1. TITLE OF CLINICAL RESEARCH STUDY

Evaluation of tofacitinib in prevention of photosensitivity in cutaneous lupus erythematosus (ALE11)

2. PRINCIPAL INVESTIGATOR

Principal Investigator: *(Insert site PI information)*

The Principal Investigator is affiliated with the *(Insert site PI affiliation)*.

CONSENT SUMMARY/ KEY STUDY INFORMATION

This consent contains information that will help you decide whether to take part in this research study. We encourage you to read the entire document. All the information is important, but here are some key points to help you understand the study. Additional information is available in the detailed consent section below.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. This study will be explained to you. You will have the opportunity to ask questions. Taking part in this study is your decision and will not affect your care if you decide not to participate. You may change your mind at any time while participating in the study. There will be no penalties or loss of benefits to which you are otherwise entitled if you do not want to take part in the study.

Carefully review this informed consent form to ensure understanding of the study requirements. You will be given a copy of the signed consent for your records.

Why is this research being done?

The purpose of this clinical research study is to evaluate the impact of tofacitinib on ultraviolet (UV) light-induced skin inflammation in patients with cutaneous lupus erythematosus (CLE). CLE is an autoimmune disease which occurs when your immune system attacks and damages your healthy skin cells. Sunlight, a source of UV light, can make CLE worse. CLE can occur in patients with SLE but not all patients with CLE develop SLE.

The study drug, tofacitinib (trade name XELJANZ® XR) is approved by the United States Food and Drug Administration (US FDA) for the treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA), ulcerative colitis (UC), and Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA). It is not approved for the treatment of CLE or systemic lupus erythematosus (SLE). Therefore, the use of the study drug in this study is considered investigational.

All participants of this study will undergo ultraviolet light exposure to a small area of skin before and after taking tofacitinib for about 25 days.

Is there any way being in this research can hurt me?
The study drug has some risks associated with it. These include infections such as upper respiratory tract infection (nasopharyngitis, the common cold), lung infection, shingles, flu. More details about risks are in section 5 below (Risks and/or discomforts).

Will being in this research study help me in any way?
This study is designed to understand the biology of CLE and the effects of tofacitinib on the UV light induced CLE flares. It is not designed to provide you with any direct benefit. However, information learned from this study may benefit people with CLE and/or SLE in the future, see section 6 below (Potential benefits*).*

What other choices do I have besides taking part in this research?
You do not have to join this study to receive treatment for your CLE. You can continue to follow with your regular rheumatologist and discuss different treatment options, or you may volunteer for another study if you qualify. Before you decide to take part in this study, you may discuss the benefits and risks of available alternatives with the study doctor. See section 7 below (Alternatives to participation).

DETAILED CONSENT INFORMATION

3. INTRODUCTION AND BACKGROUND

You are invited to take part in this research study (also known as a clinical trial) because your CLE makes your skin more sensitive to sunlight. This reaction is called photosensitivity and involves an unusually strong reaction to sunlight or other sources of ultraviolet (UV) rays. Some artificial sources of UV rays include indoor fluorescent lights, tanning beds, or black-light lamps.

Exposure to UV rays is a common trigger for increased disease activity (flare) of both CLE and SLE. These flares can include rashes, fever, fatigue, joint pain, and other symptoms.

The purpose of this clinical research study is to evaluate the impact of the study drug (tofacitinib) on UV light-induced skin inflammation in patients with CLE. Tofacitinib blocks the effect of inflammation, thus slowing the autoimmune process. In small trials and case reports, it is reported that tofacitinib is beneficial in treating CLE, however, its effects on photosensitivity have not been studied.

4. STUDY COMPONENTS

Who is sponsoring and conducting this study?
The study is sponsored (funded and supported) by the National Institute of Allergy and Infectious Diseases (NIAID), of the National Institutes of Health (NIH). The Autoimmunity Centers of Excellence (ACE) are conducting the study.

The Division of Allergy and Immunology (DAIT), a branch of NIAID will purchase the study drug.

How long will I be in the study and how many people will be in the study?
If you qualify for the study and decide to participate, your total length of time in the study, including the screening and treatment, will be about 8 weeks. This study will enroll approximately 10 people at 1-3 study sites in the United States.

