

Version Date: 11/15/2024

## CONSENT FOR RESEARCH

Penn State College of Medicine

Penn State Health

Title of Project: Exploratory Trial of Ruxolitinib 1.5% Cream for Early Stage Hidradenitis Suppurativa

Principal Investigator: Andrea Zaenglein, MD

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Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-1513. After hours call (717) 531-8521. Ask for the Dermatology doctor on 24-hour call.

Subject's Printed Name: \_\_\_\_\_

**We are asking you to be in a research study.**

**Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.**

**This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.**

Some of the people who are eligible to take part in this research study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s)/guardian(s) to give permission for their participation in the study, and we may ask them to agree (give assent) to take part. Throughout the consent form, when we say "you", we mean you or your child.

### **KEY INFORMATION**

**The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.**

#### **Why am I being invited to take part in this research study?**

We are asking you to take part in this voluntary research study because you have Hidradenitis Suppurativa also known as HS.

#### **What is the purpose of this research study?**

Version Date: 11/15/2024

The purpose of this voluntary research study is to learn about topical ruxolitinib for the treatment of HS. Topical ruxolitinib has been approved for treating patients with vitiligo and atopic dermatitis (eczema) by the U.S. Food and Drug Administration (FDA), but it is not currently approved for HS.

**How long will the research study last?**

If you participate in the entire trial you can expect to be in the study for up to about 24 weeks, including the screening and follow up periods.

**What will I need to do?**

If you are eligible to participate, you will apply the Topical Ruxolitinib 1.5% ointment to your HS skin lesions 2 times a day for 16 weeks. A coordinator will review application instructions.

In addition to applying your study medication you will need to complete questionnaires about your HS disease and how the disease affects your daily life, have the study team take photographs of your HS skin lesions, and have skin biopsies and blood collected at different time points throughout the study.

**What are the main risks of taking part in the study?**

For this study, the main risks to know about are you could be allergic to the topical medication.

**What are the possible benefits to me that may reasonably be expected from being in the research?**

Topical Ruxolitinib might have a beneficial effect on your HS activity, but there is no guarantee that this study will help you. Future patients may benefit from the knowledge that is obtained from your participation in the study.

**What happens if I do not want to be in this research?**

Participation in research is completely voluntary. You can decide to participate or not to participate.

There are alternative treatments for HS. If you do not choose to participate in this study, you may receive standard treatment including local and systemic antibiotics, pain medication, and anti-TNF- $\alpha$  agents such as adalimumab, or participate in another research study, if one is available. Acitretin is used in early stage disease. Other drugs include cyclosporine A, dapsone, and isotretinoin. All of these treatments have potential risks associated with them. You should discuss these treatment options with your study doctor.

You may choose not to take part in this research study.

**DETAILED INFORMATION**

**The following is more detailed information about this study in addition to the information listed above.**

**1. Why is this research study being done?**

This study will assess the safety and efficacy of topical ruxolitinib. We will evaluate your HS condition throughout the trial and the effects of the study medication by certain laboratory tests, physical examinations and questionnaires. This form refers to topical ruxolitinib as “study medication.”

Version Date: 11/15/2024

Approximately 24 people will take part in this research study at Penn State Health.

## 2. What will happen in this research study?

### Screening visit:

You will come to the study site for a screening visit to determine if you are eligible to participate in this study. This visit will take approximately 1 ½ hours of your time. Before any study-related tests and procedures are performed, you will be asked to read and sign this consent form. The following tests and procedures will be performed to determine if you qualify to participate in this study:

