INFORMATION AND CONSENT FORM

For Adults and Parents/Guardians of Minor Participants

For California Sites

Study Title: A Phase 3 Open Label Safety Study of A-101 Topical Solution for the Treatment of Common Warts

Study #: A-101-WART-303

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>>

Before you read this consent form, you should read a copy of the California Experimental Subject's Bill of Rights. Ask the study staff for a copy of this document if you haven't already received one.

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.

When reading this form, please note that the words "you" and "your" refer to the person or child (persons under 18 years of age) participating in the study rather than to a parent/guardian who might sign this form on behalf of the person in the study.

WHAT IS THIS STUDY ABOUT?

You are being invited to participate in this research study because you have participated in a prior study run by Aclaris Therapeutics called either, Thwart 1 or Thwart 2, which are studies for common warts. The purpose of this research study is to test the long-term safety of a new investigational drug, A-101 45% Topical Solution, that is applied only to the skin. An "investigational drug" is a drug that is being tested and is not approved for use in the United States by the U.S. Food and Drug Administration (FDA).

It is planned that about 400 people who have participated in either the Thwart 1 or Thwart 2 studies will be in this study.

Be aware that this form refers to A-101 45% Topical Solution as “study drug.”

HOW DOES A-101 45% TOPICAL SOLUTION WORK?

A-101 45% Topical Solution contains hydrogen peroxide (H_2O_2). Hydrogen peroxide is a simple chemical combination of hydrogen and oxygen. H_2O_2 is commonly used in household products including chlorine-free bleaches, general-purpose cleaning agents and disinfectants, hair dyes and tooth-whitening products. In industry it is used in waste-water treatment and, at higher concentrations (greater than 30%), in bleaching paper pulp, and textiles. In medicine H_2O_2 is used at low concentrations (3%-6%) to cleanse wounds and as a topical antiseptic/disinfectant.

A-101 45% Topical Solution is being developed to remove common skin warts. This investigational drug containing H_2O_2 may remove warts due to its ability to dissolve the wart.

If I choose not to participate in this study, what are other options I have?

You do not have to be in this study.

If you currently have warts, or develop new warts, some other things you may be able to do are:

- Topical therapies such as acids (salicylic or trichloroacetic acids), available either over-the-counter or from a physician; cytotoxic therapies (topical podophyllin, cantharidin, 5-fluorouracil, or bleomycin); topical immunomodulatory or immunotherapy (topical imiquimod, intralesional candida antigen, topical squaric acid dibutyl ester)
- Destruction of the warts by freezing (cryotherapy), electric current (electrosurgery), or scraping or cutting them off

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?

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

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 last about 6 months and includes up to 4 visits to the study center.

If you decide to be in this study, your first visit may be the same day as the last visit of the prior study, or your first visit may be scheduled for a different day.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to be in this study and all of your warts have cleared during the prior study, you will be called approximately every 6 weeks to ask if you have had a previously treated wart return, or if you have had a new wart develop. If you develop a new wart, or have a reoccurrence of a previously treated wart, you do not have to wait for the study site to call you; you can call the study site and they will request you come in to the office. After assessing the new wart, if the wart or warts (up to 6) meet the requirements, they will be treated twice a week for up to 8 weeks with A-101 45%.

If you decide to be in this study, and you currently have common warts, you will begin treatment with A-101 45%.

The study drug will be applied to up to 6 warts, which meet the requirement, twice a week for up to 8 weeks from Visit 1 through Day 53 (a few days before the 3rd office visit, called Visit 5). Participants between the ages of 12 and 17 years old will have their study drug applied by a parent or legal guardian. Adult participants will be instructed by study staff how to self-apply study drug.

Study drug will be applied to each of the selected warts for about 15 seconds. Application with study drug at each visit may be repeated 3 times to each selected wart.

You will be given a study diary to record your applications of study drug at home. You will bring your study diary with you to each study visit.

