.

The main purpose of this study is to see whether ATI-50002 Topical Solution (0.46%) can help the skin color to return in the white patches in people with vitiligo on the face. Researchers also want to find out if ATI-50002 Topical Solution applied to the face is safe and tolerable.

It is planned that about 24 people with facial vitiligo will be in this study.

Be aware that this form refers to ATI-50002 Topical Solution (0.46%) as "study drug."

HOW DOES ATI-50002 TOPICAL SOLUTION WORK?

ATI-50002 Topical Solution is an investigational drug in a Topical Solution that is designed to return color to the white areas on the face. ATI-50002 Topical Solution has not been studied in people with facial vitiligo, and whether or not ATI-50002 will work is unknown. If you receive ATI-50002 in this study and the drug is effective, early signs of color in your white facial patches (if any occurs) may take up to three months, and more color may appear after 6 months of dosing. There is no guarantee that ATI-50002 will help your facial vitiligo.

IS THERE ANYTHING ELSE I CAN DO FOR MY FACIAL VITILIGO?

You do not have to be in this study to get help for your vitiligo. Some other things you may be able to do are:

- Corticosteroids (anti-inflammatory medications), either topically applied or taken by mouth,
- Calcineurin inhibitors (immunosuppressive medications), applied to the white patches of skin
- Phototherapy, a treatment that uses ultraviolet light
- Surgery, skin grafts from your own skin with color
- Tattooing small areas of skin
- Cosmetics to cover the white patches on your skin
- Investigational drugs

Although many products are used for this condition, their effectiveness is uncertain.

You should discuss your alternatives to participating in this research with the study doctor or study staff. In addition, you may discuss your options with your regular health care provider.

WHO IS PAYING FOR THIS STUDY?

A company called Aclaris Therapeutics, Inc., the sponsor of the study, is paying for this study.

<<Quorum may add site-specific conflict-of-interest language to the form based on information the site reports to Quorum.>>

WILL IT COST ANYTHING TO BE IN THIS STUDY?

It will not cost you anything to participate in this study.

HOW LONG WILL I BE IN THE STUDY?

If you decide to be in this study and the study doctor says you can be in the study, your participation will include 11 visits to the study center and will last about 28 weeks, up to a maximum of 201 days, with a possibility of up to an additional 28 days for screening results to be received.

You will visit the study center to have the procedures and tests described in this form. Ask the study doctor or study staff about your study visit schedule.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to be in this study, you might have to stop using your regular medication or therapy during the entire study.

The study doctor or study staff will give you study drug to put on the white patches on your face. You should not apply the study drug to your eyelids or the red (mucosal) areas of your lips. You also should not get any study drug in your eyes. You will apply up to 2 mLs of the study drug 2 times a day (in the morning and evening approximately 8 to 12 hours apart) for 24 weeks. If your face is clean shaven at the screening visit, you should remain clean shaven throughout the study.

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor or study staff.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

What happens when I come for study visits?

After you sign this form, the study doctor or study staff will perform the tests and procedures listed below when you come in for the study visits. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

- **Demographic Questions:** Ask you to give personal information, such as your name, date of birth, sex at birth, and race/ethnicity.
- **Health and Medication Questions:** Ask you to answer questions about your health, your medical history, your vitiligo history, and the medications you take.
- **Physical Exam:** The study doctor or a member of the study staff will examine your overall general appearance, head, eyes, ears, nose, throat, stomach, nervous system, muscles and bones, lymphatics, and skin, and will listen to your heart and lungs.

