INFORMATION AND CONSENT FORM

Study Title: An Open-Label Pilot Study of the Safety, Tolerability and Efficacy of ATI-50002 Topical Solution Administered Twice-Daily in Adult Subjects with Non-Segmental Facial 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>>

You are currently participating in Aclaris Therapeutics, Inc.'s ATI-50002-VITI-201 study, and the study doctor or study staff has asked you to read and sign this Addendum to the Consent Form. Everything in the main study consent form you signed before still applies to your participation in this study unless otherwise noted in this form.

This form describes additional information about the 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.

WHAT IS THE PURPOSE OF THIS ADDENDUM?

Since the time you signed the last consent form for this study, new information related to the study has become available:

The study sponsor has decided to increase the duration of the study to allow application of ATI-50002 Topical Solution, 0.46% (study drug) to your face and if you have vitiligo on your neck to your neck also from 24 weeks up to 48 weeks with a 4-week after treatment follow-up visit. You had previously indicated that you wanted to apply study drug for up to 24 weeks only. If you would like to continue applying the study drug for the additional 24 weeks being offered, you will have to read and sign this consent addendum and then come into the clinic for four extra visits (Visits 12, 13, 14, & 15) scheduled 3 months apart which were not originally planned. You will then come in for a final visit as originally planned 1 month after you last use the study drug (Visit 16). During these visits, the following tests may be performed by the study staff:

- **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.
- **Blood Testing:** Take some blood through a needle in your arm to do safety and laboratory tests. If you continue with 4 additional visits, the maximum amount of blood you will have taken over the 52 weeks is slightly less than ¾ cup.
- **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 Visits 12, 13 and 14 (Day 225, 281 and 337) 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.
- **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 additional visit:

Procedures	Open-Label Treatment			Post-Treatment
	Visit 12 (Week 32)	Visit 13 (Week 40)	Visit 14 (Week 48)	Visit 15 (Week 52)
Physical exam				✓
Vital signs	✓	✓	✓	✓
Blood for safety and urine test	✓	✓	✓	✓
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 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			✓	
Questionnaire completion	✓	✓	✓	✓
Receive Study Drug	✓	✓		
Health and medication questions	✓	✓	✓	✓

DO I HAVE TO CONTINUE IN THIS STUDY?

Your decision to still be in this study is voluntary. You do not have to be in the study any longer if you don't want to, and you can change your mind at any time. There will be no penalty to you, and you won't lose any benefits. If you want to stop being in the study, tell the study doctor or study staff. If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

WILL I RECEIVE PAYMENT?

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

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