

INFORMATION AND CONSENT FORM

Parent/Guardian/Participant (Ages 18+)

Study Title: <<study title>>**Protocol #:** <<protocol number>>**Sponsor:** <<sponsor>>**Study Doctor:** <<investigator>>
<<firm name>>
<<street address>>, <<city>>, <<state>> <<zip>>**Telephone Number:** <<000-000-0000>>**After Office Hours:** <<000-000-0000>>

You have been asked to be part of a research study. This form describes the study in order to help you decide if you want to participate. This form will tell you about what you will have to do during the study and the risks and benefits of the study. If you have any questions about or do not understand something in this form, you should ask the study doctor. Do not sign this form unless you are satisfied with the answers to your questions and decide that you want to be part of this study.

Please take time to read the information carefully and discuss it if you wish with friends, relatives, and your regular doctor. Take the time to decide whether or not you wish to take part.

When reading this form, please note that the words “you” and “your” should be read as referring to the person in the study rather than to a parent, guardian, or legally authorized representative who might sign this form on behalf of the person in the study.

WHAT WILL HAPPEN DURING THIS STUDY?

Researchers want to find out if a drug called 1% SB-275833 ointment can help people with skin conditions (such as atopic dermatitis and psoriasis) that are infected with bacteria (germs). SB-275833 ointment, which belongs to a new class of drugs called pleuromutilins, is an investigational drug. An “investigational drug” is a drug that is still being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).

Some people in the study will use 1% SB-275833 ointment and other people will take a drug called cephalixin. Cephalixin, which belongs to an established class of drugs called cephalosporins, is approved by the FDA for the treatment of skin infections. The study doctor will see how well 1% SB-275833 ointment works and how safe it is by comparing it to cephalixin. About 495 people with an infected skin condition who are at least 9 months old may be in this study.

You have a skin condition that is infected. The study doctor wants to know if it is okay to give you study drug to compare 1% SB-275833 ointment with cephalixin. You can say yes or no. You can ask the study doctor or study staff questions before you decide if you want to be in the study.

WHO IS PAYING FOR THIS STUDY?

A company called GlaxoSmithKline, the sponsor of the study, is paying for this study to happen. GlaxoSmithKline is also paying the study doctor to do this study.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

You do not have to pay for study drug, study visits, or tests that have to be done for the study. To find out more about costs, you can ask the study doctor or study staff.

You may have to pay the costs of diagnosing and treating a condition or injury that you or others think may be related to the study. This could happen if:

- the sponsor and/or the study doctor do not think the condition or injury is related to the study
- you have not followed the directions the study doctor or study staff gave you about the study

HOW LONG WILL I BE IN THE STUDY?

If you decide to be in this study and the study doctor says you can be in the study, your participation will last between about 17 and 19 days. You will have to come to the study center a total of 5 times during the study.

WHAT WILL HAPPEN DURING THIS STUDY?

If the study doctor says you can be in the study and you want to be in the study, the study doctor will give you 2 capsules to swallow 2 times a day for 10 days and ointment to put on your skin 2 times a day for 5 days. However, some participants, who are 12 years of age and younger will swallow a suspension (liquid) 2 times a day for 10 days instead of swallowing capsules.

You will be assigned by chance (like flipping a coin) to 1 of 2 study groups:

- Group A: 1% SB-275833 ointment + cephalexin placebo (a capsule or liquid that looks like cephalexin but has no active ingredient)
- Group B: cephalexin capsules at a dose of 1000 mg a day or cephalexin liquid at a dose of 25 mg/kg a day + 1% SB-275833 placebo (ointment that looks like 1% SB-275833 ointment but has no active ingredient)

There is a 2 out of 3 chance you will get 1% SB-275833 ointment and a 1 out of 3 chance you will get cephalexin.

Neither you nor the study doctor will be able to pick which study group you are in. You will not know and the study doctor will not know which study group you are in, but the study doctor can find out if there is an emergency or if it is necessary to know for your health. The study doctor may or may not tell you what study group you were in at this time.

You are the only one who should use the study drugs. You should make sure that children and others who might not be able to read or understand don't use them.

What happens when I come for study visits?

If you work, your work schedule may be interrupted by visits to the study center. If the 5 visits will be a hardship for you, then you should not agree to be in this study.

Before you can start the study, the study doctor or study staff will talk to you about the study. Then you have to sign this form before the study doctor or study staff can begin the screening period. (If you are a parent or guardian who is signing this form on behalf of your child, your child will also have to sign an assent form before the study doctor or study staff can begin the screening period.)

