[INSTITUTION NAME]

PARTICIPANT INFORMATION AND INFORMED CONSENT FORM / ASSENT FORM

For Participants Ages 12 and Older, and Parents/Legal Guardians of Participants Age 17 and Younger

Protocol Title:	**L**ongitudinal **E**ndotyping of **A**topic **D**ermatitis through Transcriptomic **S**kin Analysis
Protocol Abbreviation:	LEADS
Protocol Number:	ADRN-12
Sponsor:	National Institutes of Health (NIH)/ Division of Allergy, Immunology, and Transplantation (DAIT)/ National Institute of Allergy and Infectious Diseases (NIAID)
Principal Investigator:	[Insert Principal Investigator Name]
Institution:	[Insert Institution Name]
Address:	[Insert Institution Address]
Telephone:	[Insert Study Site Team Telephone #]

INSTRUCTIONS:

Participants who are 18 years old or older will use this form to provide consent. Legal guardians of participants who are under 18 years old will use this form to provide consent. Participants who are under 18 years old (that is, ages 12 through 17) will use this form to provide assent.

In this form, the word "consent" also means assent (of minors) and permission (of parent/guardian).

In this form, the words "you" and "your" are referring to the participant who will be enrolled in this study. Parents and/or legal guardians of participants under 18 years old, keep in mind that this is not referring to you; instead, this means your child.

KEY INFORMATION ABOUT THIS RESEARCH STUDY:

The first pages of this document include a summary of key information to help you decide if you would like to participate in this research study. Detailed information is provided after this key information.

Why is this research being done?

Almost every cell in your body, including the cells that make up your skin, contains DNA (deoxyribonucleic acid). The DNA in your skin cells can be thought of as the instructions, or genetic code, that determine certain features of your skin. For example, DNA determines your skin color, skin thickness, and whether you have dry or oily skin.

The cells in your body also contain fats, called lipids, and proteins. Lipids and proteins in the body can provide energy, create shape or structure, and even fight disease.

It is possible to study DNA, lipids, and proteins in peoples' cells to try to find patterns. Scientists who do this work may try to answer questions like, "does everyone with dry skin have similar DNA in their cells?" or "do people with a specific type of protein in their skin cells all have severe itchy and red skin?"

In this research study, we are trying to learn more about certain characteristics of the skin – including the DNA, lipids, and proteins present in the skin cells. We want to learn how those elements of the skin relate to atopic dermatitis (AD), which is a type of eczema.

AD symptoms can be easy or hard to deal with, depending on the person. People with AD can experience different levels of itching, numbers of skin infections, amount of time with itchy skin, and responses to medications. Some people with AD start to have symptoms when they are very young, and others do not have symptoms until they are older. Some people with AD have other related conditions, like food allergy or asthma. Because of these differences in how AD affects different people, the researchers conducting this study think there may be differences in the DNA, lipids, and proteins in peoples' skin cells that relate to AD.

We want to specifically learn how characteristics of the skin relate to the severity of a person's AD symptoms. We also want to learn how characteristics of the skin related to the way a person responds to treatments for AD. We want to try to identify specific groups of people who have similar lipids, proteins, or sections in their DNA. We want to try to find patterns within these groups that tell us more about AD severity and treatment response. In the future, it may be possible to better predict which medications will work well for a specific person based on this information.

Why am I being asked to participate?

We are asking you to participate in this research study because you fall into one of the following three categories. You either:

1. Have no history of AD;
2. Have a history of chronic AD that has been present for at least 1 year and have not received a drug called dupilumab, also known as Dupixent; or
3. Have a history of chronic AD that has been present for at least 1 year and you have been receiving dupilumab, also known as Dupixent, for the past 4 months.

To make things easier, we call people in these groups:

4. Non-AD,
5. Dupilumab-Naïve, or
6. Long-Term Dupilumab

People in all three of these groups are important to the goals of this research study.

What treatment may be involved?

If you have no history of AD (non-AD), you will be asked to use Vanicream™ Moisturizing Cream twice daily for about 1 week at the beginning of the study and about 4 weeks at the end of the study.

If you have had AD for at least a year and have never used dupilumab (dupilumab-naïve), you will be asked to use Vanicream™ Moisturizing Cream twice daily for about 1 week at the beginning of the study. Then, you will be asked to use topical steroids (Triamcinolone 0.1% ointment and Hydrocortisone 2.5% ointment) twice daily for about 4 weeks. Depending on how your AD reacts to using these topical steroids you will either:

- Continue to use topical steroids once or twice daily for about 15 more weeks, or
- Begin using dupilumab (DUPIXENT®) every two or four weeks (depending on your age and weight) for about 15 weeks.

Finally, you will be asked to use Vanicream™ Moisturizing Cream twice daily for about 4 weeks at the end of the study.

If you have had AD for at least a year and have been using dupilumab for the past 4 months (long-term dupilumab), you will be asked to use Vanicream™ Moisturizing Cream twice daily for about 1 week at the beginning of the study and about 4 weeks at the end of the study. You will continue your dupilumab from your non-study doctor as prescribed.

No participants will receive experimental drugs or undergo experimental procedures as a part of this study. All medications used within the study will have been approved by the United States Food and Drug Administration (FDA) already.

How long will the research last?

We expect that non-AD participants' time in the study will take about 175 days (6 months). It will include 7 scheduled study visits.

We expect that dupilumab-naïve participants' time in the study will take between 175 days (6 months) and 231 days (8 months). This time will depend on whether your AD gets better, worse, or stays the same when using topical steroids. All dupilumab naïve-participants will have at least 4 scheduled study visits, but some will have 4 more scheduled study visits while others may have up to 6 more scheduled study visits for a total of 10 scheduled study visits.

We expect that long-term dupilumab participants' time in the study will take about 175 days (6 months). It will include 6 scheduled study visits.

What activities may be done as a part of this research?

The main procedures that may be completed during this study are listed below. The study doctor will explain which procedures are being done for research, and which would be done as part of your standard care even if you do not participate. The detailed consent following this section will clarify which procedures apply to your group.

- Questionnaires – including questions about your demographics (e.g., sex at birth, race), your medical history, the medications you take, and the severity of your atopic dermatitis
- Physical Exams – general and targeted exams, including to assess your skin condition if you have AD
- Collection of Vital Signs, Height, and Weight
- Urine Pregnancy Testing – only if you can become pregnant.
- Blood Sample Collection – including a sample for genetic testing
- Skin Sample Collection: Skin Tape Strips, Skin Swabs, Skin Biopsies
- Distribution and Administration of Treatment – possibly including Vanicream™, topical steroids, and dupilumab depending on your group

Is there any way being in this research can hurt me?

Taking part in this research may have risks (side effects). There are risks from study procedures and from study treatments. Side effects may range from being mild to life-threatening and may go away with treatment or be permanent. Some key risks are listed below:

- Blood Collection: pain, bleeding, bruising, lightheadedness, nausea, fainting
- Dupilumab: Injection site reactions, eye problems (irritation, vision changes), joint pain
- Skin Biopsies: pain, swelling, bleeding, infection, scarring
- Skin Tape Strips: redness, irritation
- Topical Steroids: Burning, itching, irritation, dryness

The study staff will help protect the privacy of your personal health information and study information. We cannot promise complete confidentiality.

Are there any costs to participating in this research?

The study sponsor will provide the following products to you for free if they are required to be used as a part of your participation in this study:

- Vanicream™ Moisturizing Cream
- Hydrocortisone 2.5% ointment
- Triamcinolone 0.1% ointment
- Dupilumab (DUPIXENT®)

You will not need to pay for any of these products. You will also not need to pay for any required study procedures. You will be paid back for your time spent on the study, including some travel costs.

You will still have to pay for any other costs related to your medical care. For example, you would need to pay for any non-study doctor visits, as well as any trips to the emergency room,

urgent care, or hospital, during the study. Additionally, for example, if you have AD and your symptoms flare up badly enough that you need topical steroids (or other medications) outside of the scheduled study treatment plan, you would need to pay for those medications. If you have insurance, you may be able to submit these costs to your insurer.

Is there any way being in this research can help me?

We cannot promise that you will benefit directly from the treatments provided in this study. However, information gathered during this study may help people with atopic dermatitis in the future.

What if I do not want to participate?

It is always your decision whether you would like to participate in this study. You may decide to be in the study now, but change your mind later. You can leave the study at any time.

There may be other options for treatment of your atopic dermatitis, like creating a treatment plan with your primary care provider or a dermatologist. You do not have to participate in this study in order to receive treatment at [Insert Institution Name]. Your participation in this research is entirely voluntary.