What am I being asked to do?
If you choose to take part in this study, you will have to first sign this consent and complete the screening visit to see if you are eligible to participate.

You will be required to do the following (see Table 1: Study Schedule):

- Provide information on your overall health, CLE and SLE.
- Provide blood samples four times during the study; we will take no more than 60 mL (about 12 teaspoons) at any one time
- Have areas of your right buttock exposed to UV light on Day 0 and areas of your left buttock exposed to UV light on Day 25
- Undergo three punch skin biopsies from the right buttock on Day 1 and three punch skin biopsies from the left buttock on Day 26
- Take 11 mg of tofacitinib pills daily for 25 days, beginning on Day 2

In Preparation for UVB Exposure and skin biopsies

- Avoid tanning beds and sun exposure during the time of study participation
- Do not use chemical sunscreens on the biopsy areas at least 12 hours prior to your UVB exposure appointment
- After your biopsy, do not apply topical creams other than Vaseline to the biopsy site.

Table 1: Study Schedule

			Treatment phase						
Visit	**Screening**	**1**	**2 ***	**3#**	**4@**	**5$**	**6^**	**Early Termination Visit**	**Unscheduled Visit**
Visit Days	**-30**	**0**	**1**	**14**	**25**	**26**	**40**		
Informed Consent	**X**								
Demographics and Medical History	**X**								
Medication assessment	**X**	**X**	**X**	**X**	**X**	**X**		**X**	**X**
Eligibility Review	**X**	**X**							
EULAR/ACR Lupus diagnostic criteria	**X**								
CLE and SLE disease activity assessments	**X**	**X**			**X**			**X**	
Fitzpatrick Skin Grading	**X**								
Physical Exam	**X**	**X**			**X**			**X**	**X**
Height, weight, vital signs	**X**	**X**	**X**		**X**	**X**		**X**	**X**
Adverse Event monitoring		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
UVB Exposure		**X**			**X**				
Erythema Assessment			**X**			**X**			
Skin biopsy			**X**			**X**			
Stitch Removal				**X**			**X**		
Study Drug: tofacitinib (1 pill every morning)			**X****	**X**		**X**			
Pill count and diary review (Collect remaining product at end of participation)				**X**		**X**		**X**	
Urine pregnancy					**X**			**X**	
Serum pregnancy	**X**								
Clinical labs	**X**				**X**			**X**	**X**
Research labs		**X**			**X**			**X**	
Volume for clinical labs (tsp)	**4**	**0**	**0**	**0**	**4**	**0**	**0**	**4**	**4**
Volume for research labs (tsp) at University of Michigan	**0**	**10**	**0**	**0**	**10**	**0**	**0**	**0**	**0**
Volume for research labs (tsp) if not at University of Michigan	**0**	**4**	**0**	**0**	**4**	**0**	**0**	**0**	**0**
Total visit draw volume (tsp) at University of Michigan	**4**	**10**	**0**	**0**	**14**	**0**	**0**	**4**	**4**
Total visit draw volume (tsp) if not at University of Michigan	**4**	**4**	**0**	**0**	**8**	**0**	**0**	**4**	**4**

Visit Windows

***Visit 2-20-28hrs after first UVB exposure**
 # Visit 3- Day 10-15
@ Visit 4- Day 21-29
$ Visit 5- 20-28 hrs. after 2nd UVB exposure
^ Visit 6- Day 36-41
****First dose of study drug -Take on day 2**

Screening Visit

At the Screening Visit the following will occur to determine if you are eligible to be in the study:

1. A complete medical history, demographic information, for example, age, gender and all your current medications that you are taking will be written down in the research record.
2. Other medical records such as imaging results, laboratory work, and other tests done as part of clinical care may be accessed for future research data purposes.
3. If you are a female of childbearing age, a pregnancy test will be done using a blood sample.
4. A sample of your blood will be collected for laboratory tests.
5. The study doctor will assess your skin involvement.
6. You will have a physical examination, including measurement of your weight and height.

