Characterizing the Molecular Cutaneous Phenotype of Seborrheic Dermatitis and Treatment Response to Ruxolitinib 1.5% Cream
PI: Benjamin Ungar
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STUDY INFORMATION:

Study Title: Characterizing the Molecular Cutaneous Phenotype of Seborrheic Dermatitis and Treatment Response to Ruxolitinib 1.5% Cream

Study site(s): Icahn School of Medicine at Mount Sinai

Lead Researcher (Principal Investigator): Benjamin Ungar, MD

Physical Address: Icahn School of Medicine at Mount Sinai
Department of Dermatology and The Immunology Institute
5 East 98 Street, 5th Floor, Box 1048
New York, NY 10029

Mailing Address: 5 East 98 Street, 5th Floor, Box 1048
New York, NY 10029

Phone: 212-241-3288

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to assess the effect and safety of ruxolitinib 1.5% cream on individuals and their Seborrheic dermatitis (SD) as well as to compare their response to age- and gender-matched healthy controls. At the conclusion of the trial, participants will be evaluated to determine if Ruxolitinib improves moderate-to-severe SD.

If you choose to take part, you will be asked your involvement in the study will last 7 weeks. During the time you are enrolled into this current study, you will not be able to participate in other research studies.

Prior to receiving any study treatment, you will undergo a screening visit in the Department of Dermatology Clinical Trials office at Mount Sinai Hospital to determine if you meet the qualifications for this study. The treatment group must have moderate-to-severe SD. The control comparison group must

have no personal or family history of SD. If screening is successful, you will return to the clinic for up to four additional visits for those in the SD group, and only one visit for those in the control group, which will include a baseline visit that will serve as week 0. Throughout your study participation, the site staff will administer blood tests, urine analysis, urine pregnancy tests (for participants who have the potential to get pregnant), skin assessments, and patient questionnaires. To appropriately determine progression of treatment, there will be clinical photography of the area of your skin affected by SD. In order to participate in this study, you will also need to consent to skin tape-strip samples, which involves applying special tape to the skin and removing it to analyze. There will be no charge to you for your participation in this study. Individuals enrolled in this study will be compensated for their time and effort. The study drug, study related procedures, and study site visits will be provided at no charge to you or your insurance company.

If you choose to take part, the main risks to you are burning where you apply the cream, itching and the development of acne.

You may benefit from taking part in this research. Some potential benefits are: The findings from this study may help to identify new therapies for this disease. You may also benefit from participation in this research if the study drug improves your condition, or improves your quality of life.

Instead of taking part in this research, you may take topical or oral antifungal medications or anti inflammatory medications

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you have moderate-to-severe-SD or an age and gender-matched adult with no personal or familial history of SD.

Your participation in this research study is expected to last approximately 7 weeks.

There are 45 people expected to take part in this research study at Icahn School of Medicine at Mount Sinai. There will be 25 participants enrolled with seborrheic dermatitis and 20 control participants.

Funds for conducting this research study are provided by Incyte Corporation, the manufacturer of ruxolitinib.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:
All research visits/activities will be performed only at the Icahn School of Medicine at Mount Sinai, Department of Dermatology. All procedures performed during the study are being done for research purposes only.

Visit 1 – Screening (within 28 days of Baseline) **(approximately 1-2 hours)**

- Obtain signed IRB-approved informed consent and HIPPA agreement
- Review Inclusion and Exclusion Criteria
- Record gender, race, ethnicity, and medical history
- Review personal and family history of SD and other inflammatory skin diseases
- Record all concomitant medications as well as all those received within 30 days prior to screening
- Record all prior therapies for SD
- Urine pregnancy test for all participants that have the potential to get pregnant
- SD Clinical assessments: Investigator Global Assessment (IGA) and SD Severity Score
- Record adverse events

If you qualify for the study at screening, you can proceed to complete the Baseline visit on the same day. Identical procedures will not be repeated if Screening and Baseline visits occur on the same day.

