NCT05293717

CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

Study Title:	**Topical Ruxolitinib (Jak1/Jak2 inhibitor) in Chronic Hand Dermatitis attenuates inflammation and enhances skin barrier repair.**
Principal Investigator: (Study Doctor)	**Anna De Benedetto, MD**
Telephone:	**585-273-4195** **585-275-7546 (24 Hours)**
Address:	**UR Dermatology at College Town** **40 Celebration Drive** **Rochester, NY 14620**

Key Information

- Being in this research study is voluntary – it is your choice
- You are being asked to take part in this study because you have Chronic Hand Dermatitis
- The purpose of this study is to assess the efficacy of Ruxolitinib cream 1.5% on skin lesions.
- Your participation in this study will last for about 16 weeks
- Procedures will include: reading, signing, and dating this consent form, assessments, pictures, blood sample, skin barrier measurements, vital signs, and collecting your current medication list and your medical history. If you are a female, we will complete a pregnancy test.

- There are risks from participating.
  - The most common risks is some pain when the needle goes into your skin for a blood draw.
  - Risks of medication include irritation, burning or pain, redness, peeling or stinging, blistering rash or swelling.
  - The more serious risks could involve rare possibility of an allergic reaction to the tape and infection. See the section: “What side effects or risks can I

expect from being in the study" for more information. You should discuss these risks in detail with the study team.

- You might not benefit from being in this research study.
  - If you do not want to take part in this study you can discuss other options with your doctor (for example, injections, creams, light treatments).

GENERAL INFORMATION ABOUT THIS STUDY

1.What is the Title of this research study (this "Research Study")?

Topical Ruxolitinib (Jak1/Jak2 inhibitor) in Chronic Hand Dermatitis attenuates (reduces) inflammation and enhances skin barrier repair.

2. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Anna De Benedetto, MD 585-275-7546 (24hr Number)

3. Who is paying for this Research Study?

The study is being performed by the University of Rochester and the study drug is being provided by the Incyte Corporation at no cost to you.

4. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

• 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.

a) In general, what is the purpose of the research, how long will you be involved?

This research study will explore the use of an investigational topical medication to reduce itch associated with skin lesions in individuals with chronic hand dermatitis.

Ruxolitinib cream is under development for the treatment inflammatory skin conditions. Ruxolitinib cream has been recently approved by Food and Drug Administration (FDA) for Atopic Dermatitis, which is a condition that makes the skin red and itchy.

b) What is involved with your participation, and what are the procedures to be followed in the research?

Participation will include up to 5 study visits over a 4 month (16 weeks) time period. You are being asked to apply topical medication to your skin at home and will be asked to complete daily study drug diary. Procedures at each clinic visit include a clinical exam with dermatology scoring, which your study team will perform, non-invasive skin barrier assessments, subject questionnaires, and blood draws (at screening and for any unscheduled event if needed). Urine pregnancy tests will be conducted at specified time points for women of child bearing potential and a PATCH test for contact allergens may be performed to confirm inclusion. PATCH testing is a test to discover whether a person is allergic to any of several substances that are applied to the skin under a patch

c) What are the likely risks or discomforts to you?

Some of the skin barrier assessments may be uncomfortable and redness/irritation may occur at the site of the procedure, usually resolves within 12 hours. The risks of drawing blood from a vein may cause pain and bruising at the place where the blood was taken. Rarely, some people experience inflammation (swelling) of the vein, infection at the site of the blood draw, lightheadedness, or fainting.

Risks associated with the investigational topical product include possible local (affects only one part of the body) and rarely a systemic (bloodstream) reactions to the medication.

d) What are the likely benefits to you or to others from the research?

You may or may not benefit from participation in the research. We do not know the impact of its use on the skin lesions and itch.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Your alternative is not to participate. Standard of care options can be discussed with you including other topical products such as topical steroid creams/ointments.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

5. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

All procedures are associated with the research study.

6. What will be done only because you are in this Research Study?

Study design: This is an open label, single site study and will be conducted at the UR Dermatology at College Town.

