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**CONSENT FOR RESEARCH**
Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: **S**tudy of anti-**M**alarials in **I**ncomplete **L**upus **E**rythematosus (**SMILE**)

Principal Investigator: Nancy J. Olsen MD

Address: 500 University Drive, Hershey PA 17033; Mail Code H038

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-4921.
After hours call (717) 531-8521. Ask for the Rheumatology doctor on 24-hour call.

Subject's Printed Name: _____

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

**Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.**

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

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

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

We are asking you to be in this research to find out whether the drug hydroxychloroquine (HCQ) can slow down the development of systemic lupus erythematosus (SLE) in people like you. SLE is a disease where the body's immune system makes responses to and attacks healthy tissue. This is called "autoimmunity" or "autoimmune disease". Diagnosing SLE is complicated and requires a doctor to find that you have least four features of the disease. We know that there are people like you who have two or three features of SLE. We call this condition, "Incomplete Lupus Erythematosus" (ILE). Some people with ILE will go on to develop SLE over time and some will not. Currently, we do no know if we can predict who will get SLE and who will remain with ILE. We do not know if we can stop ILE from becoming SLE.

Hydroxychloroquine (HCQ, also called Plaquenil®) is a medicine that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of SLE. Some doctors use HCQ to treat ILE, but the safety and effectiveness in ILE has never been tested and HCQ is not approved by the FDA for the treatment of

ILE. Because HCQ is not approved by the FDA for ILE, it is called an investigational agent, or study drug. In this study, we will test whether HCQ can treat the symptoms of ILE and prevent the development of SLE.

Approximately 300 people will take part in this research study nationwide.

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

What will my responsibilities be during the study?

While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Store study capsules in a secure place at home away from anyone who is unable to read and understand labels, especially children.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or is something purchased over the counter.
- Tell your regular doctor about your participation in this study.
- Carry information about hydroxychloroquine in your purse or wallet.
- Report to the researchers any injury or illnesses while you are on study even if you do not think it is related.

If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures.

Screening Procedures (Visit 1)

To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had.

You will fill out certain forms or have the following exams, tests or procedures:

- Physical exam and medical history including current medications;
- Vital signs (pulse, blood pressure and weight);
- Blood tests to check your health and look for features of SLE
- Urine tests for signs of infection, blood, protein, creatinine and glucose
- Urine test for pregnancy if female of child bearing potential
- Demographic information (age, sex, ethnic origin).

Three and ½ tablespoons of blood will be drawn by needle stick from your arm for these tests. This visit will take approximately 2 hours.

Eye examination (Visit 2)

If you qualify for the research, you will have a professional eye examination performed by an ophthalmologist (medical doctor who treats eye diseases). This will be similar to other eye examinations you may have had before. The purpose of this exam is to make sure that you do not have eye problems that will

make it less safe for you to take hydroxychloroquine. This examination is not experimental and is the standard of care. This exam will include:

- Eye drops to dilate your eyes
- The ophthalmologist will look at the back of your eyes (retina) to look for any abnormalities
- You will have a test called "ocular coherence tomography" or OCT. This is a non-invasive test that uses light waves to look at tissues in the back of your eye. This test is not usually painful, but you will have to sit motionless for about 10-15 minutes.
- You will have a test that measures your visual fields. This requires you to look at a light and press a button when you see a second light. This test takes about 5 minutes per eye.

The entire eye exam will take 60-90 minutes.

If the ophthalmologist does not find any eye problems that would make it difficult to monitor the safety of hydroxychloroquine, you will be scheduled for the rest of the study visits.

Group Assignment

If the researchers believe you can take part in this study, you will be assigned randomly (like a flip of a coin) to receive either hydroxychloroquine or placebo. You have a 1 in 2 chance of receiving hydroxychloroquine or placebo. Neither you nor the researchers will know which group you are in. However, the sponsor will release the information about your assignment to the researchers if it is needed for your safety.

Study Medication/Intervention

If you decide to participate in this study you will take either:

- 2 tablets of hydroxychloroquine (400 milligrams) once a day or
- 2 tablets of placebo (inactive substance) once a day

If you weigh less than 88 pounds (40 kilograms), you will receive only one tablet of either hydroxychloroquine or placebo per day.

Visits 3-11 (visits every twelve weeks)

- Physical exam and medical history including current medications, symptoms of lupus, and possible side effects of study medicine;
- Vital signs;
- Pen and paper questionnaires about your pain, fatigue, depression, anxiety, pain, and ability to do daily tasks.
- Blood tests to check your health and look for features of SLE
- Blood tests for research
- Urine tests for protein, creatinine, blood cells and glucose;

Four and ½ tablespoons of blood will be drawn by needle stick from your arm for these tests. These visits will take about 2 hours to complete.