Visit 2 – Baseline (Week 0) **(approximately 40 minutes)**

- Confirm all inclusion and exclusion criteria have been met
- Record concomitant medications and adverse events
- Dermatology Life Quality Index (DLQI) questionnaire
- Standardized clinical photography (including photographs of participant's entire face and close up photographs of the following facial regions: 1. left cheek, 2. right cheek, 3. forehead and glabella)
- SD clinical assessments (IGA, SD Severity Score)
- Urine pregnancy test for all participants that have the potential to get pregnant
- Collect safety blood samples for Complete Blood Count (CBC) with differential, Comprehensive metabolic panel (CMP), and C-reactive protein (CRP)

- Collect blood sample for possible future mechanistic analyses to compare molecular changes between those that have SD and those who do not.
- Urinalysis
- Perform tape strips of lesional and non-lesional skin. Lesional skin tape strips will be taken from area of skin most affected by SD
- Dispense/administer study drug

Visit 3 – Week 2

- Record concomitant medications and adverse events
- DLQI questionnaire
- SD clinical assessments (IGA, SD Severity Score)
- Urine pregnancy test for all participants that have the potential to get pregnant
- Perform tape strips of lesional skin. Lesional skin tape strips will be taken from the same location as the lesional tape strips taken at Baseline.
- Dispense study drug and assess compliance.
- Participants will report each study drug application. If you miss 4 doses from the first visit, you may be removed from participating in the study.

Visit 4 – Week 4

- Record concomitant medications and adverse events
- DLQI questionnaire
- Standardized clinical photography (including photographs of participant's entire face and close up photographs of the following facial regions: 1. left cheek, 2. right cheek, 3. forehead and glabella)
- SD clinical assessments (IGA, SD Severity Score)
- Urine pregnancy test for all participants that have the potential to get pregnant
- Collect blood samples for CBC with differential, Comprehensive metabolic panel (CMP), and C-reactive protein (CRP)
- Collect blood sample for possible future mechanistic analyses
- Urinalysis
- Perform tape strips of lesional skin. Lesional skin tape strips will be taken from the same location as the lesional tape strips taken at Baseline and Week 2.
- Dispense study drug and assess compliance.
- Participants will report each study drug application. If you miss 4 doses from the first visit, you may be removed from participating in the study.

Visit 5 – Week 6 (Follow-up)

- Record concomitant medications and adverse events

- DLQI questionnaire
- Standardized clinical photography including photographs of participant's entire face and close up photographs of the following facial regions: 1. left cheek, 2. right cheek, 3. forehead and glabella)
- SD clinical assessments (IGA, SD Severity Score)
- Urine pregnancy test for all participants that have the potential to get pregnant
- Perform tape strips of lesional skin. Lesional skin tape strips will be taken from the same location as the lesional tape strips taken at Baseline, Week 2, and Week 4.

Early Termination Visit (if applicable)

- Record concomitant medications and adverse events
- DLQI questionnaire
- Standardized clinical photography (including photographs of participant's entire face and close up photographs of the following facial regions: 1. left cheek, 2. right cheek, 3. forehead and glabella)
- Urine pregnancy test for all participants that have the potential to get pregnant
- Collect blood samples for CBC with differential, Comprehensive metabolic panel (CMP), and C-reactive protein (CRP)
- Collect blood sample for possible future mechanistic analyses
- Urinalysis
- SD clinical assessments (IGA, SD Severity Score)
- Perform tape strips of lesional skin. Lesional skin tape strips will be taken from the same location as the lesional tape strips taken at Baseline and Week 2 (if applicable)
- Assess study drug dosing compliance and retrieve all remaining study drug from participant

For Control Participants

Visit 1 – Screening (within 28 days of Baseline)*

- Obtain signed IRB-approved informed consent and HIPPA agreement
- Review Inclusion and Exclusion Criteria
- Record gender, race, ethnicity, and medical history
- Review personal and family medical conditions/diseases
- Record all concomitant medications as well as all those received within 30 days prior to screening
- Urine pregnancy test for all participants that have the potential to get pregnant

* If participant meets all entry criteria at Screening, he/she can complete Baseline Visit on the same day (identical procedures do not need to be repeated). If more than 28 days has lapsed between

screening and Baseline/Visit 2, then all procedures should be repeated except for re-obtaining informed consent.