Day 0

Once you are deemed eligible for the study, you will return for the Day 0 visit. At this visit, you will have a physical exam and blood samples taken. You will have eight small areas (¾" x ¾") of your right buttock exposed to ultraviolet light. UV light exposure is roughly similar to 15-30 minutes of summer sun exposure. The amount of UV is intended to include a dose that will cause mild redness.

Day 1

On Day 1, you will return to clinic to have the site of UV exposure assessed for redness and you will undergo 3 skin biopsies taken from your right buttock and a single stich placed at each site (each biopsy is the size of the end of a pencil eraser).

You will then be given tofacitinib 11 mg to take daily over the next 4 weeks. We will provide you with a diary to help you track your pill intake and ask that you record your daily intake including missed doses.

You will swallow the tofacitinib tablets every morning with or without food, whole and intact, do not crush, split, or chew. When you take this type of tofacitinib tablet, you may see something in your stool that looks like a tablet, this is from the medicine being absorbed into your body and leaving the tablet outer coating intact, which is normal.

Day 14
On Day 14 you will return to the study site with the bottle of tofacitinib and the pill diary for review. You will have your stitches removed and to monitor for adverse events at this visit.

Day 25
On Day 25, you will return with your bottle of tofacitinib and the pill diary. You will have a physical exam, and blood and urine samples taken. You will have small areas of your left buttock exposed to ultraviolet light. The doses of UV light are intended to include a dose that will be enough to cause some redness in most participants.

Day 26
On Day 26, you will return with your bottle of tofacitinib and diary to clinic to have the site of UV exposure assessed for redness, and you will undergo 3 skin biopsies taken from your left buttock.

Day 40
On Day 40 you will return to have the stitches removed and to monitor for adverse events.

During the study, you will be able to continue to take certain medications, including oral corticosteroids (e.g., prednisone), hydroxychloroquine, quinacrine, methotrexate, leflunomide and mycophenolate mofetil (MMF). You will need to be on a stable dose of those medications for the last 4 weeks when you enter the study. If you are taking NSAIDs you should be on the same daily dose for at least the 1 week just prior to when you enter the study.

Use of tofacitinib in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or potent immunosuppressants such as azathioprine and cyclosporine is not allowed.

You cannot receive any live or attenuated vaccines within 6 weeks prior to Visit 1 (Day 0) and throughout the study. You can receive non-live vaccines at least 2 weeks prior to initiating study drug.

It is recommended that you do not receive any type of vaccine for at least a month after you stop taking tofacitinib.

5. RISKS and/or DISCOMFORTS

For your safety, you must tell the study staff about all medications you are taking before you start the study, and any changes in your medications while in the study. There may be unknown or unforeseeable risks to participation in the study. It is important that you report any and all symptoms or possible reactions to your study doctor, even if you think it isn't related to your study participation.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects of tofacitinib have been observed in clinical trials:

Infections
Tofacitinib is a medicine that affects your immune system. Tofacitinib can lower the ability of your immune system to fight infections. Some people have serious infections while taking oral tofacitinib, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. You should not start taking tofacitinib if you have any kind of infection. People who are older than 65 years of age, people with diabetes, and people with chronic lung disease may have a higher risk of infection.

We strongly advise you to stay up to date with all current CDC vaccine recommendations.

We recommend that you be up to date with COVID-19 vaccinations per current CDC recommendations. If the CDC recommends a medication to prevent COVID-19 infection that may be an option.

Risk of chronic herpes infection:
Tofacitinib may increase your risk of outbreaks of herpes zoster (shingles) or other herpes infections ("cold sores" or "fever blisters" or ulcer involving the lips, mouth, or genital area). It is important for people who have chronic oral or genital herpes to be aware of this risk. If you or your sex partner have been diagnosed with oral or genital herpes, we recommend that you take your medicine as prescribed. If you have open sores, do not touch the fluids from herpes sores to avoid spreading it. Always use a physical barrier, (e.g., condoms) during sex to decrease the chance of getting herpes or infecting a sex partner.

If you develop an infection during your participation in the study, we will ask you to stop taking the study medication until you have recovered from the infection. We will ask that you return for a safety follow-up after you have recovered. You may be asked to restart a 25-day dose of study medication after you have fully recovered from the infection.