This overview does not include everything you need to know before deciding whether to take part. More details are given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

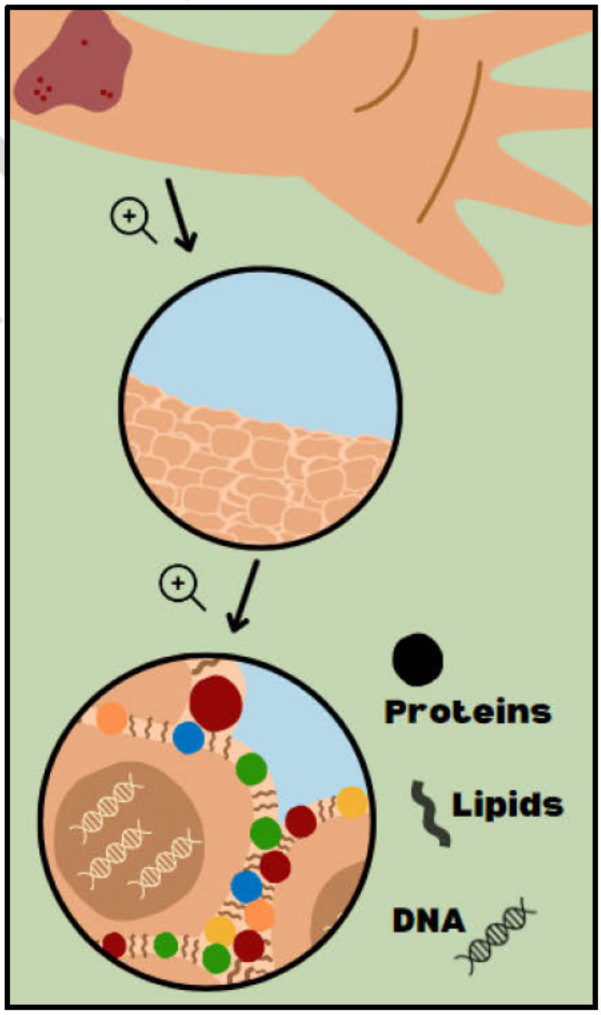
This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends, and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

The National Institute of Allergy and Infectious Diseases (NIAID) is funding this study. NIAID has given additional money to the Atopic Dermatitis Research Network (ADRN) leadership center, National Jewish Health, to organize this research. National Jewish Health has provided some of that money to [Insert Institution Name] to conduct this research study here.

PURPOSE OF THIS STUDY

Almost every cell in your body, including the cells that make up your skin, contains DNA (deoxyribonucleic acid). The DNA in your skin cells can be thought of as the instructions, or genetic code, that determine certain features of your skin. For example, DNA determines your skin color, skin thickness, and whether you have dry or oily skin.



The cells in your body also contain fats, called lipids, and proteins. Lipids and proteins in the body can provide energy, create shape or structure, and even fight disease.

It is possible to study DNA, lipids, and proteins in peoples' cells to try to find patterns. Scientists who do this work may try to answer questions like, "does everyone with dry skin have similar DNA in their cells?" or "do people with a specific type of protein in their skin cells all have severe itchy and red skin?"

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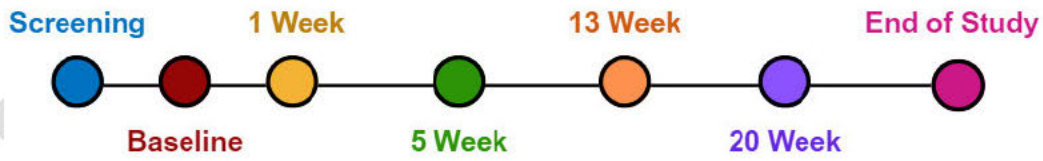
AD symptoms can be easy or hard to deal with, depending on the person. People with AD can experience different levels of itching, numbers of skin infections, amount of time with itchy skin, and responses to medications. Some people with AD start to have symptoms when they are very young, and others do not have symptoms until they are older. Some people with AD have other related conditions, like food allergy or asthma. Because of these differences in how AD affects different people, the researchers conducting this study think there may be differences in the DNA, lipids, and proteins in peoples' skin cells that relate to AD.

We want to specifically learn how characteristics of the skin relate to the severity of a person's AD symptoms. We also want to learn how characteristics of the skin relate to the way a person responds to treatments for AD. We want to try to identify specific groups of people who have similar lipids, proteins, or sections in their DNA. We want to try to find patterns within these groups that tell us more about AD severity and treatment response. In the future, it may be possible to better predict which medications will work well for a specific person based on this information.

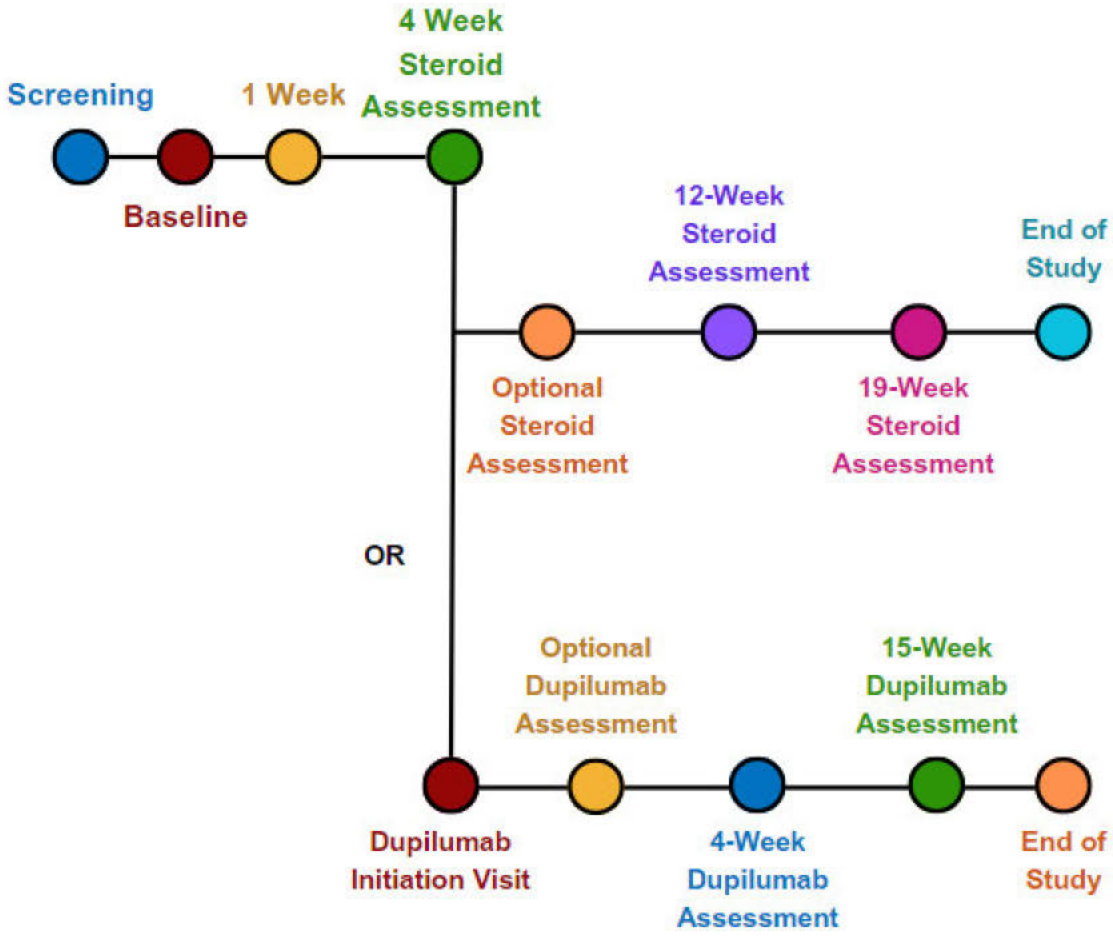
NUMBER OF PARTICIPANTS AND LENGTH OF STUDY PARTICIPATION

We expect about 600 people to join this study. These participants will be seen at several research sites across the United States. The participants who are eligible to join the study will all fall into one of three groups.

1. Participants who have no history of AD are known as "non-AD" participants. We expect about 150 non-AD participants to join this study. We expect that non-AD participants' time in the study will take about 175 days (6 months). It will include 7 scheduled study visits, shown below.



2. Participants who have a history of chronic AD that has been present for at least 1 year and have not received a drug called dupilumab (also known as Dupixent) are known as "dupilumab-naïve" participants. We expect about 390 dupilumab-naïve participants to join this study. We expect that dupilumab-naïve participants' time in the study will take between 175 days (6 months) and 231 days (8 months). This time will depend on whether your AD gets better, worse, or stays the same when using topical steroids. A diagram showing the possible visits that dupilumab-naïve participants might have is shown below.

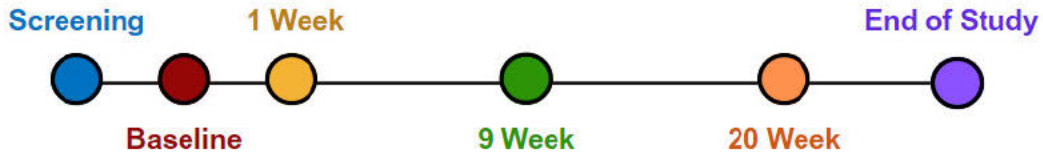


Note: Crossing over from the path for participants who respond well to topical steroids to the path for participants who do not is permissible any time before or during the 12-Week Steroid Assessment.

All dupilumab naïve-participants will start with 4 scheduled study visits. Participants who respond well to topical steroids will keep using them and have 4 more scheduled study visits. Participants who do not respond well to topical steroids will begin using dupilumab before having 4 more scheduled study visits for a total of up to 9 scheduled visits. Participants who respond well to topical steroids at first, but stop responding before their 12-Week Steroid Assessment may switch to using dupilumab. In that case, a participant could have up to 10 scheduled visits.