After you sign this form, the study doctor or study staff will do some or all of the things listed below when you come in for study visits:

- **Health and Medication Questions:** Ask you to answer questions about your health and the medications you take.
- **Physical Exam:** Give you a general physical exam, which includes measurements of your height, weight, temperature, pulse rate, and blood pressure. You should ask the study doctor about what will be done during this exam.
- **Skin Exam:** Examine your skin. You should ask the study doctor about what will be done during this exam.
- **Blood and Urine Tests:** Stick a needle in your arm to take blood out and collect a urine sample. The study doctor or study staff will explain how to collect the urine sample. These blood and urine tests are to check that your blood cells and the chemicals in your body are normal and not affected by the study drugs.
- **Pregnancy Tests:** If you are a woman and can have children, your urine will be tested to see if you are pregnant. You will be told if the test results are positive. The results of the test must be negative in order for you to be in the study. (If you are a parent or guardian of a child participating in this study, whether you are told the results of your child's pregnancy test depends on the laws of your state.)
- **Skin Sample:** Collect a sample of your infected skin to see what bacteria (germs) are causing your infection. The sample could be collected by any one of the following ways:
 - scraping your skin at the site of the infection
 - removing some fluid with a needle at the site of infection
 - rubbing your skin with a swab, which is similar to a large "Q-tip" (however, this is not the preferred method of collecting the sample)
- **Nasal Sample:** Use a swab to collect a sample from the inside of your nose to see if there are bacteria (germs) in your nose that may be related to the bacteria that is causing your skin infection.
- **Diary:** Give you a diary card and tell you how to fill it out to record your use of the study drugs.. You will need to bring your diary card with you to your visits. The doctor will take the card to add to your file on the visit after you finish all your study medication..
- **Study Drug:** Give you a supply of the study drugs and tell you how to use them. You will need to bring back study medication containers, tubes, and any remaining study medication at visit 4 or visit 5.

The study staff will tell you when to come in for your study visits. You should ask the study staff how long your visits will last.

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day 1	Day 3-4	Day 7-9	Day 12-14	Day 17-19
Health and Medication Questions	X	X	X	X	X
Physical Exam	X				
Skin Exam	X	X	X	X	X
Blood and Urine Tests	X	*	X		
Pregnancy Tests	X				X
Skin Sample	X	*	*	*	*
Nasal Sample	X	*	*	X	X

*The study doctor may not need to take samples at this visit. He/she can give you more information about this.

What will happen when the study is over?

With respect to recovery time, the estimated time it will take for 1% SB 275833 ointment to leave your body is about 0-10 hours. The estimated time it will take for cephalexin to leave your body is about 8 to 12 hours. Ask the study doctor for the recovery time of the procedures required by this study.

You should talk to the study doctor about whether you need treatment after the study for your infected skin condition.

Is there anything I need to do while I am in the study?

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study center for your visits with the study doctor.
- Tell the study doctor or study staff about any changes in your health.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

The study doctor will ask you not to apply any medications to the infected area(s) of your skin, other than the study ointment, for the entire study. This is so the study doctor can fully measure the effects of 1% SB 275833 ointment without interference from other medications. You may continue to use your normal topical (applied to the skin) medications on areas of your skin that are not infected as directed by the study doctor. While you are in this study, you must not take any prescription antibiotics.

Are any of the study tests part of my regular medical care?

Some of the study procedures might be done as part of your regular medical care even if you do not take part in this research study. The study doctor or a member of the study staff can answer any questions you may have about the procedures that are not part of your regular medical care. Using 1% SB 275833 ointment is only done in research studies like this one.

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?What can happen if I use 1% SB-275833 ointment?

In healthy people who had their skin abraded (lightly scraped) and received SB-275833 ointment at a concentration 2 times higher than the concentration used in this study, the most common side effect was skin irritation. In another study of people with simple skin infections, the most common side effect in people who used 1% SB-275833 ointment was mild itching.

What can happen if I use cephalexin?

The most common side effects of cephalexin are:

- diarrhea
- nausea
- skin rashes
- vomiting
- vaginal discomfort and infection

Serious allergic reactions that sometimes resulted in death have been reported in some people taking cephalosporin drugs, including cephalexin. These reactions can occur in people with a history of penicillin allergy. **If you have a history of allergy to penicillins or cephalosporins, you should not be in the study.**

Some things that happen during an allergic reaction are:

- a rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

Can anything bad happen when skin tissue samples are collected?