Study Timeline:
- Screening visit (-28 days before start of treatment)
- visit 1 --(V1, day 0), start of active treatment;
- visit 2 – 28 days +/- 3 days (4 weeks) treatment;
- visit 3 – 56 days +/- 3 days (8 weeks) treatment;
- visit 4 – 84 days +/- 3 days (12 weeks) end treatment;
- visit 5 – 112 days +/-3 (16 week**)** follow up

Procedures

Screening visit (-28 days)

1) Consenting and confirmation of inclusion & exclusion criteria
2) Medical history
3) Physical exam with focus on skin exam
4) Collection of concomitant medications
5) Fasting blood draw for safety laboratories
6) Urinalysis
7) Possible washout period which means the length of time that someone enrolled in a study must not receive any treatment before receiving the trial's investigational drug.
8) Possible schedule PATCH test if investigator believes it is clinical necessary to rule out contact dermatitis
9) Urine pregnancy test for woman of childbearing potential
10) Schedule visit 1

Visit 1 (Day 0):

1) Confirmation of inclusion & exclusion criteria
2) General History
3) Physical Exam
4) Review of concomitant medications

5) Urine pregnancy test for woman of childbearing potential. Counseling on acceptable birth control measures to use throughout treatment period (16 weeks or 112 days) and until 30 days after stopping study drug
6) Clinical score for chronic hand dermatitis, which is a simple way to study the course of chronic hand eczema
7) Itch and other quality of life assessments
8) Digital pictures of the target area/hands
9) Non-invasive skin barrier measurements: TransEpidermal Water Loss (TEWL) and optional pH. A TEWL test is designed to test whether a skincare or cosmetic product is causing transepidermal water loss that is leading to dry skin conditions or not. The optional pH is obtained to evaluate how acidic or alkaline our skin is. Skin with a balanced pH is effective at keeping moisture in and harmful bacteria out.
10) Repeated tape stripping from treated area. Serial measurements of TEWL will be performed after tape stripping as previously described. Tape stripping is a simple and efficient method for assessing the quality of skin findings.
11) Dispense investigational drug for 4 weeks (weight of tube will be recorded at each visit)
12) Provide instructions to complete at home diary.
13) Provide date of Visit 2
14) Weight of the tube to check to make sure you are taking using the investigational cream.
15) Skin swabs (optional)
16) Skin symptoms questionnaire (optional)

Visit 2 (Day 28 +/-3) & Visit 3 (Day 56 +/-3) and Visit 4 (Day 84 +/-3:

1) Review subject diary and address any questions, concerns, or missed doses
2) Review concomitant medications
3) Questionnaire to clinically characterize chronic hand dermatitis, review of medications and possible side effects
4) Urine pregnancy test for woman of childbearing potential
5) Clinical score for chronic hand dermatitis
6) Itch and other Quality of Life assessments, review daily diary
7) Digital pictures of the targeted area
8) Non-invasive skin barrier Measurements: transepidermal water loss/TEWL. Optional: pH
9) Repeated tape stripping
10) Dispense investigational drug
11) Review diary instructions
12) Provide date for next visit
13) Weight of the tube to check to make sure you are taking using the investigational cream at Visit 2 and Visit 3
14) Skin swabs (optional)
15) Skin symptoms questionnaire (optional)

Visit 5 – 112 +/- 3 days (16 weeks)

1) Review subject diary and address any questions, concerns, or missed doses
2) Review of concomitant medications
3) Questionnaire to clinically characterize chronic hand dermatitis, review of medications and possible side effects
4 Urine pregnancy test for woman of childbearing potential.
5) Clinical score for chronic hand dermatitis
6) Itch and other quality of life assessments
7) Digital pictures of the targeted area
8) Non-invasive skin barrier measurements: transepidermal water loss. Optional: pH
9) Repeated tape stripping
10) Review diary for completion
11) Weigh returned tubes

Unscheduled Visit(s)

If at any time during the duration of the study you do not feel well or if you have any side effects, you may be asked to come in to the Dermatology clinic for further evaluation. During this visit you may need to undergo one or more of the procedures described above per the discretion of the study team.

Study procedures & methods

Disease status assessment: 1) Investigator Global Assessment (IGA), which will provide information of the overall disease (5-point scale: clear, almost clear, mild, moderate, severe) and it is the score requested by U.S Food and Drug Administration (FDA) for clinical study. 2) Hand Eczema Severity Index (HECSI), a well-accepted and validated scoring system for disease activity. It incorporates both the extent and the intensity of the disease.

The presence or absence of skin irritation (e.g. distinct spots, and/or small, solid, usually with slight elevation of skin), redness, atrophy (waste/wither away) and telangiectasia (dilation of capillaries) will be noted at each study visit.