3. Participants who have a history of chronic AD that has been present for at least 1 year and have been receiving dupilumab (also known as Dupixent) for the past 4 months are known as “long-term dupilumab” participants. We expect about 60 long-term dupilumab participants to join this study. We expect that long-term dupilumab participants’ time in

the study will take about 175 days (6 months). It will include 6 scheduled study visits, shown below.



People in all three of these groups are important to the goals of this research study.

Regardless of which group you are in, you will be required to comply with [Institution Name]'s current policies and procedures for COVID-19. These requirements will be communicated to you at the time of visit scheduling and prior to any scheduled appointments.

STUDY PROCEDURES

If you would like to participate in this study, you will be asked to complete the following activities at the following visits.

Visits For All Participants

Screening Visit

This visit applies to all three groups: non-AD, dupilumab-naïve, and long-term dupilumab.

You will be asked to come to the clinic so that we can figure out whether you are able to join this study.

First, we will review this consent document with you to make sure that you understand this study. We will explain the planned activities to you. We will give you time to read this document on your own. We will give you time to ask questions. Once all your questions are answered, and if you decide that you would like to participate, you will sign this consent form. The conversation usually takes about 20 minutes, but we can take as long as is needed to answer your questions and discuss in detail.

This process can happen before the Screening Visit over the phone, by secure video call, or in-person. If you get this document before your Screening Visit, please read the entire thing. Please let us know if there is anything that you do not understand or would like to hear more about. Do not sign or put a date on the document until we contact you to discuss the document. We will tell you how to sign and date when we speak by phone, video call, or in-person. You may be able to sign electronically online, or you may need to sign with a pen and mail the document to us or bring it with you to your first visit.

Once this consent document is signed, the other activities of the Screening Visit can begin. This visit will take about 2 hours and include the following activities:

Visits For All Participants

- Confirmation of Pregnancy Status: For people who could become pregnant, we will ask you to tell us if you think you may be pregnant. If you are pregnant now or become pregnant, you will no longer be eligible to participate in this study. If there is any way that you could become pregnant, you must agree to use FDA-approved methods of birth control for the duration of the study. The FDA-approved methods include:
    - Hormonal contraceptives, like birth control pills, patches, or rings
    - An intrauterine device or "IUD"
    - A contraceptive implant or "rod" (e.g., Nexplanon)
    - Contraceptive injections (e.g., Depo-Provera shots)
    - Use of barrier methods like condoms or diaphragms with spermicide
    - Permanent sterilization of a monogamous partner (e.g., vasectomy)
- Questionnaires: We will ask you to provide contact information that we may use for future study communications. We will ask you questions about your sex at birth, race, and ethnicity. We will ask you about the medications you are taking and your medical history. If you are taking certain medications or have certain medical conditions, you might not be able to participate or may need to wait to participate in this study. These questions are not tests. There are no right or wrong answers. If you do not understand certain questions, you can ask us to clarify.
    - To be in this study, you must agree to stop using certain medications while participating. If you are currently using medications or therapies that are not allowed, but you meet all other requirements, a study doctor will review your medications/therapies and speak with you about whether they are safe to stop. If so, you will have the option to stop using the prohibited medications or therapies and return for your next study visit after you have stopped.

If you do not meet all eligibility requirements, or if you are unable or unwilling to stop the use of certain medications/therapies, you will not be allowed to participate in this study.

At the end of the Screening Visit – if you meet all other eligibility requirements and have not taken or received prohibited medications/therapies – you will be assigned to one of the three groups described above. You will be officially assigned to either the non-AD group, dupilumab-naïve group, or long-term dupilumab group.

You will be asked to NOT start any new prescription moisturizers or moisturizers containing ceramide, hyaluronic acid, urea, or filaggrin during the study. If you are already using one of these moisturizers before the Screening Visit, you may continue using them as you have been on some areas of your body. You will be asked not to use them on specific areas of your body for 1 day before your next study visit.

You will be asked to NOT shower or bathe 1 day before your clinic visits. You will also be asked to NOT use hot tubs, and to avoid chlorinated swimming pools within 2 days of your clinic visits. The study staff will provide you with a reminder card for you to take home.

Visits For All Participants

Baseline Visit

This visit applies to all three groups: non-AD, dupilumab-naïve, and long-term dupilumab.

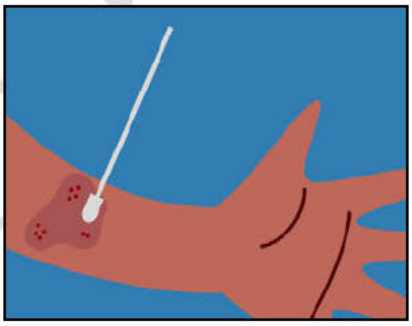
You will be asked to come to clinic for a Baseline Visit within one week of your Screening Visit so that we can check one more time that you are able to participate in the rest of the study. The Baseline Visit can sometimes be completed on the same day as your Screening Visit. If this happens, activities that are scheduled for both visits will only be done once.

The purpose of the Baseline Visit is to confirm eligibility and collect some initial samples before treatment begins. This visit will take about 2 hours to complete. The following procedures and assessments will be conducted at the visit:

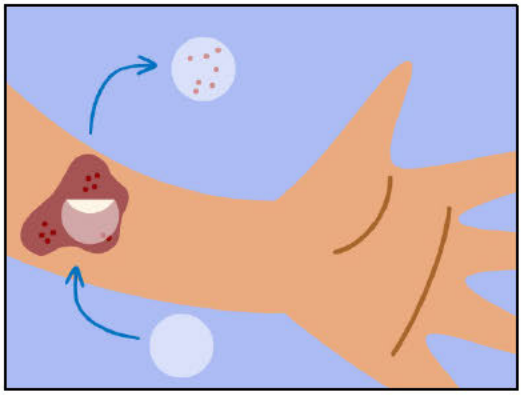
- Questionnaires: We will ask you to provide contact information that we may use for future study communications. We will ask you about the medications you are taking and your medical history. If you are taking certain medications or have certain medical conditions, you might not be able to participate or may need to wait to participate in this study. These questions are not tests. There are no right or wrong answers. If you do not understand certain questions, you can ask us to clarify.
- Physical Exam: A study clinician will complete a physical exam for you to make sure that you meet the health requirements for the study. The clinician may ask you questions during this exam about your general health and atopic dermatitis.
- Atopic Dermatitis Assessment: If you are in the dupilumab-naïve or long-term dupilumab group, we will ask you questions about your atopic dermatitis. These questions include things like how itchy your skin has been recently and how that itchiness has interrupted your daily activities. A study clinician will look at your skin for any redness, bumpiness, swelling, scaliness, or scratches.
- Confirmation of Pregnancy Status: For people who could become pregnant, we will ask you to give a small urine sample for pregnancy testing today. Results of the pregnancy test will be reported [insert site-specific reporting policies, such as "to you and your legal guardian" or "to you. We will not share these results with your parent or legal guardian without your permission."]. If you are pregnant, you will not be able to participate in this study. If there is any way that you could become pregnant, you must agree to use FDA-approved methods of birth control for the duration of the study.
- Vital Signs: We will check your temperature, blood pressure, heart rate, and breathing rate.
- Growth Parameters: We will record your height and weight.
- Selecting the Target Area: Throughout the study, we will take skin samples from the same place, called the "target area." During the Baseline Visit, a study clinician will look at your skin and pick the target area from your arms, legs, or torso. We will also ask you to apply treatments in the same way in this target

area at certain points throughout the study. For example, participants in all groups will be asked to apply Vanicream™ twice daily to the target area for about 1 week after the Baseline Visit.

- Skin Marking and Photography: We will take photographs of the places on your arms, legs, or torso where skin samples will be collected today. This helps us to collect samples from the same place on your body at every visit. Your face will not be included in any photos that are taken to prevent you from being identified. A surgical marker will be used to mark the areas where we will be collecting samples today too. You will be asked to remark the areas between visits as needed throughout the study.
- Skin Sample Collections: We will not give you the results of tests done on these samples, since they are just for research and not to help you make decisions about your health. These samples will always be labeled with a number and not your name.
    - Skin Swabs: Skin swab samples will be collected from your target area. These samples will be collected by rolling a sterile swab, which looks and feels like a Q-tip, across your skin. The procedure will take about a minute and does not hurt. Up to 6 skin swabs will be collected during your study visit. The swabs will be used to look at bacteria on your skin.



    - Skin Tape Strips: Skin tape strip samples will be collected from your target area. Tape strips are small circles that are sticky, but do not contain latex. If you have a history of serious allergic reactions to tape or glues, please tell the study team, as you will not be eligible for the study. To collect these samples, the tape strip will be firmly placed on your skin and light pressure will be applied to make sure it is sticking all the way. Then, the tape strip will be peeled off your skin slowly. Up to twenty different tape strips will be applied and removed from the same spot. This can be uncomfortable and cause mild irritation to your skin, just like putting a Band-Aid on and taking it off might sting. We will stop if your skin becomes too irritated and there is bleeding. This will be done up to two times in two different spots, for a total of up to 40 tape strips. The tape strips will be used to look at the layers and composition of your skin.



