PARTICIPANT INFORMED CONSENT FORM FOR ADULTS AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE MEDICAL INFORMATION

Sponsor / Study Title:	**Triveni Bio, Inc. / "A Phase 2a, Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Multiple Subcutaneous Doses of TRIV-509 in Adults with Moderate to Severe Atopic Dermatitis"**
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You must be from 18 to 75 years to participate in this study.

WHAT IS AN INFORMED CONSENT FORM?

This form is called an informed consent form. You are being asked to participate in a medical research study (called the "study" from now on). This study includes only people who volunteer to participate.

- The purpose of this informed consent form is to explain the study and how it may affect you. Then you can decide if taking part in the study is right for you.
- This informed consent form may contain words you do not understand. Please ask the study doctor or study staff to explain anything that you do not clearly understand.
- Ask as many questions as you need before you decide if you want to be in the study.
- Please take the time to make your decision.
- You may take home a copy of this informed consent form to discuss with others, such as family, friends, or your regular doctor.
- If you agree to be in this study, you will be asked to sign and date this informed consent form. You will also get a copy to take home with you.
- An Institutional Review Board (IRB) has reviewed this study and the informed consent form to make sure that your rights and welfare are protected after you join this study. This committee will oversee this study while you are in it.

INTRODUCTION AND BACKGROUND

Atopic dermatitis (AD), also known as eczema, is the most common inflammatory skin disorder in the developed world. Atopic dermatitis is a chronic condition that causes dry, itchy, and inflamed (red) skin. This study is being done to see whether an investigational drug called TRIV-509 works to improve the signs and symptoms of atopic dermatitis. In atopic dermatitis, the "barrier" function of the skin doesn't work normally, which means it is easier for irritating substances (like allergens) to get into the skin. TRIV-509 blocks proteins in the body called kallikrein 5 and kallikrein 7. These proteins help to maintain normal skin barrier function and have been shown to be overactive in atopic dermatitis.

The first study in humans with TRIV-509 is ongoing in healthy participants, with an estimated 40 study participants.

TRIV-509 is an experimental drug which means it is not yet approved by Health Canada or the United States (US) Food and Drug Administration (FDA). It is not approved for use outside of studies like this one.

A description of this clinical trial will be available on http://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.

Information on this study will also be posted in a similar format on a European Web site at https://euclinicaltrials.eu.

WHAT DOES IT MEAN TO BE A STUDY PARTICIPANT?

- Your participation in this study is entirely voluntary. You may or may not choose to take part.
- To be enrolled in this study, you cannot be taking other medications that can treat atopic dermatitis. Each type of medication you might be using requires a different "washout" period. Your study doctor will review all of your medications with you as part of the screening process.
- You cannot have received another experimental (investigational) treatment within the last 4 to 16 weeks, or longer, depending on the nature of the experimental treatment, to be enrolled in this study. You cannot participate in another study with an experimental treatment while you are in this study.
- If you decide to be in the study and the study doctor confirms you can be in this study, you will need to follow certain rules about the study procedures. You will also be asked to provide information about your medical and surgical history and any other drugs (including other medications, as well as alcohol and drugs) you are taking or have taken in the past, including medications you have previously taken for atopic dermatitis.
- You have to tell the study doctor or study staff of any new drugs you start to take or if your health changes in any way. For your safety, it is very important to report to the study doctor the names of all the medications you are taking. This also includes herbal or "natural" remedies and over-the-counter medications. Please check with the study doctor before you begin a new medication while you participate in this study.
- Your study doctor will speak with you about the ingredients of the study drug used in this study and will ask you if you had allergies in the past. You may be allergic to 1 or more

components of the study drug, and it is important to tell your study doctor all of your known allergies.

- You might be told to stop using the study drug or to leave the study. This may be because your condition worsens, because you had a side effect, or because you didn't follow the study instructions properly. This may also be because new information about the study drugs' safety or efficacy became available or because of administrative reasons. You could be removed from the study without your agreement, but the study doctor will tell you why. You can also decide to leave the study at any time without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.
- If you leave the study before the last scheduled visit, you will be asked to return for an early termination visit ideally within 2 weeks of your discontinuation in the study, and for a safety follow-up visit approximately 24 weeks after the last dose of the study drug. Your study doctor may also contact you afterward to find out how you are doing.
- The study staff will inform you in a timely manner of any important new information that might change your decision to be in this study. You can use this information to decide, with the help of your study doctor, whether or not you want to stay in the study. If you decide to continue in this study, you may be asked to read and sign a revised informed consent form containing the new information.

INFORMATION ABOUT THE STUDY

Triveni Bio, Inc., hereby referred to as Triveni Bio, is sponsoring this study. You are being asked to participate in this study because you have moderate or severe atopic dermatitis. The study will enroll approximately 90 participants with moderate to severe atopic dermatitis located in the United States of America (USA), Canada, and Europe.

If you decide to join the study, you can expect to be in the study for up to approximately 57 weeks.

The study will consist of three parts:

- Screening Period: up to 30 days
- Study Treatment Period: approximately 32 weeks
- Follow-up Period: approximately 20 weeks after study treatment period

The dose of TRIV-509 is 600 mg followed by 300 mg every 4 weeks administered subcutaneously (a needle injected under the skin) during different periods of study. If you do not feel you are able to receive injections, you should not participate in this study. Please notice that this form refers to both TRIV-509 and placebo as "study drug." The placebo is a formulation with no active drug (TRIV-509) in it.