- The pruritus (itching) intensity will be assessed using Itch Numerical Rating Scale (NRS; see appendix).

- You will be asked to rate the intensity of their itch using this scale. The Dermatology Life Quality Index (DLQI) measures 6 disease-specific domains (symptoms and feelings, leisure, daily activities, work and school, personal relationships, and treatment) during the last week; individual items were summed to generate an overall score. Data will be reported as change from baseline to week 8 in DLQI.

-The Work Productivity and Activity Impairment-Chronic Hand Dermatitis (WPAI-CHD) questionnaire asks the number of work hours missed, hours worked, and impairment while working/performing usual daily activities as a result of chronic hand dermatitis during the past 7 days.

- Digital pictures: A digital picture will be taken with a dedicated digital camera in our clinic. The pictures will be labeled with your study ID and date. Pictures will not include identifying information (for example: facial features, tattoo, etc.). Digital photographs will be used to record the location and monitor the size of target lesions. Your photographs may be used for educational purposes including but not limited to publication(s) and/or lecture(s).

- Blood sample: blood will be obtained for safety laboratories and to evaluate biomarkers (biological molecule found in the blood, body fluids or tissues that is the sign of a normal or abnormal condition) of disease severity.

- Skin barrier measurements: Transepidermal water loss/TEWL, +/- pH is a measurement that assess the dryness and health of the skin. The assessment will be obtained from a treatment area of an area around a lesion and on a site of inflammation. For each of the specific measurements, a probe will be gently applied on the skin surface for up to 1 minute. You will be comfortable in the room in which you are being tested to ensure that sweating due to stress or adjusting to the temperature does not alter the TEWL.

Skin barrier integrity assessment: the most superficial layers of the skin will be collected by tape stripping. This is a well-established method used in clinical research to gently disrupt the skin barrier. The first tape will be discarded to eliminate dirt and residue of skin products. Each tape will be gently pressed against the skin with uniform pressure for 5-10 seconds using a probe that measures skin hydration. You will have 5 consecutive tapes collected from lesional skin and 20 consecutive tapes from non-lesional skin. TEWL will be measured after each set of 5 tape strippings. These measurements should provide data to determine if the treatment has an effect on skin barrier integrity.

Skin sampling for biomarkers: we will use the tape stripping to collect the outermost layer of the skin at baseline and at 16 weeks to identify possible biomarkers.

Prohibited Medications and procedures: use of topical or systemic immunosuppression/immunomodulators medications and Phototherapy is not permitted during the study. Your medication list will be reviewed at each study visit. Hand surgery or other procedures (including but not limited to cryotherapy (cold therapy), ED&C (electrodesiccation and curettage which is a surgical procedure), skin biopsy) are not allowed during the study. If medically necessary, the investigator will withdraw you from the study.

Once this research study is completed, any information that could identify you will be removed from any identifiable private information or identifiable biospecimens collected. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

7. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect demographic information, results of physical exams, blood tests, and other diagnostic and medical procedures, as well as medical and medication history.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at UR Dermatology at College Town who provide study-related care, and the URMC Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

8. With whom will this health information be shared?

This health information may be shared with:

- The University of Rochester
- Incyte Corporation (who is providing the drug) (listed in Question 3 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments;
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is

shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

9. How long will you be in this Research Study?

Your involvement in this study will last approximately 5 months.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

10. How many people are expected to take part in this Research Study?

We hope to enroll 15 subjects in this clinical trial.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

11. What are the possible discomforts and risks from taking part in this Research Study?

Risks Associated with Digital Picture

There are no known risks for the digital picture. The image will not include identifying features (for example: facial features, tattoo, etc.) and will be labeled with your subject ID and date. Pictures will be taken with a dedicated camera and stored on a secure server.

Risks Associated with Barrier Assessments

There are no known risks for the barrier assessments.

Risks Associated with Tape Stripping

The risks associated with tape stripping, include the rare possibility of an allergic reaction to the tape and infection. Since the tape is removed immediately after application, the risk of reaction is extremely low. If you have a known allergy to tapes or adhesive material, you should not participate. In previous and ongoing studies involving tape stripping, it has been noted that a very mild redness may develop immediately after a series of tape stripping on one localized area of skin, probably due to the mild irritation to the skin. The redness is expected to resolve within 12 hours without issue. The risk of skin infection is extremely low since only the top skin layers are recorded with tape. You will be provided with wound care information and a department phone number to contact should you have any concerns.