- The study doctor or study staff will ask you questions about your medical history and the medications you are taking, including any medications you may have been taking in the past to treat your HS and non-prescription medications, herbal preparations or special diets. Alcohol intake and recreational drug use will also be recorded.
- Demographic information (date of birth, gender, race and ethnic origin) will be recorded.
- Vital signs (blood pressure, heart rate and temperature) will be recorded.
- An electrocardiogram (ECG) will be performed. An ECG is a test that measures the electrical activity of your heart. You will have this test performed in I.O. Silver. Cardiology office within walking distance from the research office.
- A physical examination by a dermatologist will be performed.
- Blood and urine samples will be collected for routine analysis. The results of these tests will indicate whether you are eligible to continue in this study. About 21 mL (about 5 teaspoons) of blood will be drawn and a urine sample will be collected. The blood tests also will determine whether you are infected with hepatitis B, hepatitis C.
- A tuberculosis screening will also be performed by a blood test, approximately 2 teaspoons of blood. If you have a history of a positive tuberculin test then you will have a chest x-ray performed.
- A blood sample will be taken for standard blood measurements that include liver tests. You will be asked to fast (not eat any food; water is recommended) for 8 hours before having your blood taken. Approximately 3 teaspoons of blood will be taken.
- A blood sample will be taken to test for pregnancy. This is only done for women of childbearing potential. (The study doctor or study staff will tell you if the pregnancy test results are positive.)
- If you are postmenopausal (defined as amenorrhea at least 12 months before screening, confirmed by FSH levels drawn at the clinical site, approximately 2 teaspoons of blood).
- Disease specific information such as locations and number of inflammatory nodules, abscesses, fistulae and scars will be recorded. The extent of HS severity will be assessed.
- You will be asked to complete questionnaires about your HS disease and how the disease affects your daily life.
- The study team will take photographs of your HS skin lesions.
- Certain topical preparations and certain creams are not allowed to be used for hidradenitis suppurativa treatment. If you need them, please consult your study doctor before use. If you are currently using them we may ask you to “washout”, stop taking them for a certain amount of time before you start taking the study medication.
- This visit may take up to 1 ½ hours of your time to complete.

Version Date: 11/15/2024

You will be provided a link to complete weekly questionnaires through Week 16 (duration of the study). The questionnaires will capture Numeric Rating Scale to measure your pain for the previous 24-hours, NRS pain for the 7-days previous, Hidradenitis suppurativa Quality of Life instrument (HiSQOL); medication use (assessing use of rescue medications or other potentially modifying medications or interventions). Each questionnaire is approximately 5 minutes to complete.

**Baseline/Day 0 Visit (If you meet all inclusion criteria, this will be combined with the Screening Visit):**

You will be assigned to receive Topical Ruxolitinib 1.5%. Applied to your HS lesions 2 times a day.

- Baseline visit will take approximately 1 ½ hours of your time.
- You will be asked about how you are feeling, to report any change in medical conditions and disease status, details of any problems or side effects that you may have experienced, and any medications you took since the previous visit.
- Vital signs (blood pressure, heart rate and temperature) will be recorded.
- Your lesions will be examined and any changes recorded at every visit.
- A physical examination by a dermatologist will be performed.
- If you are childbearing potential you will have a urine pregnancy test performed.
- You will have a skin punch biopsy, either a 4mm or 6mm from a HS lesion. The dermatologist and you will decide the location of the biopsy and which HS lesion is best for the biopsy. This lesion will be named the target lesion. We will map out the exact location of the lesion prior to the biopsy. The target lesion will be followed for the entire study period for changes in appearance.
- You will be asked to complete questionnaires about your HS disease and how the disease affects your daily life.
- The study team will take photographs of your HS skin lesions.

The study medication will be applied 2 times a day using a thin layer to each HS lesion. You will apply your first dose in the office. The study coordinator will provide verbal instructions on how to apply the medication so you can follow the directions when at home between visits. You will be asked to bring back all study medication tubes regardless if they are full or empty tubes.

**HS skin biopsy**

Skin biopsies will be performed by a Dermatologist using a 4 or 6 mm punch biopsy. The biopsy will be an area of HS skin that you and the dermatologist will decide and cleaned with an alcohol pad. The skin will be numbed with lidocaine 1% with epinephrine and a 4 or 6 mm punch biopsy (a round circle less than 1/8th of an inch in diameter) will be performed.

The biopsy sites will be covered with Gelfoam, Vaseline and a bandage by the research staff. You will be asked to keep the area dry for 24 hours. After 24 hours you may clean the site with soap and water, apply Vaseline and a bandage. The physician or study coordinator will educate you on signs and symptoms of infection. If you have concerns, you can call the research coordinator (717-531-1513) to discuss your care.

Version Date: 11/15/2024

What will happen to my skin biopsy?

In the research laboratory, your samples will be saved in paraffin wax and very small thin slices will be attached to glass slides. Using chemistry, we will investigate the presence or absence of many proteins in your sample. If you have any tissue leftover it will be placed in RNALater for potential use for future studies. It will not have any identifiers on the sample.