After starting tofacitinib, call your study doctor right away if you have any symptoms of any infection.

Cancer and immune system problems
Tofacitinib may increase your risk of certain cancers by changing the way your immune system works. Your risk of some skin cancers may be increased with tofacitinib. Your skin may be examined periodically by your doctor. Lymphoma and other cancers can happen in patients taking tofacitinib. Some of the other cancers that have happened include lung cancer, breast cancer, melanoma, prostate cancer, and pancreatic cancer. Some people who have taken oral tofacitinib with certain other medicines to prevent kidney transplant rejection have had a problem with certain white blood cells growing out of control (Epstein Barr Virus-associated post-transplant lymphoproliferative disorder). Tell your study doctor if you have ever had any type of cancer or if you are diagnosed with any type of cancer during the study.

Risk of heart related issues:
Taking tofacitinib may increase your risk of heart related issues such as heart attack or stroke, blood clots and death.
Let your study doctor know if you are a current or past smoker, or have had a heart attack, other heart problems, stroke or blood clots in the past as these may put you at higher risk for serious problems while taking tofacitinib.

Here are the symptoms to watch for while taking tofacitinib:
Heart attack
Someone having a heart attack may experience several symptoms including:

- Chest pain or discomfort that doesn't go away after a few minutes.
- Pain or discomfort in the jaw, neck, or back.
- Weakness, light-headedness, nausea (feeling sick to your stomach), or a cold sweat.
- Pain or discomfort in the arms or shoulder.
- Shortness of breath.

Stroke
Someone having a stroke may experience several symptoms including:

- Sudden numbness or weakness, especially on one side of the body
- Sudden confusion or trouble speaking or understanding speech
- Sudden trouble seeing in one or both eyes
- Sudden trouble with walking, dizziness, or loss of balance or coordination
- Sudden severe headache with no known cause

If you think that you may be having a heart attack or stroke, call 9-1-1 immediately.

Blood clot
Someone with a blood clot may experience any one of the following symptoms in an arm or leg:

- Swelling
- Pain or tenderness not caused by injury
- Skin that is red, discolored or warm to the touch

If you think you may have a blood clot you should seek immediate medical care.

Table 2: Frequency of adverse events

Very common (may affect > 1 in 10 people)		
Upper respiratory tract infection (nasopharyngitis, common cold)		
Common (may affect up to 1 in 10 people)		
Lung infection (pneumonia, bronchitis) Shingles (herpes zoster) Influenza (flu) Sinus infection Urinary or bladder infection (cystitis) Sore throat (pharyngitis) Increased liver enzymes, muscle enzymes or cholesterol Weight gain	Stomach (belly) pain (may be from inflammation of the stomach lining) Vomiting, diarrhea, nausea, indigestion Pain in the muscles and joints Low white blood cell count Low red blood cell count (anemia) Fever Fatigue (tiredness) Swelling of the feet and hands	Headache High blood pressure (hypertension) Poor sleep Shortness of breath, difficulty breathing Cough Rash Itching
Uncommon (may affect up to 1 in 100 people)		
Blood infection (sepsis) Tuberculosis Kidney infection Skin infection Herpes simplex or cold sores (oral herpes) Blood creatinine increased (a possible sign of decreased kidney function) Dehydration Heart attack*	Muscle strain Tendonitis Joint swelling Joint infection Ligament sprain Abnormal sensations Sinus congestion Skin redness Blood clots*	Fatty liver Inflammation of outpouchings of your intestine (diverticulitis) Tears in your stomach or intestines Viral infections Some types of skin cancers (nonmelanoma-types) Stroke*
Rare (may affect up to 1 in 1,000 people)		
Tuberculosis involving the brain and spinal cord, bones, and other organs	Other unusual infections	
*Current or past smoker, and those with a history of heart attack, heart problems, stroke or blood clots may be at a higher risk		

Tears or holes (perforation) in the stomach or intestines
Tell your study doctor if you have had diverticulitis (inflammation of outpouchings in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking oral tofacitinib get tears or holes in their stomach or intestine.