Risks of Phlebotomy

The risks of having blood drawn include some pain when the needle goes in, and a small risk of bruising and/or infection at that site. You may feel lightheaded, nauseous, or faint. 4mLs is approximately 1 teaspoon of blood and is not likely to cause lightheadedness, however you will be observed after blood draw to be sure you are comfortable with walking. You will be encouraged to drink plenty of water prior to the blood draw. Phlebotomy will be performed at the elbow pit to minimize pain and bruising. You will be seated during the blood draw to minimize dizziness and any risk of falling. Pressure will be applied to the site after the draw and a Band-Aid will be applied to minimize the risk of bleeding and infection.

Risks of Ruxolitinib 1.5% cream

Based on human and animal studies, there is a low potential for irritation or skin changes following the cream application. Skin-related adverse reactions in clinical studies have been seen with similar frequency in ruxolitinib, and control-treated lesions, have been mild, have not resulted in discontinuation of study medication, and usually have resolved with continued application.

- You may experience some irritation, burning or pain from the Ruxolitinib 1.5% cream especially in areas of open skin from scratching. You may experience redness, peeling, pain, stinging or burning sensation in the area. You might also experience a blistering rash or swelling. You may experience increased dryness from the cream formulation.

U.S. Public Law 110-85 requires registration of "Applicable Clinical Trials" at www.ClinicalTrials.gov. A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. Law. The Clinical Trials.gov identifier number is NCT05293717. 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 website at any time.

Based on FDA approved medication label information, risks include:

- Developing serious infections that may lead to hospitalization or death
- Reported infections include:
  - Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease
  - Invasive fungal infections (e.g., candidiasis, pneumocystosis)
  - Bacterial, viral, and other infections due to opportunistic pathogens
  - Thrombocytopenia (low platelet count), anemia (lack of healthy red blood cells) and neutropenia (too few white blood cells)
- If you have an active, serious infection, including localized infections you should not participate. You will be closely monitor for developing signs and symptoms of infection during and after treatment

You should moisturize in the morning and use gentle body wash to minimize these potential side effects.

In case of any abnormal reaction you can call the UR Dermatology clinical trials office (clinical coordinator: 585-275-9577 or main office: 585-275-7546) and stop using Ruxolitinib 1.5% cream until discussing symptoms with study team.

Oral ruxolitinib may have effects on the immune system depending primarily upon the level (drug concentrations in blood) and the duration of exposure to it. Topical (skin application) treatment is not anticipated to result in any meaningful systemic (blood) exposure to ruxolitinib. However, absorption through damage skin could result in increased localized absorption that could possibly reduce your ability to fight infections, if such external treatment is continuous in nature and longer term (for example: for

months rather than weeks and on large area of body). In such situations, monitoring of possible skin infections or skin cancers is recommended for ruxolitinib cream. You will be monitored closely for signs and symptoms of skin infections or cancers in the treated areas. If you have evidence of active infection or skin cancer, you will not be eligible to take part in the study.

There is a potential risk of reversible decreases in the levels of cells in the blood (for example: platelets, white blood cells, or red blood cells). This risk is low because we expect minimal to no absorption from the skin and the application will be limited to the hands only. No clinically significant decreases in platelet counts have been noted in the completed or ongoing studies with ruxolitinib cream.

Previous tolerability in healthy individuals demonstrated that ruxolitinib 1.5% cream was not phototoxic (a condition in which the skin or eyes become very sensitive to sunlight or other forms of light) and did not induce photosensitization. However, due to the potential risk of skin reaction when exposure to ruxolitinib is combined with sun exposure, you should avoid prolonged exposure to either natural or artificial sunlight (including tanning booths, sun lamps, etc.) and use sunscreen when outdoor for a prolonged period of time.

Risks to children or pets are not known and you should keep the study cream out of reach from children and pets.

Because this is an investigational medication/formulation some side effects may not yet be known. Any adverse reaction will be counted.

Reproductive Risks

Ruxolitinib should not be used by pregnant women, as there are inadequate prenatal and postnatal data in humans. If you are a woman of child bearing potential, you will be counseled to use acceptable birth control methods. You cannot participate in this study if you are pregnant, become pregnant, or are nursing an infant.