**Week 4 Visit/ Week 8 Visit:**

- Each visit will take approximately 1 hour of your time.
- You will be asked about how you are feeling, to report any change in medical conditions and disease status, details of any problems or side effects that you may have experienced, and any medications you took since the previous visit.
- If you are childbearing potential you will have a urine pregnancy test performed.
- A physical examination by a dermatologist will be performed.
- Your lesions will be examined and any changes will be recorded.
- You will be asked to complete questionnaires about your HS disease and how the disease affects your daily life.
- The study team will take photographs of your HS skin lesions
- You will return all used or unused tubes of the study medication. The study coordinator will dispense more study medication to last you until your next visit

**Week 16 Visit/Early Termination Visit:**

- This visit will take approximately 1 ½ hours of your time.
- You will be asked about how you are feeling, to report any change in medical conditions and disease status, details of any problems or side effects that you may have experienced, and any medications you took since the previous visit.
- If you are childbearing potential you will have a urine pregnancy test performed.
- Your lesions will be examined and any changes will be recorded.
- A physical examination by a dermatologist will be performed.
- You will be asked to complete questionnaires about your HS disease and how the disease affects your daily life.
- The study team will take photographs of your HS skin lesions
- A blood sample will be taken for standard blood measurements that include liver tests. You will be asked to fast (not eat any food; water is recommended) for 8 hours before having your blood taken. Approximately 8 teaspoons of blood will be taken.
- You will have a skin punch biopsy of the target lesion identified at the baseline visit, either a 4mm or 6mm from a HS lesion. The dermatologist and you will decide the location of the biopsy.
- You will return all used or unused tubes of the study medication.

**F/U Telephone Call (about 30 days post last dose of study medication):**

Coordinator will call participant and discuss any new A/E's or changes in medications since the last dose of study medication. The phone call should take less than 15 minutes of your time.

**What are my responsibilities if I take part in this research?**

Version Date: 11/15/2024

It is very important that you take the study medications exactly as instructed and that you follow all the study instructions carefully. If for whatever reason you cannot continue to take the study medication, you will still be asked to complete all the study procedures so that there is not a lot of missing information.

If you are enrolled in this study, you will have the following specific responsibilities:

- Go to all scheduled visits.
- Take the study drug following the dosing instructions that you will receive from your doctor at every study visit.
- Tell your study doctor before taking any new medications.
- Follow the study staff's directions about the study.
- Tell the study doctor about any illnesses or injuries.
- Tell the study doctor about any side effects or problems that occur during the study.
- Tell the study doctor if you plan to have any surgery or any other medical treatment or procedures.
- Continuing allowed contraception for the duration of the study and not changing it. Or stopping until after you have completed the research study.

It is important for your safety that you are completely honest with your study doctor throughout the duration of the study.

During the study, you will not be allowed to take certain medications. This includes certain types of approved or experimental medication used for the treatment of hidradenitis suppurativa or certain types of antibiotics or antifungals. Your study doctor will review these restrictions with you and let you know which medications you cannot take during the study. You will be requested to observe these restrictions until the end of the study.

### **3. What are the risks and possible discomforts from being in this research study?**

All drugs can cause side effects in some people. You must tell the study doctor or study staff about any side effect you have. As with any investigational medicine, if you do not tell the study doctor and study staff about the side effects, you may harm yourself by being in this study. Since the study drug is investigational when taken alone or in combination with other medications, there may be other risks that are unknown.

#### Allergic Reaction Risks

Symptoms of an allergic reaction includes; hives, or swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing. This could become life-threatening if it is not treated promptly.

Skin irritation has occurred with the topical cream. Stopping the study medication typically resolves the irritation within 2-3 days.

Please seek immediate medical assistance if you experience the symptoms of a severe allergic reaction. Then, contact the study doctor at the numbers given on the first page.

#### Photo-induced skin reaction

Risk of a skin reaction with topical ruxolitinib use and ultraviolet light (UV) exposure. This skin reaction resolves over a few days and does not have permanent skin damage. Avoid prolonged exposure to natural or artificial sunlight.

Version Date: 11/15/2024

### Headaches

Mild to moderate headaches were observed in a proportion of healthy volunteers exposed to ruxolitinib. You will be closely monitored for headaches at each scheduled visit.

### Systemic infections

Longer-term oral treatment with ruxolitinib can cause immunosuppression, allowing secondary infections. This medication will only be applied topically and not taken orally. When administered by mouth, ruxolitinib has caused low blood pressure, increased heart rate, and decreased blood counts (platelets, white blood cell counts, and red blood cell counts) which are reversible.

