NCT04093531

CONSENT FORM

Pilot Trial of Ustekinumab for Primary Sjögren's Syndrome (PSS)

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Sponsor: University of Rochester Medical Center
Funded by: Janssen Scientific Affairs Inc.

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice. Your medical care will not be affected if you decide you do not want to take part in this study.
- You are being asked to take part in this study because of your Sjogren's Syndrome.
- The purpose of this study is to determine the safety and effect of ustekinumab on patients with Sjogren's Syndrome.
- Your participation in this study will last for about 24 weeks.
- Procedures will include administration of a study drug and visits to assess your health.
- There are risks from participating.
    - The most common risk is infection.
    - One of the most serious risks is anaphylaxis (a life threatening allergic reaction)
    - See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You may not benefit from being in this research study.

Purpose of Study

Sjogren's syndrome (SS) is a chronic autoimmune disease, for which no treatment is currently available. The purpose of this study is to determine the safety and effect of the drug ustekinumab on patients with SS. Ustekinumab has been FDA approved for

patients with Psoriasis, Psoriatic Arthritis, and Crohn's Disease and has shown to be a safe and therapeutic treatment for these conditions. Ustekinumab has not previously been used in the treatment of SS and is not FDA approved for SS treatment. However, Psoriasis affects many of the same cells and proteins in the body as SS does. Therefore, the purpose of this study is to learn whether or not ustekinumab is safe for use in patients with SS, and if it has a similar effect on patients with SS as it does with patients with psoriasis.

Description of Study Procedures

If you decide to take part in this study, you will be asked to complete a total of 6 visits over the course of 24 weeks.

Visit 1: Screening visit (Up to 2 hours long)

The procedures performed in this visit will be used to determine if you meet eligibility criteria, including confirming your diagnosis of Sjogren's Syndrome. These procedures include:

- Review of your medical history
- Review of adverse events
- Review of your medications
- Complete physical exam
- Vital signs
- Unstimulated salivary flow assessment: You will not be able to eat or drink during or for 60 minutes prior to this test. You will be asked to spit into a cup for 15 minutes. Your saliva will then be weighed in order to determine volume. **If you are currently taking a drug to increase your saliva flow (such as Pilocarpine/ Salagen), you will be asked not to take the medication for 48 hours prior to this visit. Study staff will call to remind you of this before your visit.**
- Schirmer's test: If the results of your unstimulated salivary flow assessment do not meet a certain value needed for diagnosis, a Schirmer's Test will be performed. If your unstimulated salivary flow assessment does meet the value then this test will be skipped. For this test, a thin filter paper strip will be placed behind your lower eyelids on both eyes. You will be asked to close your eyes and remain there for five minutes. The paper strip will then be removed and the wetness of it will be measured in millimeters. **If you are currently taking medications to increase tear production (such as Restasis) you will be asked not to take the medication for 48 hours prior to this visit. If you normally use lubricating eye drops you will be asked not to use them the morning of your screening visit appointment. If you normally wear eye make-up you will be asked to not wear it to this visit. Study staff will call to remind you of this before your visit.**
- Blood Draw (28 ml; about 6 tsp): This will include a screen for HIV, Hepatitis B&C, Tuberculosis, a pregnancy test (if applicable; if you are a female of childbearing potential), safety labs and labs to confirm your diagnosis of SS.

- You may have already had some of these labs done as standard of care with your normal doctor. Even if you have had them done recently, we will not use those results. We will still collect them as part of the research study.
- You will need to sign a separate consent form to be tested for HIV. If you are found to be HIV positive, you will not be able to participate in this study. You will be notified of the positive result confidentially by your study doctor and offered counseling about HIV infection and notification of any partners. If you would prefer to receive counseling from your Primary Care Physician or another doctor, the study team will arrange this. Per the New York State law, your name will be released to the State Department of Health. Your medical records will be kept confidential to the extent permitted by the law.

- Eligibility criteria checklist

Visit 2: Baseline Visit (Up to 6 ½ hours long)

If you qualify for the rest of the study based on the results of your screening visit, you will be scheduled for the Baseline visit. The baseline visit will take place within 4 weeks of your screening visit, If you do not qualify for the study based on the results of your screening visit, you may be allowed to rescreen 4 weeks after your initial screening visit. You will not be allowed to rescreen more than one time.

- Review of eligibility criteria
- Review of changes in your medical history
- Review of changes in your medication
- Targeted physical exam
- Vital signs
- Review of any adverse events
- Unstimulated and Stimulated Salivary flow assessments: For the saliva flow rate test, you will be given a drug called Pilocarpine. Pilocarpine is a FDA approved drug used to stimulate flow of saliva and comes as a tablet to take by mouth. Before and 60 minutes after taking the Pilocarpine, you will be asked to spit into a cup for 15 minutes. You will not be able to eat or drink during or for 60 minutes prior to the test. **If you are currently taking a drug to increase your saliva flow, you will be asked not to take the medication for 48 hours prior to this visit. Study staff will call to remind you of this before your visit.** Your saliva will be weighed to determine volume.
- Assessments to measure your disease activity
- Blood draw (120 ml; about 8 tbsp.) and urine collection for safety labs, SS disease activity labs and research tests
- Urine pregnancy test / confirmation of birth control methods (if applicable)
- **Administration of study drug:** you will receive 650mg of acetaminophen and 60mg allegra at least 30 minutes but not later than 60 minutes before you receive