- **Vital Signs:** Check your blood pressure by putting a band around your arm (this will squeeze your arm for about a minute), check your pulse, listen to you breathe in and out, and take your temperature.
- **Height, Weight:** See how tall you are, and see how much you weigh.
- **Blood Testing:** Take some blood through a needle in your arm to do safety and laboratory tests. During the first visit, you will have 7 tubes of blood taken and at other visits, you will have 2 tubes of blood drawn. The maximum amount of blood you will have taken over 28 weeks is slightly less than ½ cup for the safety testing.
    - Some of your blood will be used to test for HIV, hepatitis, and tuberculosis.
        - The study doctor or study staff will tell you if these test results are positive.
        - If required by state law, the study doctor or study staff may report a positive test result to the local health department.
        - The results of these tests must be negative in order for you to be in the study.
- **Urine Testing:** You will have your urine tested.
- **Pregnancy Testing:** Test your blood and/or urine to see if you are pregnant. You will only have pregnancy testing if you are a woman and can have children.
    - The study doctor or study staff will tell you if the pregnancy test results are positive.
    - The results of the pregnancy testing must be negative in order for you to be enrolled in and continue in the study.
- **Electrocardiogram:** An electrocardiogram (ECG) measures the electrical activity of your heart.
- **Changes in Health or Medication Questions:** You will be asked about any changes in your health and the medications you are taking since the previous study visit.
- **Skin Examinations:** The study doctor or study staff will examine your face to determine the amount of white patches.
- **Questionnaires:** You will examine your face to determine and describe the appearance and severity of your facial vitiligo (white patches), and assess the impact of the facial vitiligo on your life. At Visit 7 (Day 85), you will be asked to rate your satisfaction with the study drug results.
- **Photography:** The study doctor or study staff will take pictures of your face (your face will be included in these photographs) to document the white patches. These photographs may be used for research purposes related to the study and for presentation to government health authorities, such as the U.S. Food and Drug Administration (FDA), at scientific meetings, for scientific publications, for general corporate purposes, and may be used for marketing purposes. Your identity will not be revealed in these photographs. Your identifying features, (eyes, mouth, tattoos) will be hidden in the photographs. **You do not have to let the study doctor or study staff take photographs if you don't want to; however, if you decline to have these pictures taken, you will not be allowed to participate in this study.**
- **Study Drug:** You will be given a supply of study drug and instructions for how to apply the study drug.

- **Apply study drug in the office:** At Visit 2, the study staff will instruct you on how to apply the study drug. You will apply the study drug in the office under the supervision and guidance of the study staff.
- **Subject Instruction Sheet:** You will be given a written instruction sheet.

The following is a schedule of events and tests you will have at each visit:

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11
Informed consent	✓										
Physical exam	✓										✓
A discussion about your age, birth date, medical and surgical history, and history of vitiligo	✓										
Vital signs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Height and Weight	✓										
Blood for safety and urine test	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Blood test for pregnancy, if you are a woman and can have a baby	✓										
Urine pregnancy test, if you are a woman who can have a baby		✓			✓	✓	✓	✓	✓	✓	✓
ECG	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Examination of your face and calculation of the percentage of white patchy areas	✓	✓									
Examination of your face, white facial patches, and colored areas		✓			✓	✓	✓	✓	✓	✓	✓
Examination of the percentage of your body with white patches	✓	✓					✓			✓	
Photographs of your face		✓			✓	✓	✓	✓	✓	✓	✓
Questions about how noticeable is your facial vitiligo					✓	✓	✓	✓	✓	✓	✓
Questions about how satisfied you are with the response to study drug							✓	✓	✓	✓	✓
Questions about the impact of your facial vitiligo		✓					✓	✓	✓	✓	✓
Study drug and instructions		✓	✓	✓	✓	✓	✓	✓	✓		
In office study drug application		✓									
Changes in Health or Medication Questions		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

The results from the tests at Visit 1 will determine whether you are eligible to continue in the study. If you discontinue the study early for any reason, the tests for Visit 11 will be performed.

WILL BEING IN THIS STUDY HELP ME?

The study drug may help your facial vitiligo, but there is no guarantee that being in this study will help you. Your vitiligo might not get better or may even get worse while you are in this study. Information from this study might help researchers to better understand vitiligo or come up with new tests or medications to help others in the future.

WHAT ARE THE RISKS TO ME IF I AM IN THIS STUDY?

This is the first time that ATI-50002 has been used on people with vitiligo.

You must be careful to avoid having the study drug run into your eyes because it could cause irritation.