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.
- Avoid scrubbing or irritating the warts being dosed – you may continue your regular skin care products.
- Avoid excessive sun exposure to the warts being dosed.

All subjects who sign this informed consent form who have or develop new warts or a reoccurrence of their previously treated warts, will be treated with A-101 45%.

<u>What happens when I come for study visits?</u>

After you sign this form, <u>if you do not currently have any warts</u>, the study doctor or study staff will do the following things:

Visit 1 (In Office)

- **Informed Consent:** You will be asked to sign this informed consent form.
- **Demographic Questions:** You will be asked to give personal information, such as your name, date of birth, race, etc.
- **Health and Medication Questions:** You will be asked about any changes to your health or medications.

Visit 2

- **A phone call:** You will receive a phone call from the site staff to ask you questions about any changes to your health or medications, and to ask if you have had any new warts develop since the last time you were seen in the office.

Visits 3

- **A phone call:** You will receive a phone call from the site staff to ask you questions about any changes to your health or medications, and to ask if you have had any new warts develop since the last time you were seen in the office.

Visit 4

- **A phone call:** You will receive a phone call from the site staff to ask you questions about any changes to your health or medications, and to ask if you have had any new warts develop since the last time you were seen in the office.

Visit 5 End of Study (In Office)

- **Health and Medication Questions:** You will be asked about any changes to your health or medications and if you have had any new warts develop since the last time you were seen in the office.

Early Discontinuation Visit

If you decide you do not want to be in the study anymore for any reason, the procedures for Visit 5 will be completed.

If you develop new warts or have a reoccurrence of any previously treated warts while you are being followed by phone calls, before day 102 of the study, you will be asked to come in to the office to have the wart or warts assessed and you will be able to begin treatment with A-101 according to the visit schedule below.

After you sign this form, if you currently have a wart, or warts, the study doctor or study staff will do the things listed below when you come in for study visits.

Visit 1 (In Office)

- **Informed Consent:** You will be asked to sign this informed consent form.
- **Demographic Questions:** You will be asked to give personal information, such as your name, date of birth, race, etc.
- **Health and Medication Questions:** You will be asked about any changes to your health or medications.
- **Wart Assessment:** Your skin will be assessed for warts. The study doctor will identify up to 6 common warts to be dosed with study drug. The warts will be measured.
- **Blood Testing:** Blood samples will be taken for routine laboratory evaluation, if your visit 1 is done on a day other than the last visit day (Visit 13) of the prior study.
- **Subject Instruction Sheet:** You will be given a written instruction sheet that will be reviewed with you.
- **Study Medication Application:** Study drug will be applied to common warts during the in-office visit as determined by the study doctor. If the study doctor thinks you need another application, they will provide you with enough applicators to do the remaining applications at home.
- **Evaluation of Application Area:** The areas where study drug is applied will be examined for local skin reactions before study drug application. You will be asked about any stinging/burning or itching in those areas before study drug application, if applicable.

Visit 2

- **A phone call:** You will receive a phone call from the site staff to ask you questions about any changes to your health or medications, and to ask if you have had any new warts develop since the last time you were seen in the office.

Visits 3 (In office)

- **Health and Medication Questions:** You will be asked about any changes to your health or medications.
- **Wart Assessment:** The common warts will be looked at and measured by your study doctor.
- **Study Drug Application:** Study drug will be applied to common warts during the in-office visit as determined by the study doctor. If the study doctor thinks you need another application, they will provide you with enough applicators to do the remaining applications at home.
- **Evaluation of Application Area:** The areas where study drug is applied will be examined for local skin reactions before study drug application. You will be asked about any stinging/burning or itching in those areas before study drug application, if applicable.

- **Subject Instruction Sheet:** Your study instructions will be reviewed with you, and additional study medication will be provided.

Visit 4

- **A phone call:** You will receive a phone call from the site staff to ask you questions about any changes to your health or medications, and to ask if you have had any new warts develop since the last time you were seen in the office.