Tell your study doctor right away if you have fever and stomach-area pain that does not go away, and a change in your bowel habits.

Blockage of the stomach or intestines
Tell your study doctor if you have narrowing of the stomach or intestine, e.g., a stricture. The form of tofacitinib (XELJANZ® XR) being used in the study may cause a blockage or obstruction at the site of narrowing in your stomach or intestine.

Changes in certain laboratory test results
Your study doctor will test your blood before you start receiving tofacitinib and when you finish tofacitinib (day 25). Some changes in blood tests that can occur with tofacitinib include:

- Decrease in white cell counts (white blood cells fight off infections)
- Decrease in red blood cell count (low red cell counts may cause anemia and make you feel weak and tired)
- Increase in certain liver tests
- Increase in cholesterol level
- Increase in muscle enzymes tests
- Change in tests related to kidney function

The study doctor will discuss any abnormal lab test results with you.

Risks of Ultraviolet Light Exposure
Part of this study includes a brief exposure to different doses of ultraviolet light. The areas exposed are small (about 1 cm^2 or ¾" x ¾" each), but there is a risk of some burning sensation in the areas exposed. In addition, the ultraviolet light exposure could cause a rash. If your skin reacts to sunlight, it will likely react similarly in the areas we test. In individuals without CLE and/or SLE this might include turning pink or developing a tan which usually fades within a few weeks.

Risks of Punch Biopsies
The local anesthesia used to numb the area can produce a stinging sensation that lasts for a few seconds prior to the procedure. You may experience minimal pain or bleeding after the procedure. There may also be a small scar visible after the biopsy sites heal. The procedure is performed by a specially trained and highly experienced physician, nurse, or physician's assistant. You will have a suture placed at each biopsy site and study personnel will provide care instructions and a time to return to have the sutures removed.

Risks of Blood Draws
Drawing blood from a vein in your arm may cause some discomfort, bleeding, or bruising, and rarely, infection at puncture site or fainting. A total of 120mL (about 24 teaspoons) of blood will be collected over the course of the entire study. Blood will be drawn by trained persons and sterile technique will be used to minimize the risk of infection.

Risks Associated with Stored and Shared Blood and Information:
For this project, we will collect, store, and use blood and biopsied tissue samples and health information for research. The information will be stored on a password protected computer shared drive. The only people that will have access to these are the principal investigator, Dr. Kahlenberg, and approved study team members. Details of how your identity will be protected to the extent permitted by law will be described later in this form. Also, at the end of this form you will be asked to consider allowing storage of samples for future use which may not be directly related to this study.

The Confidentiality Section later in this form describes the safeguards used to code information that could link results back to you. Every effort will be made to protect your privacy to the extent permitted by law.

Additional Risks
As with any research study, there may be additional risks that are unknown or unexpected.

6. POTENTIAL BENEFITS

If you agree to take part in this study, there is no expected medical benefit to you. Information learned from this study may someday benefit people with CLE and/or SLE. We may learn information about your health as part of research. We will share this information with you.

7. ALTERNATIVES TO PARTICIPATION

You may choose not to be in this research study. There may be other research studies that you can choose to join if you qualify.

You do not have to join this study to receive treatment for your CLE and/or SLE. You can continue to follow with your regular rheumatologist and discuss different treatment options, or you may volunteer for another study if you qualify instead of volunteering for this study. Before you decide to take part in this study, you may discuss the benefits and risks or available alternatives with the study doctor.

8. NEW FINDINGS

During your participation in this study, your study doctor will inform you of any new findings from this or other research that may affect your willingness to continue in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

9. VOLUNTARY WITHDRAWAL FROM STUDY

You may decide not to take part or to leave the study at any time. If you decide to leave the study, there is no penalty or loss of benefits in your routine medical care or any other benefit(s) that you would otherwise be entitled to receive. In addition, you should talk to your study doctor who will discuss future treatment and procedures for your continued care.