In animal testing, the following temporary side effects occurred on the skin where ATI-50002 was applied:

- Redness
- Swelling
- Skin peeling

Healthy volunteers took an oral form of ATI-50002, and the most frequently reported drug-related side effects include:

- Abdominal pain
- Flatulence
- Diarrhea
- Headache

People who took FDA-approved oral medications similar to ATI-50002 experienced:

- Infections (bacterial, viral, fungal, or other infections)
- Abnormal blood tests (decreases in white blood cells and platelets, and increases in liver function tests)
- Cancers
- Increased lipids (total cholesterol, high-density lipoprotein cholesterol [also known as HDL, the good cholesterol], and low-density lipoprotein cholesterol [also known as LDL, the bad cholesterol])

Since ATI-50002 Topical Solution is an investigational drug, there may be other risks that are unknown. Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study drug.

It is possible that using ATI-50002 Topical Solution may change how your regular medications, vaccines, or supplements work. It is very important that you tell the study doctor about any medications, supplements, or vaccines before you take them during the study.

Could I have an allergic reaction?

Sometimes people have allergic reactions to drugs. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- A rash
- A fast pulse
- Sweating
- A feeling of dread
- Swelling around the eyes and mouth
- Swelling of the throat
- Wheezing
- Having a hard time breathing
- A sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Inability to breathe without assistance

You should get medical help and contact the study doctor or study staff, if you have any of these or any other side effects during the study.

If I stop using my regular medication or therapy, what are the risks?

If you stop your regular medication or therapy to be in the study, your facial vitiligo symptoms might come back or get worse or your health might get worse. Please tell the study doctor or study staff right away if you have any problems when you stop or change your regular medication or therapy.

What are the risks of giving blood for this study?

The study doctor or study staff will take your blood by sticking a needle in your arm. Some problems you might have from this are:

- Pain
- Bruising
- Dizziness
- Infection

Risks of study photography

There are no expected physical risks if the study doctor or study staff takes photos of your face during the study. It is possible that people who see the study photos will recognize you.

Loss of confidentiality

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

What are the risks if I am pregnant or nursing a child during the study?

If you are a woman who can have a baby, you must not get pregnant during the study or for 30 days after the last study drug application. In animal testing, there were potential toxic effects to both the embryo and fetus, indicating a risk to pregnancies. If you are pregnant or nursing a child while using ATI-50002 Topical Solution, there may be risks to you, the embryo, fetus, or nursing child. Nobody knows what all the risks are right now.

If you are a woman who can have children, the study doctor or study staff will talk to you about birth control you must use during the study and up to 30 days after the last application of study drug.

If you think you are pregnant during the study, you must tell the study doctor or study staff immediately.

Women who become pregnant during the study will have to leave the study. The study doctor or study staff may ask for information about the pregnancy and the child's health at birth, and for up to 6 weeks after the birth, and may share this information with the sponsor.

What are the risks of fathering a child during the study?

If you are a sexually active male, you must not father a child during the study or for 30 days after the last dose of study drug. In animal testing, there were potential toxic effects to both the embryo and fetus, indicating a risk to pregnancies. There may be risks to an unborn embryo or fetus that you father during or after the study. Nobody knows what all the risks are right now. You must agree to use a barrier method of contraception from the first dose of study drug to at least 30 days after the last dose of study drug.

If you think your partner is pregnant during the study, you must tell the study doctor or study staff immediately. The study doctor or study staff may ask for information about the pregnancy and the child's health at birth, and for up to 6 weeks after the birth, and may share this information with the sponsor.

COULD I HAVE ANY OTHER PROBLEMS WITH MY HEALTH IF I AM IN THIS STUDY?

It is possible that you could have problems and side effects of ATI-50002 Topical Solution that nobody knows about yet, which include your facial vitiligo getting worse.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

WILL I RECEIVE ANY NEW INFORMATION DURING THE STUDY?

If the study doctor or study staff learns any new information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If, during the course of this study, any injury occurs to you as a direct result of the administration of the study drug or properly performed procedures, the Sponsor agrees to pay all medical expenses necessary to treat such injury: 1) to the extent you are not otherwise reimbursed by medical insurance; and 2) provided you have followed the directions of the study doctor.

The compensation offered by the Sponsor for any injury which occurs to you as a direct result of the administration of the study drug or poorly performed procedures by the study doctor or study staff, will be paid after the Sponsor receives all appropriate documentation and completes its review, to its satisfaction, of all documentation regarding your claim for injury.