Visit 2 – Baseline (Week 0)

- Confirm all inclusion and exclusion criteria have been met
- Record concomitant medications and adverse events
- Urine pregnancy test for all participants that have the potential to get pregnant
- Collect blood samples for CBC with differential, Comprehensive metabolic panel (CMP), and C-reactive protein (CRP)
- Collect blood sample for possible future mechanistic analyses
- Urinalysis
- Perform tape strips of non-lesional skin

Because this research study involves the use of a study drug, a note must be included in your electronic medical record that you are taking part in the research. This way, anyone involved in your medical care will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know.

HIV/AIDS

By law, positive test results for HIV/AIDS (as well as other communicable diseases such as hepatitis B, hepatitis C, and syphilis) are reported to the NYS Department of Health so they can study how people get and transmit the disease and notify sexual or needle-sharing partners they may have been exposed. If you wish to be tested anonymously for HIV/AIDS, the research team can refer you to a public testing center, but you will not be able to be in this study. New York State law protects the confidentiality of HIV test results and other related information. It is illegal to discriminate against a person based on their HIV status and services are available to help if this happens. You are free to refuse to get an HIV test, but if you refuse you cannot be part of this research study.

Pregnancy
If you can possibly get pregnant, a urine test for pregnancy will be done before you begin the study and the pregnancy test will be repeated at every subsequent visit while using the study drug.

You cannot be included in the study if you are or become pregnant, as the study drug could harm your fetus. You also should not be in the study if you are producing milk to feed a child as the study drug could harm your baby.

Unless you are at least one year past menopause or have had a successful operation to make pregnancy impossible, you should use effective birth control. Unless you are sexually abstinent (not having genital sex) the recommended methods of birth control are:

- The consistent use of approved hormonal birth control (pill, patches, or rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual activity),
- Sterilization (a vasectomy, getting tubes tied, or a hysterectomy).

All birth control methods (other than abstinence and sterilization) are only effective if you use them properly, start them at least one month before you begin the research study, and continue using them throughout the research study and for 28 days after the research study ends. If you are unsure whether the method of birth control you use is approved to use while you are in this study, you should ask the Lead Researcher before you begin the study. If you are less than one-year post-menopausal, you could still become pregnant. If you or your partner becomes pregnant, or may be pregnant, at any time, you must tell a person from the research team immediately. The team may stop the study drug and refer you/your partner to an obstetrician/gynecologist for follow-up.
Should you/your partner become pregnant, whether or not you/your partner have the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if you are no longer part of the study. You/your partner will be asked for additional written consent to share this information if that happens.

Semen/Sperm:

Drugs can be found in semen and alter sperm. Since you are taking part in a study using experimental drugs or treatments, it is recommended that 1) you use a condom, 2) you do not get a partner pregnant or expose them to semen, and 3) you do not donate semen. These recommendations apply both while you are taking the study drug, and for 90 days after you stop taking the study drug. This is because levels of the study drug may be present in the sperm and/or semen even after you stop taking the study drug. You are encouraged to tell your partner(s) and/or their doctor(s) that you are participating in this clinical trial.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

(1) Will you allow the researchers to store your data and/or samples to use in future research studies?

Please initial your choice: Yes_____ No_____

If you select No, please stop here and move to the next section, **'Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

(2) The researchers will store your data and/or samples in the following way:

a) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

I would like my data and/or samples stored with a link to my identity through the use of a code_____

(3) Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____ No_____

(4) Do you give the researchers permission to keep the data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____ No_____

(4.1) From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data and/or samples?

Please initial your choice: Yes_____ No_____

a. If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done.
b. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:
   I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.
   II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

(5) Do you give permission to have your data and/or samples given **to other researchers,** including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

Please initial your choice: Yes_____ No_____

(6) Do you give permission to have portions of your data and/or samples deposited in large public databases (repositories) for use in research with the limits you may have chosen above? Please read the paragraphs below which explains repositories, then initial your choice:

To do more powerful research, it is helpful for researchers to share data and/or samples from the people they study. They do this by putting data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. . Researchers can then use the data and/or samples from multiple studies to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases, but they will not share your direct identifiers (for

example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your data, along with that from many other people. Researchers may use your samples for genetic sequencing and other experimental testing. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are always risks associated with data and/or sample collection and sharing. They are described in more detail in the Risks section.