Visits For All Participants

At the conclusion of the Baseline Assessment Visit, if you remain eligible for this study, you will be instructed to begin regular application of Vanicream™. We will ask you to apply Vanicream™ to your target area twice daily until the day before your next clinic visit in about 1 week.

You will be asked to avoid use of any moisturizer on your target area skin for 1 day prior to any clinic visit. If you are in the long-term dupilumab group, we will ask that you also avoid applying moisturizer anywhere on your arms, legs, or torso for 1 day prior to any clinic visit.

If you are in the long-term dupilumab group, you may continue to apply any topical steroids prescribed by your primary care physician as they have instructed outside the target area. You will be asked to use your dupilumab as prescribed by your primary care physician.

We will ask you to avoid:

- Specific prohibited medications and moisturizers
- Tanning beds or phototherapy
- Bleach baths
- Swimming in pools or using hot tubs for two days before your next visit
- Bathing or showering within one day of your next visit

You will be given instructions on when to contact the research clinic should you experience any adverse events. Contact information for the study physician and the 24-hour on-call physician will also be provided to you. The physician receiving the call will assess whether you will need to be seen in clinic or whether any further treatment is necessary. You will be provided with an instructional hand card including any post-visit reminders, as applicable.

1-Week Visit

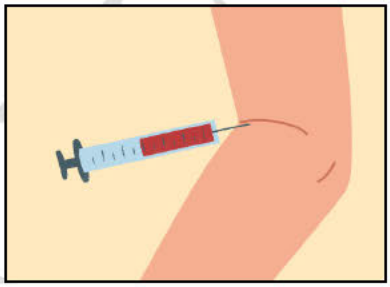
This visit applies to all three groups: non-AD, dupilumab-naïve, and long-term dupilumab.

Approximately seven days after your Baseline Assessment, you will be asked to come to clinic. The purpose of the 1-Week Visit is to collect samples after use of Vanicream™ so that we can see the impact that the moisturizer alone had on your skin. If you are a dupilumab naïve participant, you may also hear your 1-Week Visit called your “Steroid Initiation.”

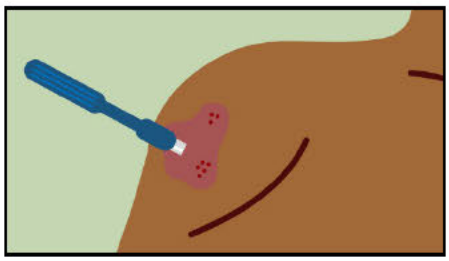
This visit will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the 1-Week Visit will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires

- Abbreviated Physical Exam: A shorter physical exam may be done. A focused look at the skin, especially the target area, will be done.
- AD Assessment, for dupilumab-naïve and long-term dupilumab participants
- Vital Signs
- Confirmation of Pregnancy Status, including a urine pregnancy test
- Blood Draw: About 1.5 tablespoons of blood will be collected. All of the blood can usually be collected in one needle stick. Your blood samples will be labeled with a number only, and not your name.
    - CBC: Just under half a teaspoon of blood will be collected for a test called a complete blood count, or CBC. The CBC test gives important information about the kinds and numbers of cells in the blood, especially red blood cells, white blood cells, and platelets. We will share the results of the CBC test with you.



    - Markers: Just under 3.5 teaspoons of blood will be collected to look at markers, like proteins, in your blood. This will be done to see if any patterns can be found that might relate specific markers to the severity of your AD (as applicable) and the overall function of your immune system. We will not give you the results of these blood tests since these are for research and should not be used to make decisions about your health.
    - Genetics: Half a teaspoon of blood will be studied to see how your DNA may affect your AD severity and your response to AD treatments (as applicable). This specific blood draw may occur at the 1-Week Visit or any visit throughout your participation. It will only be collected once.
- Skin Marking and Photography
- Skin Sample Collection: We will not give you the results of tests done on these samples, since they are just for research and not to help you make decisions about your health. These samples will always be labeled with a number and not your name.
    - Skin Swabs: Up to 9 skin swabs will be collected during this study visit.
    - Skin Tape Strips: Up to 60 skin tape samples will be collected from up to three areas during this visit.
    - Skin Biopsies: Skin biopsies are optional at the 1-Week Visit and will only be taken from adults (18+ years old). If you agree, up to three biopsies will be taken from your target area. These biopsies will be 2.5 mm across, which is just a bit bigger than the width of a grain of white rice. To collect these samples, your skin will be numbed before a device called a



biopsy punch – which is a sterile tube shape – will be pressed into your skin in a twisting motion. We will give you instructions about how to care for the place where the biopsy was taken by keeping it dry and clean.

- If you are allergic to numbing medications such as Lidocaine or Novocain or have a history of keloid-like scars, please tell the study team. Depending on your age and group, your allergy might make you ineligible to join this study. Keloids are extra scar tissue that can appear after your skin is injured or becomes swollen. They usually appear as lumpy skin with a smooth surface.

At the conclusion of the 1-Week Visit, you will be given updated treatment instructions, depending on your group.

- All participants will be allowed to continue to use Vanicream™ moisturizer as needed outside the target area. All participants will be asked to avoid using it – or any other moisturizer – on their target area for 1 day prior to any clinic visit.
- If you are in the dupilumab-naïve group, we will give you topical steroids to use twice daily until two hours before your next clinic visit.
  - You will be asked to use triamcinolone on any active lesions in non-sensitive areas like the arms, legs, and torso. Lesions are the areas of redness, bumpiness, swelling, or scaliness on your skin.
  - You will also be asked to use triamcinolone on your target area, regardless of whether it is lesional.
  - You will be asked to use hydrocortisone on any active lesions in sensitive areas like your face or neck.
- If you are in the long-term dupilumab group, you may apply any topical steroids prescribed by your primary care physician as they have instructed. You will be asked to continue to use your dupilumab as prescribed by your primary care physician.

You will be asked to avoid use of any moisturizer on your target area skin for 1 day prior to any clinic visit. If you are in the long-term dupilumab group, we will ask that you also avoid applying any moisturizer anywhere on your arms, legs, or torso for 1 day prior to any clinic visit.

You will be asked to avoid use of any topical steroids on your target area skin for two hours prior to any clinic visit. If you are in the long-term dupilumab group, we will ask that you also avoid applying topical steroids anywhere on your arms, legs, or torso in the two hours prior to any clinic visit.

We will ask you to avoid:

- Specific prohibited medications and moisturizers
- Tanning beds or phototherapy
- Bleach baths
- Swimming in pools or using hot tubs for two days before your next visit

Visits For All Participants

- Bathing or showering within one day of your next visit

You will be given instructions on when to contact the research clinic should you experience any adverse events. Contact information for the study physician and the 24-hour on-call physician will also be provided to you. The physician receiving the call will assess whether you will need to be seen in clinic or whether any further treatment is necessary. You will be provided with an instructional hand card including any post-visit reminders, as applicable.

After your 1-Week Visit, your visit schedule until the end of the study will depend on the group that you are a part of: non-AD, dupilumab-naïve, or long-term dupilumab.

Visits For Non-AD Participants

Remaining Visits for Non-AD Participants

If you are a participant in the non-AD group, you will be asked to come to clinic approximately four times after the 1-Week Visit.

The first of these visits are called the 5-Week, 13-Week, and 20-Week Visits. The 5-Week, 13-Week, and 20-Week Visits will each take about 2 hours to complete. They will include the following activities. If an activity scheduled for any of these three visits will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- Skin Marking and Photography
- Skin Sample Collection:
    - Skin Swabs: Up to 3 skin swabs will be collected during this study visit.
    - Skin Tape Strips: Up to 20 skin tape samples will be collected during this visit.

You will be asked to follow the treatment instructions below:

- Through the 20-Week Visit, you will be allowed to continue to use Vanicream™ moisturizer as needed outside the target area. You will be asked to avoid using it – or any other moisturizer – on your target area for 1 day prior to any clinic visit.
- After the 20-Week Visit, you will be asked to apply Vanicream™ to your target area twice daily until the day before your next clinic visit in about 4 weeks. You will be asked to avoid using it – or any other moisturizer – on your target area for 1 day prior to any clinic visit.

Throughout the study, you will be asked to avoid:

- Specific prohibited medications and moisturizers
- Tanning beds or phototherapy
- Bleach baths
- Swimming in pools or using hot tubs for two days before your next visit
- Bathing or showering within one day of your next visit

You will be given instructions on when to contact the research clinic should you experience any adverse events. Contact information for the study physician and the 24-hour on-call physician will also be provided to you. The physician receiving the call will assess whether you will need to be seen in clinic or whether any further treatment is necessary. You will be provided with an instructional hand card including any post-visit reminders, as applicable.

The final visit for non-AD participants is the End of Study Visit. The End of Study Visit

will take about 2 hours to complete. It will include the following activities. If an activity scheduled for this visit will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- Blood Draw:
  - CBC
  - Markers
- Skin Marking and Photography
- Skin Sample Collection:
  - Skin Swabs: Up to 3 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 20 skin tape samples will be collected during this visit.
  - Skin Biopsy: Skin biopsies are optional at the End of Study Visit and will only be taken from adults (18+ years old). If you agree, one biopsy will be taken during this visit.