It may be uncomfortable when the study doctor or study staff takes a sample of your infected skin. The sample from the inside of the nose is taken at the very front of the nasal opening, and you may feel some fullness or pressure (like a finger in the nose).

Can anything bad happen when my blood is taken?

The study doctor or study staff will check your blood by sticking a needle in your arm to take some blood out. Some problems you might have from this are:

- It may hurt.
- You may get a bruise.
- You may feel dizzy.
- You might get an infection at the place where the needle went into your arm.

About 2 tablespoons of blood will be taken out of your arm during the study.

Could I have any other problems with my health if I do this research study?

It is possible that problems and side effects of 1% SB-275833 ointment or cephalexin that nobody knows about could happen to you, which include your infected skin condition getting worse or even death. If the study doctor learns any new information about 1% SB-275833 ointment or cephalexin while you are in the study, and it is the kind of information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

Are there risks to me if I am pregnant during the study?

If you are a woman, you cannot be in this study if you are pregnant or nursing a baby. If you decide to be in the study:

- You must not be pregnant.
- You must not plan to become pregnant during the study.
- You must not be nursing a baby.

If a woman is pregnant or nursing a child while using 1% SB-275833 ointment or taking cephalexin, there may be risks to the unborn baby or nursing child. Nobody knows what these risks are right now. Some drugs cause babies to be born prematurely (earlier than they should be) or to have birth defects.

Women who can have children will be required to have pregnancy tests during the study. A pregnancy test does not stop you from becoming pregnant.

If you are a woman who can have children, the study doctor will talk to you about birth control options you must use during the study. Some types of birth control will not work when you are taking certain drugs. The birth control options you can use during the study are:

- hormonal contraceptives (such as birth control pills or implants) + barrier contraception (such as a condom or diaphragm)
- IUD (intra-uterine device)
- diaphragm or condom + contraceptive cream, jelly, or foam

If you think that you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you will be removed from the study. The study doctor may request to have information about the pregnancy and the birth of the child. The study doctor may share this information with the sponsor and Quorum Review Institutional Review Board (IRB).

WILL BEING IN THIS STUDY HELP ME?

The study drug may help your infected skin condition, but there is no guarantee that being in this study will help you. Your infected skin condition might not get better or might get worse while you are in this study. You will not have to pay for study visits, tests, or the study drug. Your participation in this study may add to the medical knowledge about infected skin conditions and the use of 1% SB-275833 ointment.

IS THERE ANYTHING ELSE I CAN DO FOR MY INFECTED SKIN CONDITION?

You should continue to go to your regular doctor even if you join this study.

You do not have to be in this study to get help for your infected skin condition or to take cephalexin for an infected skin condition. You can also take other oral (taken by mouth) or use topical (applied to the skin) antibiotic treatments. The study doctor will describe these to you based on your medical history and the treatment you have received so far.

WHAT IF I GET HURT OR SICK WHILE I AM IN THE STUDY?

If, as part of participating in the study, you are injured as a direct result of the study drugs or study-related procedures that are done according with the study plan, GlaxoSmithKline will pay for your reasonable medical expenses for treatment you need for the injury. GlaxoSmithKline will not pay you for medical expenses that are covered by your medical insurance. Be aware that your medical insurance might not cover the cost of study-related injuries.

GlaxoSmithKline is not offering to pay you for any other expenses, but you do not give up any legal rights by signing this consent form. To ask questions about this, talk to the study doctor or study staff.

WILL I GET PAID?

You will get \$000 if you finish the whole study. If you do not finish the whole study, you will get \$000 for each study visit you finish, <<not>> including the screening visit(s). The study doctor or study staff can tell you more about when you will get paid.

<<If applicable (if participants will not be paid for participation): You will not get paid for being in this study.>>

WHO CAN I TALK TO ABOUT THE STUDY?

You can ask questions about the study any time. If you feel sick, you can call the study doctor at <<phone number>> during the day. You can also call <<after hours phone number>> at any time.

This study was reviewed by Quorum Review Institutional Review Board (IRB). An institutional review board (IRB) is a group of people who review the risks and benefits of a study. If you want to ask questions about what it means to be in a research study or about your rights as a research participant, you can call Quorum Review Institutional Review Board (IRB).

Quorum Review IRB is located in Seattle, Washington.

Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.

Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

DO I HAVE TO BE IN THIS STUDY?

You do not have to be in the study if you don't want to. Your participation in this study is voluntary.

You can change your mind at any time. If you say "yes" now, you can say "no" and stop later. Your decision not to be part in the study or to stop being in the study will not affect your medical

care, and you won't lose any benefits you are entitled to except for benefits that are related to the study.

The study doctor or sponsor can withdraw you from the study at any time, even if you want to continue to be in the study. This could happen if:

- The study doctor believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor stops the study for any reason.

If you want to stop being in the study, you must tell the study doctor or study staff and return all unused study drugs and study materials. If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. They may also ask you to have some more tests done to help your withdrawal from the study happen safely.

WHAT WILL HAPPEN TO MY BLOOD SAMPLES AND TISSUE SAMPLES FROM MY NOSE AND SKIN THAT ARE COLLECTED FOR THE STUDY?

The study doctor and study staff will use your blood and skin tissue samples to check your condition. Your blood and tissue samples will not be labeled with information that directly identifies you, but will be labeled with a number that can be linked to you. The study center will keep the link between the samples' number and information that identifies you.

Your blood and tissue samples may be sent to GlaxoSmithKline or to other researchers working with GlaxoSmithKline.

WILL INFORMATION ABOUT ME BEING IN THIS STUDY BE USED AND SHARED?

This section explains how your medical and health records might be used and shared if you agree to participate in this study. If you do not sign this form, you cannot participate in the study.

During the study, the study doctor and study staff will collect and record health information about you (your "records"). Your records include the information from the tests described above. Your records also will include other information about you, such as your name and address.

Your personal information (for example, your gender, age, and the details of your medical conditions) and other information (the study information) will be given a special number (a code).

If you sign this form:

- You allow the study doctor and study staff to use your records to carry out this study.
- You allow the study doctor to share your records with the company paying for this study, GlaxoSmithKline, their representatives, and other researchers involved in this study. These people will use your records to review the study and to check the safety of the study.
- You allow the study doctor or sponsor to use some facts about you being in this study in books, magazines, journals, or meetings. If this happens, your name will not be used.

The study doctor also may share all of your records and this signed consent form with government agencies, including the U.S. Food and Drug Administration (FDA), and government

agencies in other countries. They may also share your records with regulatory agencies, like Quorum Review Institutional Review Board. These agencies may use your records to check the information collected in this study, to check how the study is done, and to check participants' safety.

There are national and state laws that make the study doctor protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information as described above. After the study doctor shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. Your records might be shared with other people who do not have to protect the privacy of your records.

The people who work for GlaxoSmithKline are required to protect the privacy of your records. GlaxoSmithKline will keep your records. Your name and address are not included in the records kept by GlaxoSmithKline. Only the study doctor will keep this information. GlaxoSmithKline has told the study doctor to keep the information about you in a safe place. GlaxoSmithKline will protect your records even in countries where laws about privacy are less strict than in the U.S.

If you get hurt or sick possibly because of being in the study and you seek medical treatment:

- The study doctor and sponsor may obtain study-related records from your other health care providers to learn more about the effects of the study and your condition.
- Information about this study might be given to your health care payer for the purpose of resolving your claim.
- The sponsor might give information that identifies you to its insurance carrier for the purpose of resolving your insurance claim.

You have the right to withdraw your consent to participate in this study at any time. If you withdraw your consent to participate in this study, no new information will be collected from you and added to other study information.

Your information will be processed by a computer or by a person working for GlaxoSmithKline. Your information will be used to help figure out the results of this study. GlaxoSmithKline may use your information for other medical or scientific purposes. For this purpose, only your information labeled with a code will be used.

You have the right to ask the study doctor about your records. You have the right to ask the study doctor to allow you to see your records and to have any required corrections made. However, if you sign this form, you might not be able to see and copy some of your records until after the study is done.

You can cancel this consent to use and share your study records at any time. If you want to cancel your consent, you must write a letter to the study doctor. If you cancel your consent:

- You will not be able to be in the study.
- The study doctor will not be able to use or share your records unless it is necessary to make sure that the results of the study are accurate.

This consent to use and share your study records expires in 50 years.

You will be given a copy of this form after you have signed and dated it.

Indicate your agreement to this authorization by checking the box below and signing:

☐ I authorize the use and release of my medical records and health information related to this study as described above.

Signature of Participant or Parent/Guardian/Legal Representative

Date