You will receive the study drug once every 4 weeks, for approximately 32 weeks. You will randomly be assigned to one of two groups at Day 1 of the study:

- **Group 1**: During the Study Treatment Period, participants originally assigned to the TRIV-509 arm of the study will receive TRIV-509 600 mg (2 injections) on Day 1 and TRIV-509 300 mg (one injection each time) at weeks 4, 8 and 12. At Week 16, participants will be switched to placebo arm and will receive placebo at Week 16 (2 injections) and at weeks 20, 24 and 28 (one injection each time). Starting at Week 32, participants will not receive any further injections.

- **Group 2**: During the Study Treatment Period, participants originally assigned to the placebo arm will receive placebo at Day 1 (2 injections) and at weeks 4, 8 and 12 (one injection each time). At Week 16, participants will be switched to receive TRIV-509 during the next 16-week period and will receive TRIV-509 600 mg (2 injections) at Week 16 and TRIV-509 300 mg (one injection each time) at weeks 20, 24 and 28.

You will not know which of the groups you will be assigned to. Groups will be assigned randomly (like flipping a coin). For this study, you will have two in three chances to be assigned in Group 1 (67%) and one in three chances (33%) to be assigned in Group 2. The study doctor, you, and the study staff will not know which group you are assigned to. In the case of emergency in which it would be useful to know what you have received, your study doctor will be able to find this out.

By comparing the results of these groups of participants, we will be able to see if TRIV-509 is safe, effective and tolerable. Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

STUDY VISITS

This section will describe the visits you will have at the study clinic and the details of the procedures to be performed at each visit. The following table summarizes your participation in the research study and all the study visits.

You will have to stay at the clinic for more than 8 hours on 2 occasions during the study (Day 1 and Week 12). During these visits, you will have your blood drawn 3 times, once before the study drug is administered, and then 2 and 6 hours after the study drug is administered. After the last blood draw, you can go home.

Screening Period

During the Screening Period, you will read and review this informed consent form, and the study doctor will also explain the study to you. If you agree to take part in the study, you will be asked to sign and date this form before performing (doing) any study procedures.

The study staff will check to see if you can participate in the study during this visit. Further participation in the study depends on the results of the completed assessment during the screening period. The study doctor, the study Sponsor and/or study staff will review the results of the screening tests and discuss with you whether this research study is suitable for you.

Study Treatment Period

If you meet all the study's eligibility requirements, you will begin the study treatment period on Day 1. Over a period of 32 weeks, you will receive study drug every 4 weeks for a total of 10 injections. Regardless of the arm to which you are assigned, you will receive 2 injections at Day 1 and Week 16. At all other visits where you receive study drug administration (weeks 4, 8, 12, 20, 24 and 28), you will receive 1 injection.

Follow-Up Period

After completing the Study Treatment Period, you will have a 20-week follow-up period. During this period, you will not receive any study drug, but you will continue to have visits to evaluate your atopic dermatitis and monitor for side effects.

After the follow-up visit at Week 52, your participation in the study will be over.

Early Study Treatment Termination Visit

During the study, your health will be monitored by the study doctor. If the study doctor believes that it is not in your best interest to continue taking the study drug, or if you decide you don't want to be in the study anymore, you can leave the study early. If you decide to withdraw from the study early, you should inform the study staff as soon as possible. If your study doctor decides you shouldn't be in the study anymore, they will explain the reason to you.

If you discontinue the study, an early termination (ET) visit should be scheduled as soon as possible, ideally within 2 weeks of discontinuation, and a safety follow-up (SFU) visit should be scheduled approximately 24 weeks after the last dose of study drug intervention.

It is possible that you or the study doctor will decide that you should not continue receiving the study drug. This decision may be made if you have side effects, for example, allergies or reaction due to the injections, that may put you at risk. If this decision is made, you will be encouraged to remain in the study. If you discontinue the study drug but stay in the study, you will continue with assessments per the Study Visits table below.

STUDY VISITS

	Screening Period	**Study Treatment Period**									**Follow-up Period**				**Safety Follow-up**
Study Visits	**Day -30 to -1**	**Day 1**	**Week 2**	**Week 4**	**Week 8**	**Week 12**	**Week 16**	**Week 20**	**Week 24**	**Week 28**	**Week 32**	**Week 36**	**Week 44**	**Week 52/ET**	**-**
Duration (hours)															
Signing and dating this informed consent form	X														
Review of study requirements	X	X													
Collection of demographic information (sex, birth date, race/ethnicity)	X														
Collection of medical and surgical history, including AD history	X	X													
Flare Questionnaire	X														
Physical examination[1]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Electrocardiogram (ECG) to monitor your heart	X	X		X		X	X	X		X		X		X	
Vital signs (blood pressure, pulse, temperature, breathing rate, weight, height (Screening only))	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy test[2a]	X	X		X	X	X	X	X	X	X	X	X	X	X	X
Follicle-stimulating hormone (FSH test)[2b]	X														
Blood tests (from 10 to 14 mL = approx. 2 to 3 tsp depending on the visit) and urine safety tests	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
HIV, Hepatitis B, and Hepatitis C evaluation (5 mL = 1 tsp)	X														

	Screening Period	**Study Treatment Period**									**Follow-up Period**				**Safety Follow-up**
Study Visits	**Day -30 to -1**	**Day 1**	**Week 2**	**Week 4**	**Week 8**	**Week 12**	**Week 16**	**Week 20**	**Week 24**	**Week 28**	**Week 32**	**Week 36**	**Week 44**	**Week 52/ET**	**-**
Duration (hours)															
Tuberculosis evaluation (4 mL = approx. 1 tsp)	X														
Blood sampling for study drug concentration (9 mL = approx. 2 tsp)		X	X	X	X	X	X	X	X	X				X	X
Blood sampling to assess your AD[3] (9 mL to 11.5 ml = approx. 2 to 3 tsp depending on the visit)		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood sampling to assess your body response to the study drug (8.5 mL = approx. tsp)		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Randomization (Assignment to study group)		X													
Study drug administration		X		X	X	X	X	X	X	X					
Self-Assessment of your itching (pruritus NRS; starts at least 7 days prior randomization)[4]	X----------X														
Self-Assessment of your disease severity and quality of life (DLQI, POEM)	X	X		X	X	X	X	X	X	X	X			X	
Medical photographs (full body)	X	X		X			X								
Visual assessments of AD by study doctor (vIGA-AD, EASI, BSA)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
SCORAD (scoring atopic dermatitis)	X	X	X	X	X	X	X	X	X	X	X			X	