### Skin Biopsy

Skin biopsies will be collected from an active HS lesion. A biopsy is a tissue sample, in this case a small skin sample, from which a lot of information can be obtained. The biopsy can be analyzed for the presence of antibodies, proteins or cells that can be measured. It is also possible to study the skin structure. Before the biopsy is performed, the skin will be first cleaned, then disinfected and locally anaesthetized (to numb the skin). After the biopsy is taken, Gelfoam will be used to stop the bleeding and a bandage will be applied to the site. You will need to keep this area dry for 24 hours after which you should clean the site with soap and water, apply Vaseline and a band aid. You should contact the study team if you notice any signs of infection, such as redness or pain at the site. Skin biopsies will have local bleeding at the site and possibly bruising, pain infection, allergic reaction to the numbing medicine used in the procedure or damage to the structures beneath the skin site.

### Chest X-ray

If you take part in this research you will have one or more medical imaging studies which use radiation. The tests or treatments you will have include a chest x-ray. To give you an idea about how much radiation you will get, we will make comparison with every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 1 extra week worth of natural radiation. The radiation dose we have discussed is what you will receive from this study only, and does not include any exposure you may have received or will receive from other tests.

### Electrocardiogram Risk

Electrocardiograms (ECGs) will be done during this study. During an ECG, electrode patches/sensors are applied to the chest area, as well as your arms and legs. You may experience temporary discomfort (pulling on the skin/hair) during removal of the sensors. You may also develop some minor skin irritation from the ECG patch adhesive.

### Blood Draw Risks

Blood samples will be taken during the study. It may be necessary to try more than once to draw blood. A new needle will be used for each blood draw. You might feel pain or be light-headed from this. You may have the following at the site of the needle stick when blood is drawn: Additional bleeding at the site of the blood draw; Temporary discomfort; Bruising; and Infection (rarely).

Version Date: 11/15/2024

### Questionnaires

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

### Risks of the standard therapies for HS

Antibiotics (doxycycline and minocycline) taken orally, are the standard treatments for HS that you may be allowed to receive while participating in this study. Although hidradenitis suppurativa is not primarily an infectious disease, antibiotics are widely used to treat HS. Doxycycline and minocycline are two common systemic antibiotics used in HS treatment. Both share the common side effects that include but are not limited to nausea, vomiting, upset stomach, loss of appetite, dizziness, blurred vision, mild diarrhea, rash, headache, vulvovaginitis (inflammation of your vulva and vagina), and sensitivity to light. Doxycycline and minocycline have been reported to rarely cause serious, autoimmune disorders (lupus and autoimmune hepatitis), symptoms of allergic reaction (trouble breathing, rash, or itchiness), anorexia (eating disorder characterized by weight loss), thyroid gland discoloration, increased blood urea nitrogen (BUN), intracranial hypertension, and blood disorders (anemia, deficiency of blood platelets, low levels of neutrophils, eosinophilia).

### Risks for testing for reportable diseases

If you decide to participate in this study, we will test you for Tuberculosis (TB), Hepatitis B and Hepatitis C. The results of the test could indicate that you have Tuberculosis (TB), Hepatitis B or Hepatitis C. If that happens, we will refer you to a doctor who specializes in treating Tuberculosis (TB), Hepatitis B, and Hepatitis C. We will make every effort to keep your personal information confidential. However, we are required by law to report positive tests to the Pennsylvania Department of Public Health. Becoming aware of a diagnosis of Tuberculosis (TB), Hepatitis B, and Hepatitis C could have serious personal and/or social consequences, including difficulty obtaining health insurance or employment. For more information about the risks of Tuberculosis (TB), Hepatitis B and Hepatitis C testing, please talk to your study doctor.

### Pregnancy Risks and Birth Control Requirements:

The effects of Topical Ruxolitinib 1.5% on pregnancy, an unborn baby, or a nursing child are not known at this time. Therefore, if you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot participate in this study. You must confirm that, to the best of your knowledge, you are not pregnant, and that you do not intend to become pregnant during the study. If you are a female of childbearing potential (i.e., not post-menopausal or surgically sterilized), your study doctor must confirm that you are not pregnant by performing a pregnancy test before study entry. If you or your partner are/is a female of childbearing potential, you must consistently use an approved birth control (contraception) method while in the study. If you or your partner are/is not willing to use approved methods of birth control during the study, you will not be able to participate in this study.