Please initial your choice: Yes _____ No _____

Whether or not you have allowed us to share your data and/or samples, the researchers at Mount Sinai will keep data and/or samples collected about you during this research study to use in future research studies consistent with the wishes you expressed above.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- While you are taking part in this study, you should not take part in another study without notifying the study doctor.
- You must follow the instructions you are given by the study doctor and study staff. If you do not follow the instructions, your visit may have to be rescheduled, or you may be discontinued from the study.
- Tell the study doctor or the study staff about all prescription and non-prescription medications, supplements, herbal preparations, or vaccines before you take them.
- Notify the study doctor or study staff if you move and provide your new address and contact information.
- Avoid becoming pregnant by adhering to the birth control methods outlined in Description of What's Involved.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

There may be costs to you for taking part in this study. Certain safety tests or assessments may uncover underlying diseases or problems that require medical attention.

If you agree to take part in this study, you will be paid $60 per visit for your time and effort, up to a total of $240 if you all complete all visits. You will not be compensated for the screening visit. If you do

not complete this study for any reason, you will be paid for the study visits you do complete. Payment will be given to you in the form of a check at the end of the study.

It can take up to 8 weeks to prepare and give you a check for study participation. If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

It is possible that products may someday be developed with the help of your data and/or samples, and there are no plans to share any profits from such products with you.

POSSIBLE BENEFITS:

There is a chance this study may benefit you, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to you include: improvement of your SD or your SD flare may be shorter. A study drug provided at no cost during a study may not be available for free, or at all, when the research ends.

POSSIBLE RISKS AND DISCOMFORTS:

Physical risks
In addition to the risks below, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).

There are risks to taking part in any research study. Side effects may occur. Some of those side effects can be treated. Some side effects may go away when you stop taking the study drug. Some side effects can be mild, but others may continue longer or become permanent. Some may be life-threatening or fatal.

As this study continues, the drug manufacturer may learn more information about the study drug. You will be given new information about this study in a timely manner. This way you can decide if you want to continue to take part in this study. You may be asked to read and sign a new consent form.

Blood Draw Risks: The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

Group Risks: Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination.

Privacy Risks - Your name and other information that could directly identify you (such as an address, date of birth, or social security number) will never be placed into a database . However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database contains genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.
Privacy risks always exist, but there are procedures in place to minimize the risk.

As of 28 June 2021, 732 participants with vitiligo, a condition where the skin loses its pigment cells, have been treated with ruxolitinib 0.15%, 0.5%, or 1.5% cream once daily or twice daily. Based on the information provided to date, the following are the most frequent side effects that have occurred:

Common

Out of 100 people who use ruxolitinib cream, at least 2 but less than 10 people (2-10%) have reported the following:

- General acne
- Infections (including common cold, upper respiratory tract infection, COVID-19, sinus infection)
- Headache
- Itching at the site of Study Cream application
- General itching

Also, the following side effect was reported in at least 1 but less than 2 out of 100 people (1-2%) who used ruxolitinib cream: Acne at the site of drug application

As of 28 June 2021, 203 participants with psoriasis have been treated with ruxolitinib 0.5%, 1.0%, or 1.5% cream once daily or twice daily. The following are the most frequent side effects that have occurred:

Common

Out of 100 people who used ruxolitinib cream, at least 3 but less than 10 people (3-10%) have reported the following side effects:

- Infections (including common cold, upper respiratory tract infection, and sinus infection)
- Application site skin reactions (including irritation and itching)
- Headache
- General itching
- Potential heart beat abnormality (electrocardiogram QT interval abnormality)

As of 28 June 2021, 83 participants with alopecia areata have been treated with ruxolitinib 1.5% cream twice daily. The following are the most frequent side effects that have occurred:

Very common

Out of 100 people who use ruxolitinib cream, 10 or more people (10%) have reported the following:

- Common cold
- General itching

Common

Out of 100 people who used ruxolitinib cream, at least 8 but less than 10 people (8-10%) have reported the following:

- Sinus infection

As of 28 June 2021, 1,595 participants with atopic dermatitis (eczema) have been treated with ruxolitinib 0.15%, 0.5%, 0.75%, or 1.5% cream once daily or twice daily. The following are the most frequent side effects that have occurred:

Common

Out of 100 people who use ruxolitinib cream, at least 2 but less than 10 people (2-10%) have reported the following:

- Infections (including common cold, upper respiratory tract infection, bronchitis)
- Headache
- Eczema
- Runny nose

Also, the following side effect was reported in at least 1 but less than 2 out of 100 people (1-2%) who used ruxolitinib cream: Burning or stinging sensation at the site of drug application

No rare but serious side effects occurred in participants with psoriasis, alopecia areata, atopic dermatitis, or vitiligo who were treated with ruxolitinib cream.