	Screening Period	**Study Treatment Period**									**Follow-up Period**				**Safety Follow-up**
Study Visits	**Day -30 to -1**	**Day 1**	**Week 2**	**Week 4**	**Week 8**	**Week 12**	**Week 16**	**Week 20**	**Week 24**	**Week 28**	**Week 32**	**Week 36**	**Week 44**	**Week 52/ET**	**-**
Duration (hours)															
Tape strips and photographs of sites tape stripped[5]		X		X			X				X				
Optional Skin biopsies and photographs of sites biopsied		X		X			X								
Optional Genetic blood sample (2.5 mL = 1/2 tsp)		X													
List of all the medications you are taking and procedures you have undergone	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Evaluation of any unwanted effects or health problems evaluation	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Abbreviations: ET=Early Termination, AD= Atopic dermatitis

[1] A full physical examination will occur during the Screening Period and on Day 1, Week 16, and End of Study Treatment or Early Termination. On other visits, your study doctor will perform a physical exam based on symptoms you report. Your AD will be evaluated at every visit separately from the physical exam.

[2a] This test will only be done in women who can become pregnant. At screening, this will be a blood test; after that, it will be a urine test.

[2b] This test will only be done in women who are less than 60 years old and have not had their period for more than 12 months, to confirm that they are post-menopausal. Women who are post-menopausal do not need to follow contraception guidance (see below). Women who are 60 or older and haven't had their period for more than 12 months do not need to do this test to confirm that they are post-menopausal.

[3]The blood is collected to detect if you have specific antibodies or other substances to evaluate your AD.

[4]Self-Assessment of your itching will be required at approximately the same time every day at least 7 days before randomization via e-diary through the day before the Week 32 visit. The Pruritus NRS is not administered from Week 32 through the End of Study.

[5] Photographs of sites tape stripped will not be done at Week 32.

STUDY PROCEDURES AND ASSESSMENTS

Injection of TRIV-509 or placebo:
During this study, you will receive TRIV-509 or placebo as an injection. Injections will be performed at study visits only (you will not take any study drug home). The study drug is injected into the tissue just below the skin using a small needle (this is called a subcutaneous injection). Before the injection(s), study staff will clean the skin on the area where you will have the injection. The injection will be in your belly (abdomen), unless your study doctor recommends that the injection be done in your thigh or upper arm, or you request this.

Assessments of your atopic dermatitis:
At every visit including the screening visit, the study doctor will examine your atopic dermatitis to document its severity and how much of your body is covered by atopic dermatitis.

Questionnaires
During your participation in this study, you will be asked to complete different study questionnaires (on paper or electronically). This includes questionnaires about symptoms associated with your atopic dermatitis, and your quality of life.

You will fill out several questionnaires in clinic at visits. Additionally, you will fill out a daily diary (one question) using an electronic diary through Week 32.

Laboratory tests:
You will have blood and urine tests during study visits for safety monitoring, to measure the amount of study drug in your blood, and to assess markers that are associated with atopic dermatitis. A small needle will be used to get blood, usually from a vein in your arm. For urine tests, you will be asked to pee in a cup. Laboratory tests are done at all visits. Blood sampling for study drug levels (PK) will be done on certain visits; if you are receiving study drug at that visit, this sample will be collected before study drug is administered. On Day 1 and Week 12, you will also have PK samples drawn approximately 2 hours and approximately 6 hours after the study drug is administered. On Week 2, blood samples will be collected to evaluate the study drug level. On weeks 4, 8, 16, 20, 24 and 28, blood samples will be collected before the study drug will be administered. You will have to stay at the study site during this time.

Infectious disease testing:
At screening, your blood will be tested for viral hepatitis (these diseases are caused by viruses that can affect the liver), human immunodeficiency virus (HIV), and tuberculosis (TB). If any of these tests are positive, these results may need to be reported to local health authorities depending on where you live.

Pregnancy testing:
If you are able to become pregnant, you will have pregnancy testing at screening and at every study visit except Week 2. Women who are pregnant or breastfeeding cannot participate in this study. The pregnancy test will be a blood test at screening and a urine test after that. For the urine test, you will pee in a cup and your urine will be tested.

Optional collection of blood for genetic testing:
If you consent, a blood sample for optional genetic testing will be taken on Day 1. Genetic samples are blood samples used for research on genes. Genes are made of DNA and are responsible for what we look like and for how our body functions. Studying genes will help

scientists to better understand what causes a medical condition, how the body reacts to medicines and how a change in a gene can modify a medical condition. Participants who do not wish to consent to genetic testing may still participate in the study. If you don't agree to this genetic testing but later decide to do it, inform your study doctor and you will be provided a new consent; this test can be done at any time during the study.

The total volume of blood collected during the research study will be about 582 mL (a little more than 2 cups). For comparison, a single blood donation is approximately 450 mL (about 2 cups).

Medical photographs:
Medical photographs will be performed of your whole body (but will not include your face), at screening and on Day 1, Week 4, and Week 16. The photographs will consist of 8 pictures, including the front and back of your upper body from the neck down, your lower body (front and back) from the toes up, and the front and back of each arm.