Visit 12 (Eye examination)

At this visit, you will have a second professional eye examination identical to Visit 2.

Extra or Unplanned Visits

You may be asked to see your study doctor in-between the visits mentioned above if your doctor believes that your disease may be getting worse. You will be asked to do some of the tests listed on the table above. No more than 3 tablespoons of blood will be taken at the visit.

The measurements of blood proteins and RNA (ribonucleic acid) in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your blood proteins or RNA to find or treat a medical problem, you will be told if they notice something unusual. You and your regular doctor can decide together whether to follow up with more tests or treatment. Because the blood protein or RNA tests done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

Procedures for storing of extra or left over samples

It is planned that blood, urine, and RNA samples will be stored after the study is completed. This will allow the study researchers and other scientist to learn more about the cause and treatment of lupus and other autoimmune disorders.

- These samples will be labeled with a study number, but not your name or other identifying information.
- Dr. Olsen will keep a "key" that can be used to contact you about your samples if you allow us to do so.
- The samples will be stored at the Oklahoma Medical Research Foundation in Oklahoma City, OK. This group is a co-investigator on this study and has extensive experience with the confidential storage of research specimens
- During the course of this study, only the study investigators (Dr. Olsen and others) will have access to the samples. After the study is completed, other investigators may ask for samples. This access will only be granted if you allow it below, and if their study is approved by an Institutional Review Board.

**Stored Samples and Information:**

- If you agree, we will store your blood samples and information in a central location in the United States. The purpose is to make these samples and information available for future research that is not yet planned and to share what is stored with other researchers.

- Your decision to allow samples and data to be stored is separate from your decision to participate in this study. If you decide to allow storage, your samples and data may be stored for an unknown length of time.

- The results of tests done on your stored samples will not be given to you or your doctor. The results will not be put in your records and will not change your medical care. There will be no benefits to you from the storage of these samples and information. However, the use of your samples and information may help researchers learn more about your disease or help study the genetics related to your disease.

- There may be risks in allowing the storage, sharing or analysis of samples and information. For example, if future research is for genetic testing and because genetic information is unique to

you there is a risk that someone could trace it back to you. Researchers are required to protect your privacy and to keep your information private to the extent permitted by the law.

- Future studies on stored samples and information will be reviewed and approved by an Institutional Review Board (IRB) for science and ethics. This does not occur all the time when information is shared with others. If information resulting from analysis of your samples is shared publically it will not contain traditional identifiers (i.e. your name, birthdate etc.). The samples and information will not be sold; however, the results of the tests could lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

- 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, the information from these tests will be used and cannot be destroyed

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

Study Procedure/Intervention

Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider.

Hydroxychloroquine may cause some, all or none of the side effects listed below.

**Frequent (more than 10% of the time)**

- Nausea, stomach pain or cramps

**Occasionally (1-10% of the time)**

- Vomiting
- Diarrhea; loss of appetite
- Blurred vision; trouble focusing; seeing halos around lights
- Headache
- Rash; itchy skin
- Nervousness

**Rare (less than 1% of the time)**

- Changes to vision such as blind spots.
- Hair loss or change in color
- Change in skin color (lighter or darker)
- Dizziness
- Nerve tingling, numbness or pain
- Muscle weakness, cramps or spasms
- Ringing in the ears; decreased hearing

**Serious but Rare**

- Lowered blood cell counts
- Low blood sugar
- Liver problems
- Heart problems
- Convulsions
- Hallucinations; suicidal thoughts
- Death
- Irregular Heart Beat

Many of these problems such as upset stomach or blurred vision go away after several weeks. They should all be reported to the study team. The most serious eye problems that can be caused by hydroxychloroquine typically occur after the first five years on the drug. The eye exams done as part of this study will help determine if it is safe for you to take hydroxychloroquine.

Since hydroxychloroquine is sold in the United States for other diseases, you will be given a copy of the Prescribing Information that you can go over with your study doctor.

**Females:** You may not participate in this study if you are pregnant or breast feeding. Being pregnant causes changes in your immune system and will make it impossible to tell if the hydroxychloroquine is having an effect. If you can become pregnant, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you participate in this study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically-acceptable birth control (contraceptives) during the study. Medically-acceptable birth control (contraceptives) includes:
(1) surgical sterilization (such as hysterectomy or "tubes tied"),
(2) approved hormonal contraceptives ( such as birth control pills, patch or ring; Depo-Provera, Implanon),
(3) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or
(4) an intrauterine device (IUD).
If you do become pregnant during this study, you must tell the researchers immediately.

Risks of Blood Drawing
Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting also are possible, although unlikely.

You will have from 3½ to 5 tablespoons of blood collected at each study visit because you are in this research study. Over the 104-week period, a total of about 21 ounces of blood will be collected for the research study.