At the conclusion of the End of Study visit, your participation in this study will be completely finished. You will be allowed to use medications and treatments that we have previously asked you to avoid. You will be allowed to bathe, shower, swim, and moisturize without any special rules.

Visits for Long-Term Dupilumab Participants

Remaining Visits for Long-Term Dupilumab Participants

If you are a participant in the long-term dupilumab group, you will be asked to come to clinic approximately three times after the 1-Week Visit.

The first of these visits is called the 9-Week Visit. The 9-Week Visit will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the 9-Week Visit will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Skin Sample Collection:
  - Skin Swabs: Up to 9 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 60 skin tape samples will be collected during this visit.

After the 9-Week Visit, you will be given updated treatment instructions.

- You will be allowed to continue to use Vanicream™ moisturizer as needed outside the target area. You will be asked to avoid using it – or any other moisturizer – on your arms, legs, or torso for 1 day prior to any clinic visit.
- You may apply any topical steroids prescribed by your primary care physician as they have instructed.
- You will be asked to avoid use of any topical steroids anywhere on your arms, legs, or torso for two hours prior to any clinic visit.
- You will be asked to continue to use your dupilumab as prescribed by your primary care physician.

The next scheduled visit is the 20-Week Visit. The 20-Week Visit will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the 20-Week Visit will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Blood Draw:
  - CBC
  - Markers

- Skin Sample Collection:
  - Skin Swabs: Up to 9 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 60 skin tape samples will be collected during this visit
  - Skin Biopsies: Skin biopsies are optional at the 20-Week Visit and will only be taken from adults (18+ years old). If you agree, up to 3 biopsies will be taken during this visit.

After the 20-Week Visit, you will be given updated treatment instructions.

- You will be asked to apply Vanicream™ to your target area twice daily until the day before your next clinic visit in about 4 weeks. You will be asked to avoid using it – or any other moisturizer – on your arms, legs, or torso for 1 day prior to any clinic visit.
- You will be asked to avoid using any topical steroids, including those prescribed by your primary care physician in your target area until your next clinic visit in about 4 weeks. You can continue to use topical steroids prescribed by your primary care physician as they have instructed outside of the target area during this time.
- You will be asked to avoid use of any topical steroids anywhere on your arms, legs, or torso in for two hours prior to any clinic visit.
- You will be asked to continue to use your dupilumab as prescribed by your primary care physician.

Throughout the study, you will be asked to avoid:

- Specific prohibited medications and moisturizers
- Tanning beds or phototherapy
- Bleach baths
- Swimming in pools or using hot tubs for two days before your next visit
- Bathing or showering within one day of your next visit

You will be given instructions on when to contact the research clinic should you experience any adverse events. Contact information for the study physician and the 24-hour on-call physician will also be provided to you. The physician receiving the call will assess whether you will need to be seen in clinic or whether any further treatment is necessary. You will be provided with an instructional hand card including any post-visit reminders, as applicable.

The final scheduled visit for long-term dupilumab participants is the End of Study Visit. The End of Study Visit will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the End of Study Visit will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam

- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Blood Draw:
  - CBC
  - Markers
- Skin Sample Collection:
  - Skin Swabs: Up to 9 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 60 skin tape samples will be collected during this visit
  - Skin Biopsies: Skin biopsies are optional at the End of Study Visit and will only be taken from adults (18+ years old). If you agree, up to 3 biopsies will be taken during this visit.

At the conclusion of the End of Study visit, your participation in this study will be completely finished. You will be allowed to use medications and treatments that we have previously asked you to avoid. You will be allowed to bathe, shower, swim, and moisturize without any special rules.

Dupilumab-Naïve Participants: 4-Week Steroid Assessment

If you are a participant in the dupilumab-naïve group, you will be asked to come to clinic between five and seven times after the 1-Week Visit. Dupilumab-naïve participants have a more complex visit schedule because they will be sorted into two groups over the course of the study: topical steroid responders and topical steroid non-responders. Your 4-Week Steroid Assessment will be scheduled approximately four weeks after your 1-Week Visit, or Steroid Initiation. The purpose of this visit is to determine whether your skin is responding well to treatment with steroids. If your atopic dermatitis cannot be managed with topical steroids alone, you will begin treatment with dupilumab.

The 4-Week Steroid Assessment will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the 4-Week Steroid Assessment will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Blood Draw:
  - CBC
  - Markers
- Skin Sample Collection:
  - Skin Swabs: Up to 6 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 40 skin tape samples will be collected during this visit

At the end of this visit, we will know whether your AD has responded to topical steroid treatment.

If so, you will be considered a “topical steroid responder” and will continue to use topical steroids after today’s visit.

- You will be allowed to continue to use Vanicream™ moisturizer as needed outside the target area. You will be asked to avoid using it – or any other moisturizer – on your target area on the day prior to any clinic visit.
- You will be asked to use the study topical steroids once or twice daily until two hours before your next clinic visit.
  - You will be asked to use triamcinolone on any active lesions in non-sensitive areas like the arms, legs, and torso.
  - You will be asked to use hydrocortisone on any active lesions in sensitive areas like your face or neck.
  - You will be asked to avoid use of any moisturizer on your target area skin

for 1 day prior to any clinic visit. You will be asked to avoid use of any topical steroids on your target area skin for two hours prior to any clinic visit.

If you did not respond to topical steroid treatment, you will be considered a "topical steroid non-responder" and will be scheduled to begin treatment using dupilumab injections.

Throughout the study, you will be asked to avoid:

- Specific prohibited medications and moisturizers
- Tanning beds or phototherapy
- Bleach baths
- Swimming in pools or using hot tubs for two days before your next visit
- Bathing or showering within one day of your next visit

You will be given instructions on when to contact the research clinic should you experience any adverse events. Contact information for the study physician and the 24-hour on-call physician will also be provided to you. The physician receiving the call will assess whether you will need to be seen in clinic or whether any further treatment is necessary. You will be provided with an instructional hand card including any post-visit reminders, as applicable.

Remaining Visits for Topical Steroid Responders

Note: If you stop responding to topical steroid treatment any time before or during your 12-Week Steroid Assessment, you will be scheduled to begin treatment with dupilumab. If you stop responding to topical steroid treatment after the 12-Week Steroid Assessment, you will be scheduled for early withdrawal from the study.

If you are a topical steroid responder, you will be asked to come in for an Optional Steroid Assessment, 12-Week Steroid Assessment, 19-Week Steroid Assessment, and End of Study Visit.

The Optional Steroid Assessment will take about 1.5 hours to complete. It will include the following activities. If an activity scheduled for the Optional Steroid Assessment will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Skin Sample Collection:

Visits for Dupilumab-Naïve Participants

- Skin Swabs: Up to 6 skin swabs will be collected during this study visit.

If your AD has continued to respond to topical steroid treatment at the Optional Steroid Assessment, you will continue to use topical steroids and Vanicream in the same way after today's visit. If your AD has stopped responding to topical steroid treatment, you may be scheduled to begin dupilumab injections.

The 12-Week Steroid Assessment will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the 12-Week Steroid Assessment will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Skin Sample Collection:
  - Skin Swabs: Up to 6 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 40 skin tape samples will be collected during this visit

If your AD has continued to respond to topical steroid treatment by the 12-Week Steroid Assessment Visit, you will continue to use topical steroids and Vanicream in the same way after today's visit. If your AD has stopped responding to topical steroid treatment, you may be scheduled to begin dupilumab injections. This is the last point where you may be eligible to begin dupilumab injections.

The 19-Week Steroid Assessment will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the 19-Week Steroid Assessment will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Blood Draw:
  - CBC
  - Markers
- Skin Marking and Photography
- Skin Sample Collection:
  - Skin Swabs: Up to 6 skin swabs will be collected during this study visit.

- Skin Tape Strips: Up to 40 skin tape samples will be collected during this visit

At the end of the 19-Week Steroid Assessment, you will receive updated treatment instructions.

- You will be asked to stop using any topical steroids within the target area.
- You will be asked to use triamcinolone on any active lesions in non-sensitive, non-target areas.
- You will be asked to use hydrocortisone on any active lesions in sensitive areas.
- You will be asked to apply Vanicream™ to your target area twice daily until the day before your next clinic visit in about 4 weeks. You will be asked to avoid use of any moisturizer – including Vanicream™ -- on your target area skin on the day prior to any clinic visit.

Throughout the study, you will be asked to avoid:

- Specific prohibited medications and moisturizers
- Tanning beds or phototherapy
- Bleach baths
- Swimming in pools or using hot tubs for two days before your next visit
- Bathing or showering within one day of your next visit

You will be given instructions on when to contact the research clinic should you experience any adverse events. Contact information for the study physician and the 24-hour on-call physician will also be provided to you. The physician receiving the call will assess whether you will need to be seen in clinic or whether any further treatment is necessary. You will be provided with an instructional hand card including any post-visit reminders, as applicable.

The final visit for dupilumab naïve participants who are topical steroid responsive will be the End of Study Visit. The End of Study Visit will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the End of Study Visit will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Blood Draw:
  - CBC
  - Markers
- Skin Sample Collection:

Visits for Dupilumab-Naïve Participants

- Skin Swabs: Up to 6 skin swabs will be collected during this study visit.
- Skin Tape Strips: Up to 40 skin tape samples will be collected during this visit
- Skin Biopsies: Skin biopsies are optional at the End of Study Visit and will only be taken from adults (18+ years old). If you agree, up to 2 biopsies will be taken during this visit.