Collection of skin samples with tape strips:
Surface skin cells will be collected by applying adhesive tape at the same area of the skin (tape strips) several times in a row. This procedure is noninvasive (i.e., a method that does not involve tools that break the skin or physically enter the body). The tape strips will be applied on one area with atopic dermatitis and one area with no atopic dermatitis prior to taking the study drug on Day 1, Week 16, and Week 32 (or earlier if you early terminate from the study). In addition, tape strips will be applied on the area with atopic dermatitis at Week 4. When tape stripping is performed at the visits after Day 1, it will be done in the same area with atopic dermatitis, even if your atopic dermatitis goes away in that area, and in the same area with no atopic dermatitis. If the area that is tape stripped cannot be seen in the pictures done for medical photography, a separate picture of the tape stripping site will be taken at each visit except for Week 32.

Optional collection of skin samples by biopsies:
If you consent to the collection of optional skin biopsies, a total of 5 skin biopsies will be performed throughout the study. A biopsy is a tissue sample, in this case a small skin sample, from which a lot of information can be obtained. In this study, skin biopsies of 3 mm (less than a ¼ of an inch) will be performed. The biopsy can be used to look at the skin structure under a microscope, and can also be analyzed for levels of markers that are associated with atopic dermatitis. Before the biopsy is performed, the skin will be first cleaned, then disinfected. The study doctor or another qualified person will use numbing medicine (anesthetic) to eliminate pain during the biopsy procedure which will be injected into the site of the biopsy with a needle. After the biopsy is performed, the wounds will be closed with stitches, if necessary. Additional visits may be required to remove any stitches.

On Day 1 and Week 16 (or earlier if you early terminate from the study), two skin biopsies will be performed, one from an area with atopic dermatitis and one from an area with no atopic dermatitis. In addition, one skin biopsy will be performed from the area with atopic dermatitis at Week 4. When biopsies are performed after Day 1, they will be collected from the same area with atopic dermatitis, even if your atopic dermatitis goes away in that area, and the same area with no atopic dermatitis. If the area that is biopsied cannot be seen in the pictures done for medical photography, a separate picture of the biopsy site will be taken at each biopsy visit. The skin samples may be stored for up to 15 years after the last participant's dosing. Participants who do not wish to consent to skin biopsies may still participate in the study.

Electrocardiogram:
At certain study visits, you will have an electrocardiogram (ECG). An ECG is a test that checks the electrical activity of your heart. Small sticky pads called electrodes are placed on your chest, arms, and legs, and are connected to a machine that records how your heart is working. This test takes a few minutes and does not hurt. At some visits, more than one ECG will be collected.

SPECIAL INSTRUCTIONS

Throughout the study period, these special instructions must be followed:

- You should not take any medications that could treat atopic dermatitis during the study. If you need to add or change any medication you are taking, even if it is not for atopic dermatitis, you should contact your study doctor. This includes herbal and "natural" medicines.
- You should apply an over-the-counter moisturizer (like a lotion or cream) that does not contain ingredients that could affect your atopic dermatitis. Your study doctor can give you examples of moisturizers that are allowed in the study. You should apply the moisturizer once or twice daily to your whole body from at least one week before Day 1 of the study and throughout your participation in the study. You should not change the brand of moisturizer that you are using or the number of times a day you are applying it (one or two). You can choose two different moisturizers for your face and the rest of your body, but whichever ones you choose should be the same for the whole study. On study visit days, you should not apply moisturizer until after the visit.
- For the whole duration of the study, you should avoid excessive sun exposure and should not plan a trip to a sunny climate. You should also not use tanning booths or sun lamps and should minimize your exposure to natural and artificial sunlight or other ultraviolet light sources.
- You should not have major surgery 8 weeks prior to Day 1 of the study and should not plan to have surgery during the study.

HOW LONG WILL YOU BE IN THE STUDY?

Your participation in the study may last up to approximately 57 weeks, including the screening and follow-up periods. During the study, you will come to the clinic for 14 visits, including the Screening visit. Please refer to the Study Visits section for more details on study duration and the number and frequency of the study visits. Additional visits may occur to remove the stitches (if needed) after skin biopsies, or if your study doctor asks you to return to the clinic for any other reason (for instance, to repeat a blood draw). In some cases, you may exit the study early or the study could be terminated for other reasons. If this is the case, you may not receive the study drug for the full 32 weeks, and the total duration of your participation in the study may be shorter.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Follow the instructions of the study doctor and the study staff and the special instructions listed above.
- Provide the study doctor and study staff with a complete list of all the medications (prescribed or not) you are taking. This includes herbal or "natural" remedies, vitamins, antacids and over-the-counter medications. Talk to your study doctor before changing any of your medicines or starting new medicines.

- Come to all the planned study visits. If you cannot come to a visit, contact the study staff to reschedule as soon as you know that you will miss the appointment.
- Provide truthful and complete information about your medical history and current medical condition.
- Promptly report any side effects or health problems you are having even if you don't think they are important or related to the study procedures.
- Complete participant daily eDiary as instructed and bring it to the site at each visit.
- Do not participate in another study with a treatment or a medical device while you are in this study.

If you feel that this study would take too much time or that you cannot comply with the requirements of the study, you should not agree to participate.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

While you are in the study, you may have side effects from the study drug. During the study, if you have any change in your health, you should contact the study doctor as soon as possible.

You may experience an injection site reaction (redness, pain, swelling or itching at the injection site). These types of reactions are usually mild and go away on their own in a few hours or days. If you have discomfort, you can use a cool compress, or you can ask your study doctor for medicines that might help, like acetaminophen (do not take any medications without talking to your study doctor first).

As with any medication, there may be a risk of allergic reactions. Symptoms of an allergic reaction include 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. Please seek immediate medical assistance if you experience the symptoms of severe allergic reaction. Then, contact the study doctor at the numbers given on the first page.