When they are used correctly and consistently, the following examples of contraceptive methods are highly effective defined as those, alone or in combination, that result in a low failure rate (less than 1% per year): combined (estrogen and progestogen) hormonal contraception associated with inhibition of ovulation (oral, intravaginal, or transdermal), progestogen-only hormonal contraception whether by pill, injection, or implant, intrauterine device (IUD), intrauterine hormone releasing system (IUS), sterilization by tying of both fallopian tubes, sterilization of your sole male partner (with the appropriate post-vasectomy documentation of the absence of

Version Date: 11/15/2024

sperm in the ejaculate), complete sexual abstinence if it is in accordance with your usual lifestyle. If you use this method, you must agree to abstain from heterosexual intercourse until 4 weeks after the last dose of study drug.

#### Loss of Confidentiality

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

#### **4. What are the possible benefits from being in this research study?**

##### **4a. What are the possible benefits to me?**

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study is your HS may improve.

##### **4b. What are the possible benefits to others?**

The results of this research may guide the future treatment of HS and medical science may gain further understanding of this disease.

#### **5. What other options are available instead of being in this research study?**

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Receive commercially available treatments including local and systemic antibiotics, pain medication, and anti-TNF- $\alpha$  agents such as adalimumab, or participate in another research study, if one is available. Acitretin is used in early stage disease. Other drugs include cyclosporine A, dapsone, and isotretinoin.
- Be part of a different research study, if one is available.
- Choose not to be treated for your medical condition and only receive care to make you more comfortable.

Before you decide if you want to be in this research, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

Because it is investigational, the therapy offered in this research is only available to you if you take part in the research study.

#### **6. How long will I take part in this research study?**

If you agree to take part, it will take you up to 24 weeks to complete the study. You will have scheduled visits in the Dermatology Research Office at Screening, Baseline/ Week 0 (can be combined based on criteria), Week 4, Week 8, and Week 16. Each of these visits is expected to last for up to 1 to 1 ½ hours to complete. About 30 days after your last dose of study medication, you will have a follow up phone call with a study coordinator. This call will take approximately 5-10 minutes.

#### **7. How will you protect my privacy and confidentiality if I decide to take part in this research study?**

Version Date: 11/15/2024

**7a. What happens to the information collected for the research?**

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

In our research files at Penn State Health (PSH) and Penn State College of Medicine (PSU) we will include these identifiers: initials, date of birth, medical record number, a code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Zaenglein's research office.
- Your research records will be labeled with your code number, your initials, your date of birth and will be kept in a safe area in Dr. Zaenglein's research office.
- Results of some of the research-related clinical tests Chest X-Ray, laboratory tests and ECG will be kept in your PSH medical record.
- Specimens will be stored in the research laboratory. They will be labeled with your initials and date of visit.

For research records sent to Incyte, you will be identified by: date of birth, your initials, code number.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

**7b. What will happen to my research information and/or samples after the study is completed?**

We may use your research information and your biological samples in future studies or may share your information or biological samples with other investigators for future research without your additional informed consent. Before we use or share your information or samples we will remove any information that shows your identity.

**7c. How will my identifiable health information be used?**

In general, under federal law (including the Health Insurance Portability and Accountability Act – HIPAA or privacy laws) your health information is private. By signing this form, you are authorizing us to collect, use, and disclose your identifiable health information, sometimes referred to as "Protected Health Information" or "PHI" under HIPAA, for the purposes of this research study. We will use and disclose your information only as described in this form, in the PSH Privacy Notice, and as may be required or allowed under the applicable privacy laws.

The research team may use the following health information:

- Past, present, and future medical records, including identifiable information
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- PSH/PSU research staff involved in this study

Version Date: 11/15/2024

- The PSH/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The PSH/PSU Human Subjects Protection Office
- The PSH/PSU Research Quality Assurance Office
- Non-research staff within PSH/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- The PSH/PSU pharmacy
- The sponsor(s) of this study, monitors and auditors, and other people or groups it hires to help perform this research
- A group that oversees the data (study information) and safety of this research

These groups may also review and/or copy your original PSH/PSU records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable health information and samples may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

We may remove identifying information from your protected health information. Once we do this, the remaining information will not be subject to the privacy laws. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the

Version Date: 11/15/2024

front of this form. Once permission is withdrawn, you cannot continue to take part in the study.

- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

**8. What are the costs of taking part in this research study?**

**8a. What will I have to pay for if I take part in this research study?**

For costs of tests and procedures that are only being done for the research study:

- The study medication Topical Ruxolitinib will be provided by Incyte at no cost to you while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- The research-related tests and procedures that will be provided at no cost to you include: Clinic visits, Chest X-Ray, ECG, Photography, urine samples, skin biopsies and Blood tests.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

**8b. What happens if I am injured as a result of taking part in this research study?**

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal

Version Date: 11/15/2024

investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

Sponsor's compensation for injury –

To pay these medical expenses, you will need to complete a form for the sponsor. This form will ask you for your name and if you have ever been enrolled in Medicare Part A or Part B. If you have been enrolled in Medicare you will also be asked to provide your date of birth and either your Medicare Claim Number or your Social Security Number. The sponsor will need to know this information about you because the sponsor has to report the payment it makes to Medicare. The sponsor will not use this information for any other purpose.

When you sign this form you are not giving up any legal right to seek compensation for injury.

**9. Will I be paid to take part in this research study?**

You will receive \$50.00 per visit for your participation in this research study for up to a total of \$250.00. If you do not complete the study for any reason, you will be paid for the visits you have completed. The payment will be provided by Greenphire ClinCard.

This reimbursement will be issued by an external company called Greenphire, which will issue your reimbursement. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process this reimbursement and will not share it with anyone for any other purpose. Details of the debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the replacement fee.

When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Study/Subject ID, Name, Address, date of birth and Social Security Number.

You will have the option to receive updates related to payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your Mobile Phone Number and/or E-mail Address.

Payment received as compensation for participation in research is considered taxable income. If payments from Greenphire exceed \$600 in any one calendar year, Greenphire will file a 1099 (Miscellaneous Income) form on behalf of Penn State.

It is possible that your research information and/or specimens (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

**10. Who is paying for this research study?**

The sponsor Incyte is paying PSH/PSU for the research to be done.

**11. What are my rights if I take part in this research study?**

Version Date: 11/15/2024

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

Your research doctor or the sponsor may take you out of the research study without your permission.

- Some possible reasons for this are for example: continuing the research would be harmful, your condition has become worse, you become pregnant, you did not follow the instructions of the study doctor, you experience serious side effects.
- Also, the sponsor of the research may end the research study early.
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

During the course of the research, you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

## **12. If I have questions or concerns about this research study, whom should I call?**

Please call the head of the research study (principal investigator), Dr. Zaenglein at (717) 531-1513 or the Dermatology doctor on 24-hour call at (717) 531-8521 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the PSH Human Subjects Protection Office (HSPO) at (717) 531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at <http://med.psu.edu/clinical-research/faqs> for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

Version Date: 11/15/2024

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

## **INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH**

### **Signature of Person Obtaining Informed Consent**

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

\_\_\_\_\_  
Signature of person who explained this research      Date      Time      Printed Name  
(Only approved investigators for this research may explain the research and obtain informed consent.)

### **Signature of Person Giving Informed Consent and Authorization**

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

### **Signature of Subject**

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

\_\_\_\_\_  
Signature of Subject      Date      Time      Printed Name

### **Signature of Parent(s)/Guardian for Child**

By signing this consent form, you indicate that you permit your child to be in this research and authorize your child's information to be used and shared as described above.

\_\_\_\_\_  
Printed name of child

Version Date: 11/15/2024

\_\_\_\_\_  
Signature of Parent/Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

☐ Parent

☐ Individual legally authorized to consent to the child's general medical care. (See note below.)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

### **ASSENT FOR RESEARCH**

The research study has been explained to you. You have had a chance to ask questions to help you understand what will happen in this research. If you are a female capable of becoming pregnant you will be tested for pregnancy. The results of your test will not be shared with your parent/guardian without your permission. However, your parents may find out if you are pregnant because you will no longer be able to take part in this research.

You **DO NOT** have to be in the research study. If you agree to participate and later change your mind, you can tell the researchers, and the research will be stopped.

You have decided:     **(Initial one)**

\_\_\_\_\_ To take part in the research.

\_\_\_\_\_ NOT to take part in the research.

\_\_\_\_\_  
Signature of subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name