Visits 5 (In office)

- **Health and Medication Questions:** You will be asked about any changes to your health or medications.
- **Wart Assessment:** The common warts will be looked at and measured by your study doctor.
- **Evaluation of Application Area:** The areas where study drug was applied will be examined for local skin reactions. You will be asked about any stinging/burning or itching in those areas, if applicable.

Visit 6

- **A phone call:** You will receive a phone call from the site staff to ask you questions about any changes to your health or medications, and to ask if you have had any new warts develop since the last time you were seen in the office.

Visit 7

- **A phone call:** You will receive a phone call from the site staff to ask you questions about any changes to your health or medications, and to ask if you have had any new warts develop since the last time you were seen in the office.

Visit 8 – End of Study (In office)

- **Health and Medication Questions:** You will be asked about any changes to your health or medications.
- **Blood Testing:** Blood samples will be taken for routine laboratory evaluation.
- **Wart Assessment:** The common warts will be looked at and measured by the study doctor.
- **Evaluation of Application Area:** The areas where study drug was applied will be examined for local skin reactions. You will be asked about any stinging/burning or itching in those areas.

Early Discontinuation Visit

If you decide you do not want to be in the study anymore for any reason, the procedures for Visit 8 will be completed.

Will I need time to recover after my participation in the study?

Ask the study doctor or study staff for the estimated recovery time of your participation in this study.

WILL BEING IN THIS STUDY HELP ME?

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

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

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. Hydrogen peroxide has been used in people for other reasons, and when it is applied topically the common adverse effects include:

- Temporary discomfort in the dosing area (burning, stinging and/or itching)
- Temporary redness in the dosing area
- Temporary and reversible whitening (NOT BLEACHING) of the skin
- Blistering
- Bleaching of the hair within the dosing area.

In a previous study of subjects using hydrogen peroxide the side effects seen included:

- Stinging or burning sensation at the study drug application site
- Mild discomfort at the site

While not a side effect, H_2O_2 may bleach clothing that overlies the application area or comes in contact with the study drug.

Precaution: The study drug is a high-strength hydrogen peroxide product. High strength hydrogen peroxide products may cause serious harm or death if ingested. High strength hydrogen peroxide products are highly corrosive, and the FDA considers the substance to be dangerous. A-101 hydrogen peroxide should only be applied topically as indicated for skin warts.

It is possible that using A-101 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.

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.

If you feel that A-101 45% topical solution has come in contact with your eyes, mouth or nose, tell your study doctor immediately. Serious eye problems may happen if the solution gets into your eyes. Eye problems may include, pain, swelling, redness, irritation and in some cases, blindness.

Could I have an allergic reaction?

All topical drugs have a potential risk of an allergic reaction, which could result in a rash (red or rough skin) or a worse skin reaction at the area of application.

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

If you stop your regular medication, therapy, or supplements to be in the study, your warts symptoms might come back or 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, therapy, or supplements.

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

Unknown risks

It is possible that you could have problems and side effects of A-101 45% topical solution that nobody knows about yet, which could include your warts getting worse.

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.

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; 2) provided you have followed the directions of the study doctor.

Compensation 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 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 form.

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 you are entitled to. 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:

- 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.

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.

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), Aclaris Therapeutics, Inc. and Quorum Review (a group of people who review research studies to protect the rights and welfare of research participants) may look at your study and medical records.

Your blood samples will not be labeled with your name or other directly identifying information. Your samples will have a code 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. 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.

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 payment, 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, progress 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, and to seek government approval of A-101 45% 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 (If an Adult) or Parent/Guardian | Date

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. I agree to allow the collection, use, and sharing of my information as described above.

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 (if an Adult) Date

If participant does not have the legal capacity to consent to his/her participation:

I am the parent/guardian of the participant named above and I consent to his/her participation in this research study. I also authorize the collection, use and sharing of the participant's information.

_____
Printed Name of Parent/Guardian

_____ _____
Signature of Parent/Guardian 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