RISKS OF OPTIONAL SKIN BIOPSIES

- The local anesthetic injected before skin incision and biopsies may induce a brief burning sensation. While rare, you could have an allergic reaction to the anesthetic. Symptoms of an allergic reaction include hives or swelling of the face, lips, tongue, or throat, which may cause difficulty in breathing or swallowing. This could become life-threatening if not treated promptly. Please advise the study doctor if you have had a previous reaction to any local anesthetics.
- Serious side effects from a skin biopsy are rare.
- If you feel pain, please tell the study doctor so he or she can inject more anesthetic to make the procedure painless. The biopsy area might feel uncomfortable after the skin sample is taken.
- A small scar (approximately 3-mm about the size of a pencil eraser) will form once the area has healed. Occasionally, some people who do not heal well may have a thick and itchy scar that is larger than the skin biopsy site (this is called hypertrophic scar or keloid). Please let the study doctor know if you have ever developed a bad scar after a skin cut or after surgery.

- There is also a small chance that the biopsy site may become infected, which could result in pain, redness, or swelling of the area. If you think your biopsy site may be infected, please contact your study doctor.
- There is also a small chance that a superficial nerve (a nerve that is responsible for the sense of touch) might be cut during the procedure. If this happens, the skin around the biopsy site may become insensitive to touch or pain.
- Discomfort or pain is sometimes present for a few weeks after a skin biopsy. Your study doctor will give you guidance on what to do if you have discomfort. If you feel like you need to take a medicine to treat the discomfort associated with this procedure, please contact your study doctor first.

RISKS OF OTHER STUDY PROCEDURES

- Subcutaneous injection of study drug: This procedure can cause pain or swelling. In rare instances, the needle could hit a nerve, which could cause numbness at the site, or you could develop a scar or lump at the site that doesn't go away. You could develop a skin infection at the site of the needle stick; study staff will clean the site before the injection to decrease this risk. Sometimes, people have dizziness or fainting associated with needles; if you have experienced this in the past, please let the study staff know.
- Blood samples: Possible side effects from blood drawing include temporary discomfort from the needle in your arm, feeling like you might faint or fainting, inflammation of the vein, or pain, bruising, swelling, or bleeding at the site of puncture. In rare instances, you could develop a skin infection at the site of the needle stick; study staff will clean the site before inserting the needle to decrease this risk.
- Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used.
- Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.
- Tape stripping: This procedure is noninvasive and painless. You might have redness, mild skin irritation and itching at the site of tape stripping; this irritation usually lasts only a few hours.

If you are taking medicines for atopic dermatitis, you will be asked to stop taking these medicines during the screening period (washout period). During this time, your symptoms may not improve or may get worse. If your symptoms get worse, tell the study doctor immediately.

UNFORESEEN RISKS

Since the study drug is investigational, there may be other risks that are unknown.

One of the reasons for doing this study is to see how safe TRIV-509 is to be used in people. If any new information about this study becomes available that might affect your decision to continue your participation, you will be informed as soon as possible. At every visit, your study doctor and study staff will ask you about any side effects you may have experienced. If you have any problems, you should let your study doctor know right away.

Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

Similarly, it is unknown whether TRIV-509 is found in the semen of men. It is possible that TRIV-509 in the semen may cause birth defects to an unborn child of your partner.

BIRTH CONTROL RESTRICTIONS

Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study. During this study, you also cannot retrieve or donate eggs (ova) or sperm.

Women Only:

If you are a woman who can become pregnant, you will have a blood pregnancy test before you can be in this study, and you will have urine pregnancy tests during the study.

If you are 60 or older and have not had your period for 12 months, you do not need to have pregnancy tests, and you will not need to use contraception during this study. If you are younger than 60 and have not had your period for 12 months, you will have a special blood test called a Follicle Stimulating Hormone (FSH) test at screening; if the FSH test shows that you are post-menopausal, you will not need to use contraception during this study, but if the FSH test doesn't show that you are postmenopausal, you will need to use contraception.

If you have had any of the following procedures, you do not need to use contraception:

- Surgical removal of your uterus,
- Surgical removal of both ovaries,
- Surgical removal of your Fallopian tubes.

If none of the cases above apply to you, you must agree to avoid getting pregnant for the duration of the study in order to take part in the study and use contraception. You should use a method of birth control listed below that is acceptable to you from 4 weeks before Day 1 and until the end of your participation in the study or at least 24 weeks after the last dose of study drug, whichever is longer. Acceptable methods of birth control for use in this study are listed below. The study doctor or study staff will discuss this with you:

- Intrauterine Devices or systems (IUD or IUS),
- Tubal occlusion (blocking of the Fallopian tubes)
- Vasectomized partner or partner who does not produce sperm for a medical reason,
- Combined (estrogen and progestogen) oral, intravaginal, transdermal (patch), or injectable that blocks ovulation
- Oral or injectable progestogen-only hormonal contraception that blocks ovulation

You can practice abstinence if it is your preferred and usual lifestyle, but you must agree to use one of the contraception methods above if you start engaging in sexual activity that could lead to pregnancy during the study. Periodic abstinence (when you are only abstinent certain times of the month) is not allowed in this study.

You must agree to avoid ova (egg) retrieval or donation during the study or for 24 weeks after the last dose of study drug, whichever is longer.

If you become pregnant while you are participating in this study or within 24 weeks after the last dose of study drug, tell the study doctor or study staff immediately. You will not receive any more injections and your participation in this study will be ended. The study doctor may ask your permission to follow your pregnancy after participating in this study.

Men Only:

If you have a partner who can get pregnant, you must use a condom AND a method of birth control listed above that is acceptable to your partner from 4 weeks before Day 1 and until the end of your participation in the study or at least 24 weeks after the last study drug administration, whichever is longer. The acceptable birth control methods are the same as mentioned in the section for women above. The study doctor or study staff will discuss this with you.