At the conclusion of the End of Study visit, your participation in this study will be completely finished. You will be allowed to use medications and treatments that we have previously asked you to avoid. You will be allowed to bathe, shower, swim, and moisturize without any special rules.

Remaining Visits for Topical Steroid Non-Responders

If you are a topical steroid non-responder, you will be asked to come in for a Dupilumab Initiation Visit, an Optional Dupilumab Assessment, 4-Week Dupilumab Assessment, 15-Week Dupilumab Assessment, and End of Study Visit.

Dupilumab initiation can be completed on the same day as your 4-Week Steroid Assessment. When this happens, activities that overlap will not be repeated. The Dupilumab Initiation Visit will take 1 - 2 hours to complete. It will include the following activities. If an activity scheduled for the Dupilumab Initiation Visit will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Growth Parameters
- AD Assessment
- Confirmation of Pregnancy Status, including a urine pregnancy test
- Blood Draw:
  - CBC
  - Markers
- Skin Marking and Photography
- Skin Sample Collection:
  - Skin Swabs: Up to 6 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 40 skin tape samples will be collected during this visit.
  - Skin Biopsies: Skin biopsies will only be taken from adults (18+ years old). There are both optional and required skin biopsies at the Dupilumab Initiation Visit. Up to two biopsies will be taken from your target area. If you agree, up to two more biopsies will be taken from your target area.
- Dupilumab Loading Dose Administration: Your first injections of dupilumab will be given by study staff during your visit. The study staff will teach you or your

caregiver how to inject the dupilumab so that you can inject it at home according to your dosing schedule. The injections of dupilumab will be given just under your skin, and not in your muscle. During the dupilumab administration visit, you will receive two injections in the skin of either your belly, thighs, or upper arms. This procedure may be slightly uncomfortable due to the needle stick.

At the end of the Dupilumab Initiation Visit, you will receive updated treatment instructions. You will continue to use the regimen below until your 15-Week Dupilumab Assessment.

- Instructions for home injections and your dosing schedule will be provided to you.
- You will be asked to give yourself one dupilumab injection every two or four weeks, depending on your age and weight.
- You will be asked to stop using any topical steroids within the target area.
- You will be asked to use triamcinolone on any active lesions in non-sensitive, non-target areas.
- You will be asked to use hydrocortisone on any active lesions in sensitive areas.
- You will be asked to avoid use of any topical steroids anywhere on your arms, legs, or torso for two hours prior to any clinic visit.
- You will be allowed to continue to use Vanicream™ moisturizer as needed outside the target area. You will be asked to avoid using it – or any other moisturizer – on your target area on the day prior to any clinic visit.

Throughout the study, you will be asked to avoid:

- Specific prohibited medications and moisturizers
- Tanning beds or phototherapy
- Bleach baths
- Swimming in pools or using hot tubs for two days before your next visit
- Bathing or showering within one day of your next visit

You will be given instructions on when to contact the research clinic should you experience any adverse events. Contact information for the study physician and the 24-hour on-call physician will also be provided to you. The physician receiving the call will assess whether you will need to be seen in clinic or whether any further treatment is necessary. You will be provided with an instructional hand card including any post-visit reminders, as applicable.

The Optional Dupilumab Assessment will take about 1.5 hours to complete. It will include the following activities. If an activity scheduled for the Optional Dupilumab Assessment will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs

Visits for Dupilumab-Naïve Participants

- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Skin Sample Collection:
  - Skin Swabs: Up to 9 skin swabs will be collected during this study visit.

The 4-Week Dupilumab Assessment is scheduled next. This visit will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the 4-Week Dupilumab Assessment will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Blood Draw: For markers only
- Skin Marking and Photography
- Skin Sample Collection:
  - Skin Swabs: Up to 9 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 60 skin tape samples will be collected during this visit

The 15-Week Dupilumab Assessment is scheduled next. This visit will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the 15-Week Dupilumab Assessment will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Blood Draw:
  - CBC
  - Markers
- Skin Marking and Photography
- Skin Sample Collection:
  - Skin Swabs: Up to 9 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 60 skin tape samples will be collected during this visit.
  - Skin Biopsies: Skin biopsies will only be taken from adults (18+ years old). There are both optional and required skin biopsies at the 15-Week Dupilumab Assessment. Up to three biopsies will be taken from your target area. If you agree, up to three more biopsies will be taken from

Visits for Dupilumab-Naïve Participants

your target area.

At the end of the 15-Week Dupilumab Assessment, you will receive updated treatment instructions.

- You will be asked to stop using dupilumab injections.
- You will be asked to use triamcinolone on any active lesions in non-sensitive, non-target areas.
- You will be asked to use hydrocortisone on any active lesions in sensitive areas.
- You will be asked to avoid use of any topical steroids anywhere on your arms, legs, or torso for two hours prior to any clinic visit.
- You will be asked to apply Vanicream™ to your target area twice daily until the day before your next clinic visit in about 4 weeks. You will be asked to avoid use of any moisturizer – including Vanicream™ -- on your target area skin for 1 day prior to any clinic visit.

Your final visit as a dupilumab naïve participant who is topical steroid non-responsive will be the End of Study Visit. The End of Study Visit will take about 2 hours to complete. It will include the following activities. If an activity scheduled for the End of Study Visit will happen in the exact same way as it did before, the full description has been left out here. New or different activities are fully described here.

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Blood Draw:
  - CBC
  - Markers
- Skin Sample Collection:
  - Skin Swabs: Up to 9 skin swabs will be collected during this study visit.
  - Skin Tape Strips: Up to 60 skin tape samples will be collected during this visit
  - Skin Biopsies: Skin biopsies are optional at the End of Study Visit and will only be taken from adults (18+ years old). If you agree, up to 3 biopsies will be taken during this visit.

At the conclusion of the End of Study visit, your participation in this study will be completely finished. You will be allowed to use medications and treatments that we have previously asked you to avoid. You will be allowed to bathe, shower, swim, and moisturize without any special rules.

Visits For All Participants

Early Termination Visits

For participants in all groups, you will be asked to complete an Early Termination Visit if your participation in this study ends before you complete the End of Study Visit. This could happen for many reasons. Some examples are below:

- You are a dupilumab naïve participant who was responsive to topical steroids through your 12-Week Steroid Assessment, but then had a serious flare up.
- You are a dupilumab naïve participant who initiated dupilumab, but have stopped using your injections.
- You would like to end your participation in this study early, but are willing to come to clinic for a final visit.
- You have a serious allergic reaction to a study drug and can no longer follow the study treatment plan.

The Early Termination Visit will take about 1.5 - 2 hours to complete. It will include as many activities as possible from the End of Study Visit for your group (non-AD, dupilumab-naïve, or long-term dupilumab). This could include:

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Confirmation of Pregnancy Status
- AD Assessment
- Skin Marking and Photography
- Blood Draws
- Skin Sample Collections

However, based on the reason for ending your participation, some activities may be skipped. For example, samples might not be collected during this visit if you are leaving the study because you are taking a prohibited medication that might impact the sample results.

Early Withdrawal/Termination Follow-Up Visit

If your participation in this study ends before the End of Study Visit, we may call you after your last clinic visit to ask you about any new symptoms you may have experienced and if you have had any changes in your medications. This will be a brief phone call.

Unscheduled Visit

If your AD condition gets worse, or other concerns arise between regularly scheduled visits, you will be instructed to contact study personnel, and you may be asked to return to the study site for an "Unscheduled Visit". You may also be asked to return to the clinic for Unscheduled Visits to provide additional skin swabs, skin tape strips, and/or skin biopsies for further studies, or if samples are lost or destroyed, or if insufficient amounts were obtained at a previous study visit. During the visit the following could occur:

Visits For All Participants

- Questionnaires
- Abbreviated Physical Exam
- Vital Signs
- Growth Parameters
- Confirmation of Pregnancy Status
- AD Assessment
- Blood Draws
- Skin Marking and Photography
- Skin Sample Collections

If you believe you are experiencing any side effects from your dupilumab treatment, please contact the doctor who prescribed the dupilumab – either the study doctor or your primary care physician. These side effects could include new or worsening eye problems, including eye pain or changes in vision, worsening asthma symptoms, swollen lymph nodes, joint pain, or other issues.

If you are receiving dupilumab through the study, contact information for the study doctor and the 24-hour on call physician are listed on the first page of this consent and on your emergency contact hand card.

GENETIC RESEARCH

Your genes are in the cells in your body. Genes make you different from anyone else. Some genes are responsible for inherited traits like hair and eye color. Some genes affect the chances that a person will get a certain disease or how their body responds to drugs. This study is being done to help researchers understand why people may react differently to the study drugs and how genes may affect severity of AD. No tests other than those described in this form will be performed on your sample without your permission. Your sample will be destroyed when it is no longer needed. To help protect your privacy, your sample will be identified by a random barcode and the date. Only study staff will be able to link this random barcode to your participant number, and only the study staff at [Institution] and other authorized persons will be able to link your participant number with your name. Neither you nor your study doctor will be given the results of the testing. The genetic research includes analysis of all of your genes (genome).