10. REASONS WHY YOU MAY BE TAKEN OFF STUDY WITHOUT YOUR CONSENT

You may be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to, the following:

- Your study doctor determines that it is in your best interest not to take part
- You are unable to complete required study treatments and examinations
- You become ineligible to participate
- Your condition changes and you need treatment that is not allowed while you are taking part in the study
- You do not follow instructions from the researchers

- The study is stopped by the Institution, the sponsor, or other health authorities

If you are removed from the study your study doctor will notify you about treatment or procedures for your continued care.

11. PREGNANCIES, BREASTFEEDING AND BIRTH CONTROL

Tofacitinib may affect the ability of females to get pregnant. If you are female of childbearing potential, a pregnancy test will be performed prior to your enrollment and on day 25 of this study. If you are a male or female who engages in sexual activity that could lead to pregnancy, you must agree to use complete abstinence or an FDA-regulated contraception for the duration of the study and for one month after stopping the study drug to prevent pregnancy. Periodic abstinence and withdrawal are not acceptable methods of contraception.

Acceptable forms of birth control include:

- Oral birth control pills (combined hormone or progestin alone)
- Injectable or implantable progestogens
- Intrauterine devices or estrogen vaginal rings
- Double barrier methods (e.g., condom and occlusive cap with spermicidal agent)
- Tubal ligation-both sides
- Male sterilization (This must be a female participant's only partner)

You should not take tofacitinib if:

- You are pregnant
- You are breastfeeding
- Are unable or unwilling to use an effective form of birth control (see below)

Treatments and procedures involved in this research project may involve unexpected risks to your unborn.

If you are a female participant who becomes pregnant or if you are a male participant whose female partner become pregnant during the study, you must notify your study doctor immediately.

For female participants who become pregnant during the treatment, the study drug will be discontinued.

For male and female participants, we will continue to follow you until the baby is born or the pregnancy stops. Your study team will ask you about the length of the pregnancy, whether it is ongoing, whether a baby was born and the health of the baby.

12. COSTS TO THE PARTICIPANT (YOU)

You will not be charged while you are participating in this study. Also, all procedures that are required for this study, and are not part of your regular medical care, will be provided to you at no charge. Any costs related to usual clinical care of your CLE and/or SLE or other medical problems will be billed to you and/or your insurance provider(s).

Ask your study doctor about any expected added costs that may result from your participation in this study. Insurance companies and other carriers sometimes refuse to pay the costs of treatment when individuals are participating in research. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may lead to added costs for you or your insurance company. There will be no charge to you or your health insurance company for any costs which are directly related to this study.

13. REIMBURSEMENT

You will be paid (*XX*) for each study visit. Compensation will be considered for travel, hotel accommodations, etc., as needed. In addition, if you travel more than 50 miles away, you will be offered compensation for mileage based on Internal Revenue Service (IRS) regulations. There will be no financial charge for the medication.

If you receive payment of (*XX*) for taking part in this study, (*insert institution name here*) accounting department will collect your name, address, social security number, payment amount, and related information. The information collected will be used for tax reporting purposes if you participate in additional studies and the total amount of study payment exceeds $600 in a calendar year. In this situation (*insert your institution name here*) accounting department is required for tax reporting purposes to submit this information to the IRS.

14. RESEARCH-RELATED INJURY

If you are injured or get sick while in this study, it is important to tell your study doctor.
If you should be injured or become ill as a result of your participation in this study, emergency medical care is available to you, but you or your insurance company will be charged for this treatment. The hospitals and/or treating physicians reserve the right to bill you and/or your insurance provider(s) for services you receive for the injury. No payment or additional compensation is available to you as a result of such injuries or illnesses. There is no provision for free medical care or monetary compensation from the study sponsor, the NIAID, NIH. You do not lose any legal rights by signing this form.

15. CONFIDENTIALITY

Your medical and research records will be confidential to the extent permitted by law. Every effort is made to keep your identity private. However, we cannot always guarantee complete confidentiality.

You will be identified by a study code, not your name. The key to the code is kept in a secured electronic file where only *<Insert PI name>* and other designated study personnel will have access. Personal data from your records will not be released without your written permission.

You will not be named in any publication about this study. Any paper documents will be kept in a locked room during the study with access only to Dr. Kahlenberg and other designated study personnel.