You must also refrain from donating sperm or fathering a child from Day 1 until at least 24 weeks after the last study drug administration.

If your female partner becomes pregnant while you are participating in this study tell your study doctor or study staff immediately. The study doctor may ask your partner's permission to follow the pregnancy after participation in this study.

MEDICAL PHOTOGRAPHS

The study procedures include taking full body photographs (not including your face).If you agree to take part in this study and sign and date this informed consent., photographs will be taken of your full body (front and back) at 4 visits (Screening, Day 1, Week 4 and Week 16).

The purpose of this skin photography is to document how your skin is reacting to treatment during the course of the study.

In addition, these photos may be used in external marketing and/or scientific educational materials such as scientific journals or in other media, for reproduction or distribution in scientific reports of the study results, for scientific presentations at scientific or medical meetings. Your confidentiality will be maintained to the extent permitted by regulations. Every effort will be made to ensure your identity will be kept confidential. Your name will not be used; you will only be identified by a special number.

Photographs will be taken by the study doctor/study staff/trained medical photographer in a suitable environment. 8 body photographs (front and back of the torso, upper limbs and lower limbs) will be taken. The goal is to have as much data visible in the images as possible which will require disrobing to a certain degree and wearing a disposable thong. If the location of tape stripping is not visible in these photographs, separate photographs of the tape stripped sites will be taken. If you have consented to biopsies and the biopsy location is not visible in these photographs, separate photographs of the biopsy sites will be taken.

Your name will not be present on any of the photography data; your photographs will only be labeled with your participant identification number. Your photographs will be viewed by individuals such as your study doctor, study staff, the study Sponsor Triveni Bio, Inc / clinical research organization (CRO) Indero, and Sponsor/CRO authorized representatives. The photographs taken may include identifiable features such as birth marks, piercings, jewelry or

tattoos that will be electronically veiled by a third-party photography vendor so that the photographs cannot be used to identify you.

ELECTRONIC DIARY (eDIARY)

As part of this study, you will use an electronic diary (eDiary) to complete a questionnaire. This process, called "electronic participant-reported outcome," helps collect valuable data on your health and quality of life.

The eDiary app, **MyVeeva for Patients**, can be accessed via a smartphone app or a web browser on a mobile device, computer, or laptop. If you don't have a compatible smartphone, a pre-configured device will be provided at no cost, solely for study use.

The eDiary app is provided by a software company called Veeva. Setting up your **MyVeeva for Patients** account requires your name and year of birth. You may also use your email and/or phone number for notifications. Only authorized study staff can access your personal information—**the Sponsor cannot view or export this data**, so your personal identifying information will not be associated with your responses**.**

You will receive prompts to complete a specific questionnaire daily until Week 32. This questionnaire consists of one question and should take a few seconds to complete. Your responses will be stored in the study database and reviewed by the study doctor, staff and the Sponsor.

Study staff will provide training on how to use the eDiary, and support will be available throughout the study. For any issues, contact your study doctor.

By consenting, you agree to use the eDiary for this study. Please review the **MyVeeva for Patients Privacy Notice** for details on data processing. For questions, contact your study doctor.

ADDITIONAL QUESTIONS?

You should talk with the study doctor or study staff if you have any questions.

FUTURE RESEARCH OF BLOOD SAMPLES

After they have been analyzed, your blood samples will be stored by Triveni Bio or a bioanalytical facility in a secure storage space and may be used for future research by Triveni Bio. The storage space has adequate measures to protect your confidentiality. Information sent from the study site will contain a barcode, but it won't contain your name.

No genetic testing will be done on your samples except one-time testing if you consented to it. These samples may be used for possible future analyses by Triveni Bio to better understand the effects of TRIV-509. Samples will be stored for up to, but no longer than, 15 years from the end of the main study. Triveni Bio will not use your samples or data generated from those samples for any purpose other than what is described in this informed consent form. Your samples and the accompanying data will only be used by researchers at Triveni Bio or people, universities, or companies that Triveni Bio works with. Your samples will not be sold to other people or companies. Your samples may be used when developing new tests, procedures and commercial products. If this happens, you will be asked to consent to it. Triveni Bio does not plan to share any profits with you.

If you change your mind about participating in the study, no further samples will be collected from you. In addition, you may request that any samples already collected from you that are still at the study center and can be identified be destroyed. However, the Sponsor may retain and use both any study data derived from samples already taken from you and any samples that have already been sent to the Sponsor by the study center to maintain the quality of the study and for future scientific research by the Sponsor.

OPTIONAL GENETIC SAMPLING

Participation is optional. If you do not wish to participate, you may still participate in the study. If you agree to participate in this optional genetic research part of the study, study staff will draw about (2.5 mL = 1/2 tsp) of blood from your arm at the Day 1 visit.

The blood will be collected at the same time as other blood samples being collected in the main study. The study staff will put the blood sample into vials that are labeled only with the protocol number and your participant identifier. Your name will not be on any of these blood samples. These blood samples may be stored for up to 10 years, or other period as per local requirements.

POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY

You should not expect any benefit from taking part in this study. Your condition may get better, stay the same, or get worse. The information from this study may help the understanding of the safety of TRIV-509 and its potential effectiveness in participants with atopic dermatitis. This may contribute to the advancement of knowledge in the field of dermatology. Your participation in this research may not benefit you but may benefit future patients with your disease or condition.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

You do not have to participate in this study to be treated for your atopic dermatitis. Alternatives to participating in this study for the treatment of your atopic dermatitis include cortisone-containing creams and ointments (such as desonide, hydrocortisone, mometasone, betamethasone, fluticasone and desoximetasone), medicated creams and ointments without cortisone (tacrolimus, pimecrolimus, crisaborole, ruxolitinib), and oral systemic medication (such as cortisone tablets, methotrexate, cyclosporine, and Janus Kinase (JAK inhibitors)). There are also other injectable medications that have been approved for the treatment of atopic dermatitis (dupilumab, tralokinumab, lebrikizumab).