RISKS AND DISCOMFORTS

Treatment and procedures in this research study may involve risks that are not possible to predict. You will be informed of any new risks that may be identified during this study. Please ask your study doctor or the research staff to explain any procedures or risks that you do not understand.

- **Questionnaires:** You might think that some of the questions are too personal. You are allowed to refuse to answer any questions that make you feel uncomfortable. There is also a possibility that your answers may be read by others outside of this study. Your

name is not put on the questionnaires.

- **Physical Exam:** There are no known risks for the physical exam or abbreviated physical exam.
- **Medication/Therapy Washout:** Stopping medications and/or therapies prior to enrollment and for the duration of your study participation may cause worsening of your atopic dermatitis.
- **Pregnancy Test:** There are no known risks for the pregnancy test.
- **Vital Signs and Growth Parameters:** There are no known risks for having your vital signs (blood pressure, heart rate, breathing rate, and temperature), height, and weight measured.
- **Blood Collection:** The risks of having blood taken may include pain, bleeding, or bruising. Some people may experience lightheadedness, nausea, or fainting. There is a potential for slight psychological stress from the procedure. If you or the study staff think the stress is too much for you, the procedures will be halted.
- **Skin Swab Collection:** There are no known risks for the skin swab collection.
- **Skin Tape Stripping:** Skin tape stripping may cause mild redness and irritation of the skin where the tape was applied. Redness and irritation should disappear after about 12 hours. There is a small risk of infection at the tape stripping site. There is also a possible risk of rare allergic reactions to the tape. If you have a history of serious or life-threatening allergic reactions to tape or adhesives, you will not be able to participate in this study.
- **Skin Biopsy (as applicable):** Biopsies will only ever be taken from adult (18+ years old) participants. The risks of a skin biopsy include pain and the possibility of swelling, bleeding, and infection. A tiny scar may form at the biopsy site. In very rare instances, injection of the lidocaine to numb the skin can cause allergic reactions, which can be mild to life-threatening. These can range from hives, itching, swelling of the throat, mouth, or lips, difficulty breathing or significant drop in blood pressure. If you are allergic to lidocaine or have a history of keloid-like scars, you might not be eligible to join this study depending on your age and group.
- **Triamcinolone and Hydrocortisone Use (as applicable):** The following local side effects are rarely reported with topical corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, secondary infection, and thinning of the skin. Although rare, body-wide absorption of topical corticosteroids can cause high levels of sugar in the blood and in the urine in some patients.
- **Dupilumab Use (as applicable):** The most common risks (occurring in greater than or equal to 1% of participants) associated with injection of the study treatment are:
    - Injection site reactions including:
        - Pain or tenderness, swelling, redness at the site, rash, hives, or itching
    - Eye conditions including:
        - Conjunctivitis (redness and swelling of the white part of the eye and the inner surface of the eyelid); dry, itchy eyes; swelling of the eyelid
    - Joint pain including:
        - Symptoms that lead to decreased mobility or gait disturbances (changes

in the way you walk)
- Increased eosinophils, a type of white blood cell involved in the immune response

Genetic Research Risks:

Your privacy is important to us, and we will use safety measures to protect your privacy. Despite all the safety measures that we use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

While we will not use information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It is also possible there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. There may also be other privacy risks that we have not foreseen.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), 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 will get 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 will get 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 and all employers with 15 or more people must follow this law.

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

NEW INFORMATION

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in this study.

The overall results of this study may or may not be available to you at the end of the study.

The study doctor will also explain if you receive Complete Blood Count (CBC) results that may have clinical significance. Other test results, except for CBC results, will not be given to you since testing is done for research and not for diagnostic purposes.

BENEFITS

There may or may not be a direct medical benefit to you. If you have AD, your AD may or may not improve while in this study. There is a possibility that your AD symptoms will improve while you are receiving study medications. Stopping medications and/or therapies prior to enrollment or during the study may cause your AD to get worse.

Information learned from this study may someday benefit the future treatment and care of people with atopic dermatitis.

ALTERNATIVES TO STUDY PARTICIPATION

There are other options available for you if you decide not to enroll in this study. You may receive treatment from a doctor without being in this study. You may choose to enroll in another study. You do not have to participate in this study in order to receive treatment at [INSTITUTION].

COSTS OF PARTICIPATION

There will be no charge to you or your health insurance company for any costs related to the study treatment. The study sponsor will provide the following products to you for free if they are required to be used as a part of your participation in the study:

- Vanicream™ Moisturizing Cream – for all participants
- Hydrocortisone 2.5% ointment – for dupilumab naïve participants
- Triamcinolone 0.1% ointment – for dupilumab naïve participants
- Dupilumab (DUPIXENT®) – for dupilumab naïve participants whose AD does not respond to topical steroid treatment

You will not need to pay for any of these products if you receive them through this study. You will also not need to pay for any required study procedures. You will be paid back for your time spent on this study, including some travel costs.

You will still have to pay for any other costs related to your medical care. For example, you would need to pay for any non-study doctor visits, as well as any trips to the emergency room, urgent care, or hospital, during this study. Additionally, for example, if you have AD and your symptoms flare up badly enough that you need topical steroids (or other medications) outside of the scheduled study treatment plan, you would need to pay for those medications. If you have insurance, you may be able to submit these costs to your insurer.

There will be no charge to you or your health insurance company for any costs directly related to this study's procedures – including blood draw, skin swab collection, skin tape strip collection,

or skin biopsies.

REIMBURSEMENT

You (or your parent/guardian for participants under 12 years of age) will be paid back for your time spent on each study visit. You will be paid only for the visits you complete. If you leave the study early, or if we must take you out of this study, you will not be paid for the visits you do not complete.

The money you can expect for each study visit is listed in the tables below. You will be reimbursed by [insert site-specific language about acceptable payment methods (e.g., ClinCard at the conclusion of each study visit).]

In addition to being reimbursed for the time you spend on study activities mentioned in the tables below, you will be reimbursed up to [redacted] per visit for the actual cost of any transportation or parking expenses.

In each table, "basic visit activities" refers to the amount paid for doing any of the following activities: questionnaires, AD assessments (if applicable), physical exams, vital signs, and pregnancy testing (if applicable).

Non-AD Participants

If you do not have atopic dermatitis, you will be considered a "Non-AD" participant and will be reimbursed as outlined in the table below.

Reimbursements for Participants without AD							
	Screening[1]	Baseline	1-Week Non-AD Assessment	5-Week Non-AD Assessment	13-Week Non-AD Assessment	20-Week Non-AD Assessment	End of Study
Basic visit activities	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Blood collection	--	--	[redacted]	--	--	--	[redacted]
Skin swabs	--	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Skin tape strips	--	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Optional skin biopsies[2]	--	--	[redacted]	--	--	--	[redacted]
Visit Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
						Study Total	[redacted]

[1] If Screening is done on the same day as the Baseline Assessment, you will not repeat any activities from Screening and will only be reimbursed for the additional skin swab and skin tape strip collections.
[2] Adults only; reimbursed at [redacted] per biopsy.

Long-term Dupilumab AD Participants

If you have atopic dermatitis and have been on dupilumab for at least 4 months, you will be considered a "Long-term Dupilumab Participant" and will be reimbursed as outlined in the table below.

Reimbursements for Long-term Dupilumab Participants						
	Screening[1]	Baseline	1-Week Assessment	9-Week Assessment	20-Week Assessment	End of Study
Basic visit activities	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Blood collection	--	--	[redacted]	--	[redacted]	[redacted]
Skin swabs	--	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Skin tape strips	--	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Optional skin biopsies[2]	--	--	[redacted]	--	[redacted]	[redacted]
Visit Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
					Study Total	[redacted]

[1] If Screening is done on the same day as the Baseline Assessment, you will not repeat any activities from Screening and will only be reimbursed for the additional skin swab and skin tape strip collections.
[2] Adults only; reimbursed at [redacted] per biopsy.

Dupilumab-Naïve Participants

Topical Steroid Responders

If you have AD and have never received dupilumab before, at your Steroid Initiation Visit, you will be given topical steroids. You will then be seen for an assessment of how well the steroids are working to treat your AD after using them for four weeks. If the steroids are working to treat your AD, you will be considered a "Topical Steroid Responder" and will be reimbursed as outlined in the table below.

Reimbursements for Topical Steroid Responders								
	Screening[1]	Baseline Assessment	Steroid Initiation	4-Week Steroid Assessment	Optional Steroid Assessment	12-Week Steroid Assessment	19-Week Steroid Assessment	End of Study
Basic visit activities	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Blood collection	--	--	[redacted]	[redacted]	--	--	[redacted]	[redacted]
Skin swabs	--	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Skin tape strips	--	[redacted]	[redacted]	[redacted]	--	[redacted]	[redacted]	[redacted]
Optional skin biopsies[2]	--	--	[redacted]	--	--	--	--	[redacted]
Visit Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
							Study Total	[redacted]

[1] If Screening is done on the same day as the Baseline Assessment, you will not repeat any activities from Screening and will only be reimbursed for the additional skin swab and skin tape strip collections.
[2] Adults only; reimbursed at [redacted] per biopsy.

