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UR MEDICINE
MEDICINE of THE HIGHEST ORDER

PARENTAL PERMISSION / CONSENT FORM

ASPIRE: DETERIMINING THE IMPACT OF CRISABOROLE (Eucrisa) AND TACROLIMUS 0.03% ON PATIENT-REPORTED OUTCOMES AND CAREGIVER BURDEN IN CHILDREN WITH ATOPIC DERMATITIS

Principal Investigators: [redacted]

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision.
Please read this form carefully.

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean "you"; "your child" means your child with atopic dermatitis eligible for the study; and "we" means the study staff.

The study personnel will explain this study to you and your child. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about the study and to discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your medical care plan will not be changed in any way.

INTRODUCTION

This consent form describes a research study and what to expect if you decide to participate. You are encouraged to read this consent form carefully and to ask the person who presents it to you any questions you may have before deciding whether or not to participate.

You are being asked to take part in this research study because you have are the caregiver (i.e., parent or guardian) of a child between the ages of 2-15 years (inclusive) who has been diagnosed with mild to moderate atopic dermatitis.

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Expiration Date: 6/21/2021

WHY IS THIS STUDY BEING DONE?

The purpose of this clinical trial is to evaluate the impact of two Food and Drug Administration (FDA)approved, non-steroidal topical treatments (crisaborole and tacrolimus 0.03%) for atopic dermatitis on the overall health of children with atopic dermatitis and their caregivers using of several patient-reported outcome measures (PROs). This study will collect meaningful data on how PROs can be used to monitor disease activity and response to different interventions, with the ultimate goal to improve quality of life for the patient and their family members or caregivers.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 40 parent/child pairs (i.e., a total of 80 subjects) will take part in this study. This a local study being performed in the [redacted]

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Your participation in this study will last 12 weeks during which you will have three study visits. After agreeing to participate in the study, you and your child will be complete the ASPIRE On Study Form with study personnel. You will be asked about demographic information (i.e., age, race, ethnicity, gender), medical history of your child, all current medications of your child, and any previous treatment your child has received for atopic dermatitis. You will also provide your mailing address for reimbursement of study participation on the Study Reimbursement Form and W9 form for a check to be mailed to you at the end of the study. Your child will also complete a W9 form for reimbursement at the beginning of the study. Your child will complete a Pediatric Subject Reimbursement Form at each study visit to receive a $10 gift card for participation. You may assist your child in completion of these forms, however your child must sign the Pediatric Subject Reimbursement Form.

Your child will be randomized to one of two topical treatments for atopic dermatitis (crisaborole or tacrolimus 0.03%). Randomization means that you are put into a group by chance, like picking a number from a hat. Since this is an open-label study, you will know what group your child is in. Your child will have an equal chance of being placed in any one of the two groups. If randomized to crisaborole, study staff will give you a tube of the topical ointment at the first study visit. If randomized to tacrolimus 0.03%, staff will give you a tube of the topical ointment at the first study visit. Your child will apply their assigned topical ointment to all areas of atopic dermatitis twice daily for the remainder of the study (i.e., 12 weeks).

Washout Period: If your child is currently taking tacrolimus (Protopic), criasborole (Eucrisa), or another steroid-sparring medication, he/she is still eligible for the study. You and your child must agree to discontinue using your current medication for two weeks (i.e., 14 days) prior to the start of study procedures. After two

weeks, you will be schedule for your Baseline Assessment study visit at a time that is convenient for you and your child. At the Baseline Assessment study visit, our child will be randomized to one of the two topical treatments for atopic dermatitis (crisaborole or tacrolimus 0.03%) for the study. Your child will have equal chance of being placed in any of the two groups. If randomized to crisaborole, study staff will give you a tube of topical ointment at the first study visit. If randomized to tacrolimus 0.03%, staff will give you a tube of the topical ointment at the first study visit. Your child will apply their assigned topical ointment to all areas of atopic dermatitis twice daily for the remainder of the study (i.e., 12 weeks).

You will perform the same study activities during the three study visits (Baseline Assessment, 6 Week Assessment, and 12 Week Assessment). These visits will be scheduled on a date and time that is convenient for you and your child within the study timeframe. The 6 Week and 12 Week Assessments may be scheduled by telemedicine (i.e., zoom visit). Each visit involves the clinical assessment of atopic dermatitis by trained study personnel (MD) and the completion of several PROs on an iPad. Your child (age $\geq$ 5 years) will complete five different PROs (Itch, Pain Interference, Anxiety, Depression, and Children's Dermatology Life Quality Index) on an iPad. You will be able to assist your child in the completion of these PROs. These five PROs should take 20 minutes or less to complete. You, as the parent/caregiver, will complete three different PROs (Child's Sleep Habits Questionnaire, Caregiver Burden Inventory, and Family Dermatology Life Quality Index) on an iPad. These three PROs should take 5 minutes or less to complete.

Study personnel will call you by phone periodically during the study to inquire about any problems or side effects from the topical treatments, as well as to remind you about your upcoming visits.

During this study, you and your child are allowed to continue any other medications (prescribed or over-the counter) that you were taking before the start of the study. Your doctor may prescribe your child additional treatments during the study for better control of the atopic dermatitis. If your child is newly prescribed a systemic anti-inflammatory medication for control of the atopic dermatitis during the study, you and your child will be withdrawn from the study. If you child is enrolled in the study on a stable dose of systemic anti-inflammatory medication for atopic dermatitis, an increase or decreased in this medication dose is allowed if deemed medically necessary and will not affect your participation in this study.