All alternative treatments have advantages and side effects. Advantages for corticosteroid creams include easy application and effective reduction of inflammation; risks include skin thinning, easy bruising or tearing. Non-corticosteroid creams may cause burning sensations and itchiness. Advantages of systemic medications include reduction of skin inflammation and improvement of atopic dermatitis. Cortisone pills may increase the risk of developing infections, diabetes, hypertension and osteoporosis. Methotrexate can cause anemia, nausea, loss of appetite, liver damage, tiredness and hair loss. Cyclosporine can lead to kidney damage. For JAK inhibitors, the most common side effects are upper respiratory tract infection, headache, and acne, but they can also be associated with serious side effects such as blood clots, cancer and serious infections. The most frequent risks of dupilumab include skin reactions at the site of injection, inflammation and itchiness of the eyes and eyelids, and cold sore reactivations. Moisturizers are safe and well-tolerated but are less effective than medications. Other injectable medications can also cause side effects, including injection site reaction. Tralokinumab may

also cause burning, dry or itchy eyes, body pain, swelling of the eye, and headaches. Lebrikizumab may also cause skin infection, pink eye, cold sores and fatigue.

Your study doctor will review treatment options that are appropriate for you and their important potential risks and benefits. You can decide with your study doctor if this study is appropriate for you or if another drug or treatment would be better.

This study is for research purposes only. The only alternative is to not participate in this study.

CONFIDENTIALITY:

Your identity will be kept confidential at all times in accordance with applicable law. Except as required by law and except as otherwise stated in this informed consent form, you will not be identified on any study form by name, social security number, address and telephone number or any other direct personal identifier. Instead, you will be assigned a participant identification number (code). The study doctor will keep a list that matches participant identification numbers to participant names, but the study doctor will not share that list with the sponsor. However, the study forms will contain other information about you, such as your age, sex and medical history so it is possible that this other information could be used to identify you even though your name does not appear.

Medical information collected during this study and the results of any tests or procedures that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company. The results of this study may be presented at scientific or medical meetings or published in scientific journals. In this case, your identity will not be made known.

Other groups may need to look at your medical records and study forms to make sure that the information is correct and to evaluate the conduct of this study. These include the following:

- The sponsor of this study, Triveni Bio, and its designees, including any contract research organization helping the sponsor with the study.
- The Advarra Institutional Review Board.
- Regulatory agencies in the United States, such as the Food and Drug Administration, Department of Health and Human Services and the Office for Human Research Protections, and regulatory agencies in countries outside the United States where the sponsor seeks approval of the study drug or where this study is or may be conducted.

The data collected from you and from testing the biological samples collected from you will be used by the sponsor to carry out the study, to develop the study drug, to meet its legal obligations in connection with the conduct of the study and to make publications and presentations about the study. In addition, the sponsor and parties working with or on behalf of the sponsor may use the data collected from you and from testing the biological samples collected from you to perform additional unknown future research. Although the exact nature of the research that may be performed is not known at this time, such research will be in connection with patient care and public health, including the development of new drugs and treatments for diseases. The sponsor will limit and monitor access to the data collected from you and from testing the biological samples collected from you and put restrictions in place so efforts are not made to identify you and to ensure that the data collected from you and from testing the biological samples collected from you are only used for the purposes described in

this informed consent form. For certain reasons, you may have a right to oppose the use of the data collected from you or from testing the biological samples collected from you for additional future unknown research. If you wish to object to such use, please contact your study doctor.

The study doctor is required by law to protect your health information. By signing this document, you authorize the study doctor to use and disclose your health information, in order to conduct this study.

A federal law, called the Genetic Information Nondiscrimination Act, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor obtains from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor obtains from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law as of May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

You do not have to sign this consent form, but if you do not, you will not be able to take part in this study.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy. There is a possible risk of loss of privacy with use of the diary app

By signing this consent form, you consent to the collection, access, use, and disclosure of your information as described above.

WHO IS ORGANIZING AND FUNDING THE STUDY?

This study is being sponsored by Triveni Bio. and is under the direction of the study doctor and the study staff. The sponsor is paying your study doctor for his or her time, effort, and expenses to conduct this study.

WHAT ARE YOUR LEGAL RIGHTS?

You do not lose any legal rights by signing this consent form. Your signing does not release the study doctor or sponsor from their legal and professional obligations.

COMPENSATION FOR INJURY

If you are injured during this study, medical treatment will be available. Your study doctor will discuss with you the available medical treatment options.

If you are injured as a direct result of taking the study drug(s) or of having procedures for the purpose of this study that you would not have received as part of the routine medical care for your disease, the Sponsor will reimburse you for your medical expenses for acute and/or emergency care to treat your injury that are not covered by your commercial medical insurance or any other non-government third party coverage. The Sponsor and your study doctor will work together to determine if your injury qualifies for reimbursement. The Sponsor will only reimburse you for these injuries if you have followed the instructions of your study doctor. You will not receive reimbursement for any injuries that are a result of the natural course of your underlying disease or any pre-existing condition. There are no plans to provide other compensation, including for such things as lost wages, disability, or discomfort.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

The Sponsor has no plans to offer you any other payments or other type of compensation.

This will not imply any admission of negligence of the study doctor or the sponsor. By signing this consent form, you are not giving up your legal rights, including your right to claim compensation for injury where you can prove negligence.