General Risks

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

When participating in any research study there is a possibility for invasion of privacy or breach of confidentiality. Because we will be collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. To minimize this risk, we will assign you a study number/identifier instead of labeling the information we collect from you with your name or medical record number. Further, any research performed, or data generated, will be linked with your assigned study number and not with any personally identifying information. All the information we collect that is personally identifiable will be stored in a secure manner and only study team members will have access to it.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

12a. What are the potential benefits to you for taking part in this Research Study?

You may or may not benefit from participation in this clinical trial. The investigational medication may temporally improve or worsen the dermatitis on your hands. The nature of this exploratory study does not promise benefit for the individual.

12b. How could others possibly benefit from this Research Study?

We hope that this research will increase our understanding of hand dermatitis and hopefully will lead to development of new therapies aiming at repairing skin barrier and skin driven inflammation.

12c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

12d. Will you be allowed to see the research information collected about you for this Research Study?

Results from blood work for clinical safety labs and physical exam may be shared with you at your next study visit. Other Information collected about you may be shared with you at the end of the study.

13. What other choices do you have if you do not want to be in this study?

Your alternative is not to participate. Standard of care options can be discussed with you including other topical products such as topical steroid creams/ointments.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

14a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

14b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- The PI or Sub-Investigator believes it is in your best interest
- The sponsor stops the study

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

15. If you choose to take part in this Research Study, will it cost you anything?

No, there will be no additional costs to you or your health plan as a result of your participation in this study. However, if you feel you have received a bill related to this study, please contact the Principal Investigator.

If you receive any healthcare at UR Dermatology at College Town is not related to this study, this care will be billed as usual.

16. Will you be paid for taking part in this Research Study?

You will receive $35.00 for screening and $50.00 for all other visits after that that are completed. You will only receive payment for each completed study visit. You will not be paid for visits that you do not complete.

For this study we use a subject payment system called Advarra Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help you create a "subject profile" in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile which is required to set up a subject account and for customer service purposes. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have an Advarra account (because you are in another study that uses this system), your existing profile will be used to provide payment. See the 'Information Sheet for Advarra Participant Payments" for additional information.

Payment received for participation in research is considered taxable income. If you receive payment for your participation in studies at the University of Rochester and its affiliates of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. Depending on the amount you are paid, you may be asked to submit a W-9 form, which includes your Social Security Number.

What if you are injured while in this Research Study?

If you are directly injured by the Ruxolitinib 1.5% cream being studied, or by medical procedures needed because of this study, and you receive medical care for the injury,

you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the University, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

CONFIDENTIALITY OF RECORDS AND AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will code all samples and questionnaires collected; allow access to study records to only those involved in the study; retain all study related documents in a secure, locked location, giving access to only those who are involved in the study. All study data collected will be identified by a code number and your identity will remain unknown. All information, which is collected about you as well as collected samples that leave the clinic, will have your name removed so that you cannot be recognized by it. The study doctor will be responsible for keeping a code list which would make it possible to link your assigned number to your name. This will be kept in a safe place to ensure that in case of an emergency you can be identified and contacted. The code list will be kept until the last marketing application has been received for the study drug. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publication, but your name will not be used.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator 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, including records of external providers that are available via your electronic health record at URMC & Affiliates
- 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:

- The Department of Health and Human Services
- The University of Rochester
- The study sponsor, its representatives "sponsor" and their business partners.
- The U.S. Food and Drug Administration (FDA) may also need to inspect study and copy 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. However, absolute confidentiality cannot be guaranteed.

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.

Financial Disclosure	Dr. De Benedetto has received consulting fees from the sponsor in the past 12 months. Please feel free to ask any further questions you might have about this matter.

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? This permission will last indefinitely.

May I cancel my permission to use and disclose information?

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address listed on page one. 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.

RETURN OF INDIVIDUAL RESULTS

If individual research results about you become available, do you want us to contact you and ask whether you want to receive the results?

Yes No

CONSENT TO FUTURE USE OF INFORMATION / SAMPLES

May we share your samples, health information, with other researchers to study hand dermatitis?

Yes No

May we share your samples, genomic data, and health information with other researchers for future research projects related to other topics?

Yes No

SIGNATURES

Subject Consent

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 agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (printed by subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (print)

_____ _____
Signature of Person Obtaining Consent Date