Additional tubes of crisaborole or tacrolimus 0.03% will be distributed to you if needed to complete the assigned treatment and assessment period of the study (i.e., 12 weeks).

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for approximately 12 weeks. If a study visit is missed, the visit must be rescheduled within 7 days or you will be withdrawn from the study.

CAN I STOP BEING IN THE STUDY?

You can decide to stop participation in the study at any time. You can withdraw from the study at any time, for any reason. We encourage you to speak with the study personnel and your doctor to discuss your concerns and your decision to stop participation in the study.

The study doctor may stop you from taking part in this study at any time if he/she thinks it is in your best interest; if you do not follow the study rules; or if the study is stopped.

ARE THERE ANY REASONS WHY I SHOULD NOT BE IN THIS STUDY?

If your child is prescribed systemic anti-inflammatory medication for atopic dermatitis and the dose of this medication has not been a stable dose for at least 6 weeks prior to enrollment, neither you nor your child can participate in this study.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

- There is a risk of invasion of privacy. To protect your confidentiality, all data collected will not contain any personal identifiers. Majority of data collected will be electronically captured and stored in the secure, password-protected, University-owned database. Informed consent forms will be the only record kept of subjects who have participated in this research and will be kept in a locked office in a locked file cabinet in the Department of Dermatology Clinical Trials Unit.
- Crisaborole is approved for use in ages 2 years and older. Known side effects include pain at the site of application. These localized symptoms may occur during the first few days of use and subside as atopic dermatitis lesions improve.
- Tacrolimus 0.03% is approved for use in ages 2 to 15 years. Known side effects include burning sensation, stinging, soreness, and itching at the site of application. These localized symptoms may occur during the first few days of use and subside as atopic dermatitis lesions improve. Sun exposure should be limited during tacrolimus treatment. Ultraviolet light therapy, sun lamps, or tanning beds should not be used during tacrolimus treatment. Do not cover tacrolimus-treated skin with bandages, dressings or wraps. Contact of tacrolimus with eyes and mouth should be avoided.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You and your child may not benefit from being in this research study. The potential benefit of this proposed

clinical trial may be a better understanding of the impact of topical treatment for atopic dermatitis on your child's health and caregiver burden.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

If you do not take part in this study, your child cannot participate in this study. If you do not take part in this study, the medical care for your child with atopic dermatitis will be unchanged. Your child will receive standard medical care as deemed necessary by your doctor for the treatment of atopic dermatitis.

WHAT ARE THE COSTS?

There is no cost to you for participation in this study. Study medication (tacrolimus 0.03% or crisaborole) will be provided to you without cost during the study. All other study materials will be given to you without cost. Any additional medications prescribed by your doctor for control of atopic dermatitis are not part of the study and will be the responsibility of you and/or your insurance company.

WILL I GET PAID FOR PARTICIPATING IN THE STUDY?

Your child will receive a $10 gift card at the completion of each study visit (i.e., a total of $30) for his/her participation in this study. You will be paid $100 for your participation in this study. Payment will be based on the number of study visits completed. You will be paid $20 for completion of Baseline Assessment; $40 for completion of 6 Week Assessment; and $40 for completion of 12 Week Assessment. A check will be mailed to you by the University of Rochester for your participation.

IS THERE A SPONSOR SUPPORTING THIS STUDY?

This study is supported by the ASPIRE Dermatology Award from Pfizer.

WHAT ARE CIRCUMSTANCES FOR DISMISSAL FROM STUDY?

We may decide to take you off the study without your consent if we feel that it is in your best interest, if you child's condition worsens, if you are unable to complete study procedures as instructed, if your child develops an allergy to the topical treatment, or if the study stops. Additionally, you and your child will be removed from the study if you and/or your child ask to stop participating.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

The University of Rochester will make every effort to keep the information collected from you private. In order to do so, we will store your data in a locked office in a locked cabinet and/or on a password-protected computer in a locked office. All of your personal information will be kept in a separate document from your study data. Results from the study may be presented at meetings or published in scientific journals, but no identifying

information will be included in these reports. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the [redacted] please ask the investigator or study personnel for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- Department of Health and Human Services
- [redacted]
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
Records will be destroyed after five years.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your child's health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
Participation in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason, without risking loss of present or future care and benefits you would otherwise expect to receive. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. The date of withdrawal and reasons for withdrawal will be recorded. We will tell you about new information that may affect you or your child's health, welfare, or willingness to stay in this study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

[redacted]

Please contact the [redacted]

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

WHERE CAN I GET MORE INFORMATION?

[redacted]

VOLUNTARY PARTICIPATION

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

SIGNATURES/DATES

SUBJECT CONSENT

I have read the contents of this consent form, asked questions, and received answers. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Study Subject (Caregiver) _____ Print Name

_____ Study Subject Signature

_____ Date

PARENTAL PERMISSION

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my permission for my child to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Parent/Guardian [redacted] Print Name

Signature

[redacted] Date

PERSON OBTAINING CONSENT

I have read this form to the subject/parent/guardian and/or the subject/parent/guardian has read this form. An explanation of the research was given and questions from the subject/parent/guardian were solicited and answered to the subject's/parent's/guardian's satisfaction. In my judgment, the subject/parent/guardian has demonstrated comprehension of the information. A signed copy of the consent has been provided to the subject/parent/guardian.

[redacted] Print Name & Title

Signature

[redacted] Date

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