COMPENSATION

All study tests, examinations, and medical care required as part of this study are provided at no cost to you or your private medical insurance (if any).

If you meet all requirements and are enrolled in the study until the final follow-up visit, financial compensation of up to $1980 will be given to you for your time and expenses incurred (travelling, parking, etc.).

If you leave the study before the end, you will receive an amount of $100 for each planned study visit attended. On Day 1 and Week 12, you will receive an additional $50 as multiple blood samples will be taken. On Day 1 and Week 12, you will receive an additional $140 as you will need to remain at the clinic for 8 hours. At the Screening visit, and on Day 1, Week 4, and Week 16, you will receive an additional $50 for the medical photographs that will be taken of your lesions. The compensation will be prorated to the number of study visits you completed and the activities you completed on each study visit.

If you agree to have skin biopsies, you will receive an additional $100.

You will only receive compensation for the visits and study periods you do complete according to the following schedule:

Visit Type	***Rate***
Screening	*$150*
Day 1	*$340*
Week 2	*$100*
Week 4	*$150*
Week 8	*$100*
Week 12	*$290*
Week 16	*$150*

Visit Type	***Rate***
Week 20	*$100*
Week 24	*$100*
Week 28	*$100*
Week 32	*$100*
Week 36	*$100*
Week 44	*$100*
Week 52	*$100*
Total	*$1980*

If you are asked, by the study staff, to come back to the clinic for an unplanned visit, you may receive an additional $100 depending on the procedures performed during the visit.

You will be paid following each completed visit.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this informed consent form document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact the IRB:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00087490.

Although Advarra IRB has reviewed the information provided in this informed consent form and has reviewed the study doctor to conduct the study this does not mean Advarra IRB has

approved your participation in the study. You must evaluate the information in this informed consent form for yourself and decide whether or not you wish to participate.

Do not sign this information and consent form unless you have had a chance to think about it and ask questions, and unless you have received satisfactory answers to all of your questions.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study, at any time, for any reason, without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. If you decide to withdraw from the study, please talk to your study doctor to make sure this is done safely.

Please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the Sponsor can stop your participation without your consent for any reason. For example, your participation may be stopped:

- If it appears to be medically harmful to you;
- If you fail to follow instructions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

CONSENT

By signing this informed consent form, I acknowledge the following:

- ✓ I have read all pages of this informed consent form, and understand the information in this informed consent form document.
- ✓ I had a chance to ask questions, and all of my questions were answered to my satisfaction.
- ✓ I voluntarily agree to participate in this study until I decide otherwise.
- ✓ I give my permission to the study doctor to use and disclose my protected health information as described in this informed consent form.
- ✓ I do not give up any of my legal rights by signing this informed consent form document.
- ✓ I will receive a signed copy of this informed consent form.
- ✓ If a positive result for tuberculosis, HIV, hepatitis B, or hepatitis C is found, my study doctor may inform the local public health authorities, as required by law.
- ✓ If applicable, I will inform my female partner that I am in a research study and will ensure that we use acceptable contraception.

The study doctor has my permission to tell my family doctor about my being in this study:

Yes ☐ No ☐ I do not have a family doctor ☐ Initials: _____

I agree to have skin biopsies performed and have medical photographs taken of the biopsy sites on Day 1, Week 4, Week 16:

Yes ☐ No ☐ Initials: _____

I agree to have blood samples collected for genetic testing on Day 1:

Yes ☐ No ☐ Initials: _____

I agree to allow remaining mandatory samples to be used for optional exploratory research by the Sponsor:

Yes ☐ No ☐ Initials: _____

I agree to allow any remaining specimens to be used for exploratory research by the Sponsor:

Yes ☐ No ☐ Initials: _____

Date (dd-mmm-yyyy)	Printed Name of Participant	Signature of Participant
Date (dd-mmm-yyyy)	Printed Name of Person Conducting the Consent	Signature of Person Conducting the Consent

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ

The study participant has indicated that he/she is unable to read. This consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

Date (dd-mmm-yyyy)	Printed Name of Impartial Witness	Signature of Impartial Witness

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

What information may be used and shared?

The study doctor and study staff will use and share your health information as part of this research study. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

Examples of the information that may be used are:

- Medical records (from any doctor, hospital or other healthcare provider)
- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests

Who will receive information about you?

The study doctor and study staff will share your protected health information with:

- The Sponsor, including persons or companies working for or with the Sponsor
- The Institutional Review Board (IRB)
- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Other regulatory agencies
- Home healthcare support

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

The Sponsor and the groups above will use your health information:

- To complete this research
- To evaluate the results of the study
- To check that the study is being done properly

- To obtain marketing approval for new products resulting from this research

Is my health information protected after it has been given to others?
Your health information may be further shared by the groups above. If shared by them, the information may no longer be covered by federal privacy law. These groups are committed to keeping your health information confidential.

What if I decide not to allow the use of my health information?
You do not have to sign and date this form. If you do not sign and date this form, you cannot take part in this research study.

May I withdraw or revoke (cancel) my permission?
YES. You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor at the address listed on the first page of this form. If you withdraw your permission, you will not be able to continue being in the research study.

What happens if I want to withdraw my authorization?
Information that has already been gathered may still be used and given to others. If you withdraw your Authorization, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends, but no new study related treatment or procedures will be performed.

Will my authorization expire?
This Authorization will expire December 31, 2070, unless you withdraw it in writing before then.

May I review or copy the information obtained or created about me?
YES. You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

By signing and dating this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

Date (dd-mmm-yyyy)	Printed Name of Participant	Signature of Participant

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ

The study participant has indicated that he/she is unable to read. This Authorization document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

Date (dd-mmm-yyyy)	Printed Name of Impartial Witness	Signature of Impartial Witness