Placebo
If you receive a placebo, you will not receive active medication for your health problem. If your problem becomes worse, your participation in the research will stop. If this happens, your study doctor can discuss alternative care with you.

Other Risks
The process of randomization means that you are not able to pick your treatment, you will be assigned to either the active medication or placebo, and neither you nor the study staff will know which one you are receiving.
There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

**How will risks be minimized or prevented?**
All of the study doctors are experienced in treating lupus patients and use hydroxychloroquine to treat their patients. They are familiar with the common and rare side effects, as well as the signs and symptoms of lupus. They will watch you closely for any problems and monitor your blood values for any changes. The standard eye examinations will tell the study doctors if it is safe for you to take hydroxychloroquine. If you develop signs or symptoms that tell the study doctor you have developed systemic lupus erythematosus or another autoimmune disease, they will stop your participation in the study and direct

you to obtain appropriate care. If you have a side effect or other adverse event that requires stopping the study drug, the study doctors will take you out of the study and direct you to obtain appropriate care. The study doctors will use trained personnel to do the blood draws to minimize pain and bruising. The study data that can identify you will be stored in secure computer centers at Penn State Hershey Medical Center.

**If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?**
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

**What should I do if I think I am having problems?**
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

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

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

### 4a. What are the possible benefits to me?
There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include improvement in your symptoms; however if you receive placebo, you are not likely to see an improvement in your symptoms.

### 4b. What are the possible benefits to others?
We hope the information learned from this study will benefit others with early forms of systemic lupus erythematosus in the future. Information gained from this research could lead to better treatment and possible prevention of SLE.

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

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

- Your regular doctor may decide to give you hydroxychloroquine (the drug in this study).
- Your regular doctor may give you medications to apply to your skin
- Your regular doctor may give you medicine to treat pain or inflammation such as ibuprofen (Motrin), naproxen (Aleve) or prednisone.
- Your regular doctor may give you other medications to suppress your immune system.
- You may decide not to take any treatment at all for your condition.

Please talk to the researchers or your personal doctor about these options.

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

The therapy offered in this research is available to you without taking part in this research study.

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

If you agree to take part, your participation in the study will take 104 weeks and you will be asked to come to the research site for 12 scheduled visits during that time.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

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

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

Efforts will be made to limit the use and sharing of your personal research information. In our research files at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) we will include these identifiers: your name, address, phone number, electronic mail address, date of birth, medical record number, and a study code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Olsen's office.
- Your research records will be labeled with your code number, your initials, your medical record number, and will be kept in a safe area in Dr. Olsen's research office.
- Your research samples will be labeled with a code number and will be stored in Dr. Olsen's research laboratory C 7733-C7735 and are accessible only by her lab personnel; these rooms are locked when not occupied.
- A copy of this signed consent form will be included in your HMC medical record. This means that other HMC healthcare providers will know you are in this study.

For research specimens sent to UT Southwestern Medical Center in Dallas TX and Oklahoma Medical Research Foundation in Oklahoma City OK, you will be identified by code number only.

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

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

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so. We will use and disclose your information only as described in this form and in the HMC Privacy Notice.

The research team may use the following health information:

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

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

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

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

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

Your privacy rights:

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

necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.

- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

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

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

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

- The study drug, hydroxychloroquine or placebo, will be provided at no cost to you while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- The research-related tests and procedures that will be provided at no cost to you include: blood tests to monitor your health condition and two eye examinations.

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

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

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

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

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

HMC/PSU compensation for injury

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.

- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

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

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

You will receive $50 per visit for your participation in this research study for a total of 10 visits. If you do not complete the study for any reason, you will be paid for the visits you have completed. The payment will be provided by Greenphire Clincard.

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

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

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

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

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

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

The institution and investigators are being supported by a grant from the National Institutes of Health to support this research.

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

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.

- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

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

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

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

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

Please call the head of the research study (principal investigator), Dr. Nancy Olsen at 717-531-4921 or the rheumatology doctor on 24-hour call at 717-531-8521 if you:

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

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

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

You may visit the HSPO's web site at http://pennstatehershey.org/irb under research subject information for:

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

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

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

**Signature of Person Obtaining Informed Consent**

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

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

**Signature of Person Giving Informed Consent and Authorization**
Before making the decision about being in this research you should have:

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

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

**Signature of Subject**

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

_____ _____ _____ _____
Signature of Subject Date Time Printed Name

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

By signing this consent form, you indicate that you permit your child to be in this research and agree to allow his/her information to be used and shared as described above.