You will not lose or give up any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for negligence or intentional misconduct by signing this consent document.

There are no plans to provide financial compensation for such things as lost wages, disability, or discomfort due to injury.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

WILL I RECEIVE PAYMENT?

<<Quorum will add site-specific compensation language to the form based on information the site reports to Quorum.>>

DO I HAVE TO BE IN THIS STUDY?

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won't lose any benefits except for benefits having to do with the study. If you want to stop being in the study, tell the study doctor or study staff.

The study doctor or study staff or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if, for example:

- The study doctor or study staff believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor stops the study for any reason.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. The study doctor or study staff may ask you to participate in some procedures or tests to help you leave the study safely and/or to collect more information for the study.

If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

If you change your mind later, be aware that your samples may or may not be withdrawn from the research, depending on the sponsor's policies. You can ask the study doctor or study staff about this.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your identity will be protected as required by law and according to any policies the study center or sponsor may have. Be aware that your study records (which include your medical records, your signed consent form, and other information) will be shared as needed for the study. For example, the U.S. Food and Drug Administration (FDA), the sponsor, and Quorum Review may look at your study and medical records.

Your blood and urine samples will not be labeled with your name or other directly identifying information. Your samples will have a code (a unique subject identifier) instead. The list that matches the code with your name will be stored separately from your samples. Your samples will be kept only until we are able to complete the tests described in this form, and then your samples will be destroyed.

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.

WHO CAN I TALK TO ABOUT THIS STUDY?

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

You can ask questions about the study at any time. You can call the study doctor or study staff at any time if you have any concerns or complaints. You should call the study doctor or study staff at the phone number listed on page 1 of this form if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.QuorumReview.com.

> Quorum Review is located in Seattle, Washington.
> Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
> Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

HOW WILL MY INFORMATION BE USED AND SHARED FOR THIS STUDY?

This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the study.

The study doctor and study staff will collect, use, and share health information about you, including any information needed to do the study and other identifying information about you, such as your name, address, phone number, or social security number. The information used and shared will include:

- information from your medical records
- information collected about you during the research, including study visits, notes, tests, procedures, photographs, etc.

Your information may be used and shared with these people for the following purposes:

- The study doctor and study staff to conduct this research.
- The sponsor, Aclaris Therapeutics, Inc.; people who work with or for the sponsor; and other researchers involved in this study. These people will use your information to review the study, to check the safety and results of the study drug, and to seek government approval of ATI-50002 Topical Solution.
- Others required by law to review the quality and safety of research, including the FDA, Department of Health and Human Services, Office for Human Research Protections, other government agencies in the United States and other countries, and Quorum Review.

After your information is shared with the people and companies listed above, the law may not require them to protect the privacy of your information.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study.

If you cancel your authorization, the study doctor and study staff will still be able to use and share your information that they have already collected.

This authorization to use and share your information expires in 50 years.

_____ _____

Signature of Participant Date

<<Quorum staff: Include the following for Indiana sites:

In **Indiana,** you must complete the following information:

_____
Participant's Street Address

_____
Participant's City, State, ZIP>>

REGULAR DOCTOR OR SPECIALIST NOTIFICATION OPTION

For your safety, you or the study doctor should tell your regular health care provider that you are in this study. This is recommended so that your primary care doctor may contact the study doctor if they have any concerns or questions about your care.

Please indicate below whether you want us to notify your regular doctor or your specialist of your participation in this study.

☐ Yes, I want the study doctor to inform my regular doctor/specialist of my participation in this study:

_____ _____

Name of Doctor Phone

☐ No, I do not want the study doctor to inform my regular doctor/specialist of my participation in this study.

☐ I do not have a regular doctor/specialist.

☐ The study doctor is my regular doctor/specialist.

CONSENT

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study. They have answered all my questions. I voluntarily agree to be in this study.

By signing this form, I do not give up any of my legal rights. I will get a signed copy of this consent form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

I attest that I or my representative discussed this study with the individual providing consent.

_____
Signature of Principal Investigator or Sub-Investigator