No side effects occurred during the use of ruxolitinib 1.5% cream in healthy participants that were very common, common, or rare but serious.

Oral Ruxolitinib

While this Study will evaluate ruxolitinib as a cream, another form of ruxolitinib is taken by mouth and is known as "oral ruxolitinib." This oral ruxolitinib is approved for the treatment of adult patients with myelofibrosis (a disease of the fatty substance inside bone where blood cells are produced), polycythemia vera (a blood cancer wherein too many red cells are produced), and in the US for the treatment of adult and pediatric patients 12 years and older with graft versus-host disease (a complication that can develop after a person has had a bone marrow or stem cell transplant).

In clinical studies with oral ruxolitinib, the most common side effects seen in participants with myelofibrosis, polycythemia vera, or graft-versus-host disease were thrombocytopenia (low platelet count), anemia (low red blood cells), and neutropenia (low white blood cell count). Changes in blood cell counts are believed to be related to increasing dose of the drug. The most frequent side effects that were not directly related to the blood cells were bruising, dizziness, headache, increased liver enzymes, high cholesterol, constipation, and herpes zoster (shingles) infection.

When considering these side effects of ruxolitinib given by mouth, it is important to understand that the dose strengths that produced these side effects are much higher than for ruxolitinib cream. Also, an oral dose of the drug results in much higher levels of ruxolitinib in the body than the amount that can be absorbed from applying ruxolitinib cream to the skin. The amount of ruxolitinib cream absorbed in the body after application is about 90% lower than that of the oral ruxolitinib. Therefore, the risk of theseside effects from topical use of the drug is anticipated to be very low. So far, they have not been observed with ruxolitinib cream.

If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death) for the pregnancy. You should not become pregnant or impregnate a woman while on this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

Instead of being in this research study, your choices may include: topical corticosteroids and antifungal creams. However, they have a maximum duration of use. Using corticosteroids over a long period of time may result in thinning of the skin.

The study doctor will discuss other options and their potential risks and benefits with you before you decide whether you will take part in this study. You may also discuss your options with your regular doctor.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you are injured or made sick from taking part in this study, you will get medical care. The group funding this research study will pay you for any reasonable and necessary medical expenses to diagnose and treat research-related injury or illness. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.
The Centers for Medicare and Medicaid Services (CMS) is the government agency that oversees Medicare and Medicaid. Funding agencies who make payments for injuries related to studies must report payments to CMS. In order to do this, the funder must have certain information about you, such as your name, date of birth, Social Security Number, Medicare or Medicaid ID numbers, date of injury, and description of injury. The funding agency is only allowed to use this information to report payments related to the injury should this be necessary or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. For your safety, once you stop the study drug you will be asked to complete the End of Treatment Visit and Follow-Up Visit tests (as described in the description section of this form).

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide to stop being in the research study, the following may occur: any improvements in your SD may be lost or your SD may worsen.

If you stop being in the research study, the research team may not remove information they have already placed in the study database, and may continue to use that data as part of this study. The research team may ask you whether they can continue to collect information from your medical record.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 212-241-3288.

If there is an emergency, call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed. Once you are able to, please contact the study team.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

The company sponsoring this research study, Incyte, makes the drug being tested and has a financial interest that could be affected by the outcome of this research study.

Incyte Corporation is the study sponsor and developer of the study drug, ruxolitinib.
Dr. Emma Guttman (a co-investigator in this study) receives financial compensation as a consultant for the study sponsor, Incyte Corporation. Dr. Guttman also receives financial compensation as a consultant for companies that research and develop treatments for dermatological diseases.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail social security number, or photographic images

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature.
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV

Why is your PHI being used?

Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration (the government organization that approves drugs or devices for medical use): Incyte Corporation
- The United States Food and Drug Administration.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to

inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION: ○ N/A

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time