Topical Steroid Non-Responders

If you have AD and have never received dupilumab before, at your Steroid Initiation Visit, you will be given topical steroids. You will then be seen for an assessment of how well the steroids are working to treat your AD after using them for four weeks. If your AD symptoms are not helped with topical steroids, you will be considered a "Topical Steroid Non-Responder" and be given dupilumab. For the remainder of the study, you will be reimbursed as outlined in the table below.

Reimbursements for Topical Steroid Non-Responders									
	Screening[1]	Baseline	Steroid Initiation	4-Week Steroid Assessment	Dupilumab Initiation[2]	Optional Dupilumab Assessment	4-Week Dupilumab Assessment	15-Week Dupilumab Assessment	End of Study
Basic visit activities	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Blood collection	--	--	[redacted]	[redacted]	[redacted]	--	[redacted]	[redacted]	[redacted]
Skin swabs	--	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Skin tape strips	--	[redacted]	[redacted]	[redacted]	[redacted]	--	[redacted]	[redacted]	[redacted]
Required skin biopsies[3]	--	--	--	--	[redacted]	--	--	[redacted]	--
Optional skin biopsies[3]	--	--	[redacted]	--	[redacted]	--	--	[redacted]	[redacted]
Visit Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
								Study Total	[redacted]

[1] If Screening is done on the same day as the Baseline Assessment, you will not repeat any activities from Screening and will only be reimbursed for the additional skin swab and skin tape strip collections.
[2] If Dupilumab Initiation is done on the same day as the 4-Week Assessment,12- Week Assessment, or 19-Week Assessment, you will not repeat any activities from those visits and will only be reimbursed for the additional procedures that are a part of the Dupilumab Initiation visit.
[3] Adults only; reimbursed at [redacted] per biopsy.

Other Visit Reimbursements

If you are asked to return to clinic for an Unscheduled Visit due to experiencing increased disease activity, adverse reactions to the study medication, or other concerns, you will receive [redacted] for each visit.

If you are asked to return for an Unscheduled Visit to provide additional blood, skin swabs, skin tape strips, or skin biopsies, you will be compensated based on the number and type of samples provided. If you are requested to provide multiple sample types at the Unscheduled Visit, you will be compensated for each sample you provide. The table below outlines the compensation you will receive per sample.

Amount	Activity
[redacted]	Basic visit activities – including questionnaires, physical exam, vital signs, growth parameters, AD assessments, and pregnancy testing
[redacted]	Blood collection
[redacted]	Skin biopsy collection (per biopsy, adults only)
[redacted]	Skin swab collection
[redacted]	Skin tape strip collection

If you choose to, or are asked to, leave the study before it is finished, you may be asked to conduct an Early Termination visit. This visit would likely contain all activities scheduled during your planned End of Study Assessment, although some sample types may not be collected depending on the reason for discontinuing. You will only be compensated for the activities you complete.

Tax law may require the payer (e.g., research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you received from the study.

Your biospecimens, with or without identifiers, may be used for commercial profit, and you will not share in this profit.

COMPENSATION FOR INJURY

For medical emergencies, call 911. If you become ill or are hurt while you are in this study, contact your study doctor immediately. The study doctor will assist you in obtaining appropriate medical treatment. The NIAID Division of Allergy, Immunology, and Transplantation does not have programs to pay if you are hurt or have other bad results from participating in this study.

You or your health insurance provider will be billed for the payment for any treatment you require as a result of a study-related injury.

No other compensation will be offered by the sponsor or [INSTITUTION] or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort. You are not waiving any legal right to seek additional compensation through the courts by signing this form.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

You will be identified by a code, and personal information from your records will not be released without your written permission. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other information that can identify you. The purpose is to make study data available to other researchers. Information from this study may be put into databases along with information from other studies. There are different kinds of databases; some are publicly accessible, and some are restricted. Anyone on the internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases. Traditionally used identifying information about you (such as name, phone number, address) will NOT be included or shared with others.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you

must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this research study 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.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The National Institute of Allergy and Infectious Diseases, (NIAID) sponsor of the research
- NIAID representatives, agents, employees, contractors (such as Rho and PPD), and other persons assisting in conducting, monitoring, or analyzing the study. This also includes the [INSTITUTION IRB], Principal Investigator, and research staff at [INSTITUTION].
- Department of Health and Human Services agencies
- Biomedical Research Alliance of New York (BRANY)
- Accrediting agencies

- Data safety monitoring boards
- Health insurers and payers
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out this research study. The sponsor will analyze and evaluate the results of this study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information:

HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law

requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies responsible for protecting your rights.

FUTURE USE OF YOUR DATA/BIOLOGIC MATERIALS

Information about you, including your biospecimens, collected for this study may be shared with other researchers. It may also be used for other research studies. We will make sure that your identity cannot be linked to the information we share; your data and biospecimens will be coded so that other investigators will not have access to your personal information. We will not ask you for additional permission before sharing the information.

We are asking your permission to store unused samples of blood, skin swabs, skin tapes, and skin biopsies collected during the course of this study to be used in the future for tests that aren't yet planned.

Your stored samples may be used to obtain knowledge, including genetic information, in relation to related diseases, and/or the immune system. The results of tests performed on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor, and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to a specific condition. The purpose of storage and sharing data is to make information available for use in health research and to share what is stored with other researchers. Collecting, storing, sharing information, and making it available for other studies may help people in the future. Coded information put into databases together with other stored information from many studies conducted in different places allow researchers to study the combined information and learn even more about health and many different diseases. Samples will be stored in the study's biorepository. If you decide to allow storage, your samples and information may be stored for an unknown length of time.

Although your stored research samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

There may be unknown risks associated with the storage of samples and information. For example, if the future research involves genetic testing it is possible that it could be traced back to you because your genes are specific to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

You can change your mind at any time and ask to have your samples destroyed. This request

should be made in writing to the study doctor. If you make this request, all remaining stored samples will be destroyed. However, the results of any previous tests using your stored samples will be used. Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

Please indicate your responses below:

I agree to the storage and sharing of blood, skin swabs, skin tapes, and skin biopsy samples for genetic tests not currently planned.

☐ Yes ☐ No

_____

Initials of Parent/Legal Guardian or Adult Research Subject

I agree to the storage and sharing of blood, skin swabs, skin tapes, and skin biopsy samples, and information resulting from the analysis of my samples for other tests not currently planned.

☐ Yes ☐ No

_____

Initials of Parent/Legal Guardian or Adult Research Subject

OPTIONAL SKIN BIOPSY COLLECTION

Biopsies will only ever be taken from adult (18+ years old) participants. Skin biopsy collections at the 1-Week Visit and End of Study Assessment for all participants are considered optional. If you are in the long-term dupilumab group, an additional skin biopsy collection is optional at the 20-Week Assessment. If you are in the dupilumab-naïve group and receive dupilumab treatment through the study, there are additional optional skin biopsy collections at the Dupilumab Initiation Visit and the 15-Week Dupilumab Assessment.

If you are enrolled in the dupilumab-naïve group and end up becoming a topical steroid non-responder, there are some *required* skin biopsies within this study. Please review the reimbursements tables and "Remaining Visits for Topical Steroid Non-Responders" section to see where optional and required biopsies are scheduled for topical steroid non-responders. You do not need to agree to provide optional skin biopsies in order to provide required skin biopsies.

In this section, we are asking specifically about whether you agree to the *optional* skin biopsy collections. Your decision regarding the collection of optional skin biopsy samples will not affect your ability to participate in this study. You can change your mind at any time.

Please indicate your response below:

I agree to the optional biopsy collection. I understand that biopsies will only be collected from adult research subjects.

☐ N/A – Research subject is not an adult currently and is not expected to turn 18 during their participation in the study.

☐ Yes ☐ No

_____

Initials of Parent/Legal Guardian or Adult Research Subject

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate, or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor's office for a final study visit for your safety.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. [Principal Investigator] at [PI Phone Number].

If you have any questions about your rights as a research participant or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at [redacted]. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

STATEMENT OF CONSENT – SIGNATURES

_____
Printed Name of Research Subject, Recorded by Consent Administrator

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.
- I voluntarily agree to participate in this study.

Subject Signature: Section only required for subjects at least 12 years old.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date of Subject Signature

Witness Signature: Section only required for subjects 12-17 years old. Witness must be a third party unrelated to the subject.

_____
Printed Name of Witness

_____ _____
Signature of Witness Date of Witness Signature

Parent/Legal Guardian Signature: Section only required for subjects 6-17 years.

Printed Name of Parent/Legal Guardian	Relationship to Subject
Signature of Parent/Legal Guardian	Date of Signature

Second Parent/Legal Guardian: Section only required for subjects 6-17 years with potential eligibility for the Non-AD or Long-term Dupilumab groups.

Printed Name of Second Parent/Legal Guardian	Relationship to Subject
Signature of Second Parent/Legal Guardian	Date of Signature

Consent Administrator Signature:

Printed Name of Consent Administrator	
Signature of Consent Administrator	Date of Signature

For Subjects Who Turn 18 Years Old during the Study

I have read (or re-read) this consent form. I agree to continue to participate in this research study.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date of Signature

_____
Printed Name of Consent Administrator

_____ _____
Signature of Consent Administrator Date of Signature

(NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the research participant. A copy should be placed in the research participant's medical record, if applicable.)