After the study is completed, the study data may be placed in a central storage location. The purpose is to make study data available to other researchers who must request permission from NIAID/NIH. This data does not include names of any of the participants and your privacy is protected whenever this data is used. As an NIH funded study, you are further protected through a policy that prevents the investigator from disclosing sensitive study information that would lead to your identity. This does not prevent you or a family member from voluntarily releasing information about yourself or your involvement in this research**.**

Medical and research records from this study will be reviewed by the United States agency funding this study (the National Institute of Allergy and Infectious Diseases), including its, representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring, or analyzing the study.

A description of this clinical trial (NCT #05048238) is available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include:

- The National Institute of Allergy and Infectious Diseases, (NIAID) sponsor of the research
- NIAID representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring, or analyzing the study
- The U.S. Food and Drug Administration
- State and other health authorities

16. PROBLEMS OR QUESTIONS

If you have questions about this study, you should contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Insert Site PI
Mailing Address:	Insert site address
Telephone:	Insert site phone number
Study Coordinator:	Insert site coordinator
Mailing Address:	Insert site coordinator address
Telephone:	Insert site coordinator phone number

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the *(Insert site contact information)*

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

17. FUTURE USE OF DATA/BIOLOGICAL SAMPLES

Stored Samples and Information:

Information about you, including your biospecimens and other data, collected for this study may be shared with other researchers. It may also be used for other research studies. This information 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.

Your samples/data may be shared with other researchers; this data would be coded so that other investigators would not have access to your personal information.

We are asking additional permission to store leftover samples of blood and biopsy tissue that are collected during your participation in study to be used for research and sharing with other investigators in the future for tests that aren't yet planned. These tests will be related to the study of CLE, the response to medication, autoimmune disease, and the immune response. The tests may include genetic tests to study large chunks of your DNA (whole exome testing) or all of your DNA at once (whole genome testing).

The results of tests performed on stored samples or reports resulting from the analysis of your samples:

- will not be given to you or a doctor who is not an investigator in this study
- will not be put in your medical record
- will not identify you
- will not affect your routine medical care

There is no benefit to you from the storage and sharing of samples and the information learned from the research using them. However, the use of your samples and information may help researchers learn more about your disease. The purpose of storage and sharing data is to make information available for use in health research. Collecting, storing, sharing information, and making it available for other studies may help people in the future.

Samples will be stored at the University of Michigan. If you decide to allow storage, your samples and information may be stored for an unknown length of time. Any research conducted using your stored samples will be reviewed and approved by an Institutional Review Board (IRB). This board evaluates the science, integrity and ethics of clinical research involving human subjects.

Although your stored samples will not be sold, information obtained from the 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.

Researchers are required to protect your privacy and to keep your information private to the extent permitted by law. There may be risks in allowing the storage or analysis of samples and information. Your samples will be coded with a number so that you cannot be identified. Only your study doctor will have the code that links your identity to your specimens. Although we remove personal identifiers, we cannot guarantee complete confidentiality. For example, because genetic information is unique to you there is a risk that someone using your samples for genetic studies could trace the sample back to you or to those related to you.

You can change your mind at any time during the study and ask to have your samples destroyed. This request should be made in writing to the study doctor. If your samples have not

been used, they will be destroyed. If your samples have already been tested before your request is received, the information from these tests will be used and cannot be destroyed.

Your decision regarding the storage and sharing of samples for future research that is not part of this study and the information (data) resulting from the analysis of your samples will not affect your routine medical care or your ability to participate in this clinical trial. 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.

Consent/Assent to Collect for Unspecified Future Research
This project involves the option to allow the study team to keep your collected specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____ Date (mm/dd/yyyy):_____

Please sign below if you agree to take part in this study.

- **you have read the informed consent and/or had it explained to you**
- **you were given the opportunity to ask questions about the information, and**
- **you voluntarily agree to take part in the study**

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 16 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____ Date (mm/dd/yyyy): _____

Signature of investigator or designated person explaining and obtaining the consent

_____	_____	_____
Name and Title *(Typed or printed)*	**Signature**	**Date (mm/dd/yyyy)**

(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 subject. A copy should be placed in the research subject's medical record, if applicable.)