_____ _____ _____ _____
Signature of Parent/Guardian Date Time Printed Name

**Witness to Consent for Limited English Speaking Subjects (Using a "Short Form" written in the subject's own language)**

**Witness Statement:** As someone who understands both English and the language spoken by the subject or subject representative, your signature indicates that the English version of the consent form was presented orally in the language of the subject or subject representative, and that he/she was given the opportunity to ask questions.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Witness Signature | Date | Time | Printed Name |

**Witness to Consent of Subjects Who Cannot Read or Write**

**Witness Statement:** Your signature indicates that you were present during the informed consent discussion of this research for the above named subject, that the information in the consent form and any other written information was presented orally to the subject or subject representative, that he/she was given the opportunity to ask questions, that the informed consent decision was freely made by the subject or subject representative who indicated his/her consent and authorization for participation by (check the box as applicable):

☐ Making his/her mark
☐ Other means: _____
(fill in above)

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Witness Signature | Date | Time | Printed Name |

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**ASSENT FOR RESEARCH**

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

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

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

___ To take part in the research.
___NOT to take part in the research.

| _____ | ____ | _____ | _____ |
|---|---|---|---|
| Signature of subject | | Date | Printed Name |

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**Optional part(s) of the study**
In addition to the main part of the research study, there is another part of the research. You can be in the main part of the research without agreeing to be in this optional part.

Optional Storage of Tissue for Future Research

In the main part of this study, we are collecting blood, urine, DNA and RNA samples from you. If you agree, the researchers would like to store leftover sample(s) and health information for future research.

- These future studies may be helpful in understanding systemic lupus erythematosus and other diseases.
- It is unlikely that these studies will have a direct benefit to you.
- The results of these tests will not have an effect on your care.
- Neither your doctor nor you will receive results of these future research tests, nor will the results be put in your health record.
- Sometimes tissue is used for genetic research about diseases that are passed on in families. Even if your sample(s) are used for this kind of research, the results will not be put in your health record.

Your leftover samples will be labeled with a code number.

- These samples will be stored at the Oklahoma Medical Research Foundation in Oklahoma City, OK. The leader of this group is a co-investigator on the study and has extensive experience with the confidential storage of research specimens.
- The length of time they will be used is unknown.
- You will be free to change your mind at any time.
- You should contact the principal investigator Dr. Nancy Olsen, and let her know you wish to withdraw your permission for your blood and urine samples to be used for future research. Any unused blood and urine samples will be destroyed and not used for future research studies.

You should initial below to indicate what you want regarding the storage of your leftover blood, urine, DNA and RNA samples for future research studies.

a. Your sample*[s]* and related health information may be stored and used for future research studies to learn about, prevent, treat or cure systemic lupus erythematosus.

_____ Yes _____ No

b. Your samples and related health information may be stored and used for research about other health problems.

_____ Yes _____ No

c. Your sample*[s]* and related health information may be shared with other investigators/groups without any identifying information.

_____ Yes _____ No

**Signature of Person Obtaining Informed Consent**

Your signature below means that you have explained the optional part(s) to the research to the subject or subject representative and have answered any questions he/she has about the research.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of person who explained this research | Date | Time | Printed Name |

**Signature of Person Giving Informed Consent**

**Signature of Subject**

By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part(s) of the research study.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of Subject | Date | Time | Printed Name |

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

By signing this consent form, you indicate that you have read the information written above and have indicated your choices for the optional part(s) of the research study.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of Parent/Guardian | Date | Time | Printed Name |

**Witness to Consent for Limited English Speaking Subjects (Using a "Short Form" written in the subject's own language)**

**Witness Statement:** As someone who understands both English and the language spoken by the subject or subject representative, your signature indicates that the English version of the optional part of the consent form was presented orally in the language of the subject or subject representative, and that he/she was given the opportunity to ask questions.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Witness Signature | Date | Time | Printed Name |

**Witness to Consent of Subjects Who Cannot Read or Write**

**Witness Statement:** Your signature indicates that you were present during the informed consent discussion of the optional part of the research for the above named subject, that the information in the consent form and any other written information was presented orally to the subject or subject representative, that he/she was given the opportunity to ask questions, that the informed consent decision was freely made by the subject or subject representative who indicated his/her consent and authorization for participation by (check the box as applicable):

☐ Making his/her mark
☐ Other means: _____
(fill in above)

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Witness Signature | Date | Time | Printed Name |

Version Date: 19 OCTOBER 2020

**ASSENT FOR RESEARCH**

The optional part(s) of the research study has been explained to you. You have had a chance to ask questions to help you understand what will happen. You Do Not have to be in the optional part(s) of the research study. If you agree to participate and later change your mind, you can tell the researchers, and the optional part(s) of the research will be stopped.

You have decided: **(Initial one)** ___
_____ To take part in the optional part(s) of the research.

___NOT to take part in the optional part(s) of the research.

_____ ____ _____ _____
Signature of subject Date Printed Name