the study drug. These medications are to help prevent an infusion related reaction (such as itchy skin or back pain). If you have a history of an allergic reaction to either of these pre-medications, you will be offered an equivalent substitute. You will then receive an intravenous loading dose of study drug. The ratio is 6mg of study drug for every kg of body weight. The amount of drug you will receive will be calculated based on your body weight. The infusion will take approximately 60 minutes but could take up to 3 hours depending on how well you tolerate the infusion. For instance, if you have a mild reaction to the infusion the infusion will be paused and restarted at a slower rate. If you have a serious reaction to the infusion, the infusion will immediately be stopped and emergency medications will be administered if needed. You will be asked to wait for 60 minutes after the infusion so that you can continue to be monitored for any adverse reaction to the drug.

Visits 3, 4, 5: Week 4, 12, and 20 Visits +/- 4 days (Up to 1 hour long)

- Review of changes in your medical history
- Review of changes in your medication
- Targeted physical exam
- Vital Signs
- Review of any adverse events
- Blood draw for safety, research and SS disease activity lab tests
  - Week 12 - 120 ml; about 8 tbsp.
  - Weeks 4 & 20 - 9 ml; about 2 tsp.
- Urine pregnancy test/ confirmation of birth control methods (if applicable)
- **Administration of study drug:** you will receive 90mg of study drug as a subcutaneous (under the skin) injection. You will be asked to wait for 15 minutes after the injection in order to monitor you for any adverse reactions to the drug.

Visit 6: Week 24 +/-4 days / Early Termination Visit (up to 2 hours long)

- Review of changes in your medical history
- Review of changes in your medication
- Targeted physical exam
- Vital Signs
- Review of any adverse event(s)
- Unstimulated and Stimulated Salivary flow assessments: For the saliva flow rate test, you will be given a drug called Pilocarpine. Pilocarpine is a FDA approved drug used to stimulate flow of saliva and comes as a tablet to take by mouth. Before and 60 minutes after taking the Pilocarpine, you will be asked to spit into a cup for 15 minutes. You will not be able to eat or drink during or for 60 minutes prior to the test. **If you are currently taking a drug to increase your saliva flow, you will be asked not to take the medication for 48 hours prior to this**

visit. Study staff will call to remind you of this before your visit. Your saliva will be weighed to determine volume.

- Assessments to measure your disease activity
- Blood draw (120 ml; about 8 tbsp.) and urine collection for safety, research and SS disease activity lab tests

Follow-Up Phone Call (for female subjects of childbearing potential and male subjects with female partners of child bearing potential only)

A study team member will call you approximately 15 weeks after your last dose of study drug to see if you / your partner have become pregnant. If you / your partner are not pregnant then there will be no other follow-up. If you / your partner have become pregnant, the study team will follow the procedures as outlined in the reproductive section of this consent form.

Unscheduled visits

Should you experience symptoms of increased disease activity or new onset symptoms in between your normal scheduled visits, you may be asked to come in for an unscheduled visit. You will not be paid for unscheduled visits. Unscheduled visits may include:

- Review of changes in your medical history
- Review of changes in your medication
- Targeted physical exam
- Vital Signs
- Review of any adverse event(s)
- Blood draw (9 ml; about 2 tsp.) for safety labs

Information about your study participation and study results may be included in your electronic health record. If you have given a health care proxy access to your electronic health records, your test results might be accessible to them, including HIV status. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects

Approximately 15 subjects will take part in this study.

Drug Specific Risks

The possible discomforts, side effects and risks related to ustekinumab treatment are not all known. Most side effects are not serious. Some may be serious and may require treatment or additional testing. This section describes how frequently side effects occurred in subjects who were treated with ustekinumab.

In this section, the following terms are used:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100

- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000

Very Common:
- None

Common:
- Infection of the throat, airway or sinus
- Sore throat
- Fatigue
- Redness, pain or itchiness at drug injection site
- Headache
- Dizziness
- Diarrhea
- Nausea/ vomiting
- Back, joint or muscle pain

Uncommon:
- Swelling, itching, hardness, bleeding, bruising and irritation where the injection is given.
- Shingles (a painful rash)
- Depression
- Inflammation of tissue under the skin. Signs include warmth, swelling, redness and pain
- nasal congestion
- a form of psoriasis with raised bumps on the skin that are filled with pus
- Allergic reactions including rash or raised, itchy bumps
- tooth infections
- acne
- feeling weak
- vaginal yeast infection
- chest infection

Rare:
- Serious allergic reactions, which could be life-threatening (including low blood pressure, trouble breathing, swollen face, lips, mouth and/or throat)
- A form of psoriasis with redness and scaling of a much larger area of your skin or your entire body (erythrodermic psoriasis)
- In rare cases, symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction to ustekinumab
- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps, fever or joint pain (vasculitis).

Infections

Ustekinumab is a drug that may change how your body fights infections.
Serious infections requiring hospitalization for medical observation and /or treatment have been seen in ustekinumab studies. Some of these infections have also been life threatening.

Tell your study doctor if you have a new infection, if an infection keeps coming back, or if you have any signs of infection such as:

- Fever
- Chills
- Headache
- Coughing
- Congestion
- Chest tightness
- Shortness of breath
- Flu-like symptoms
- Night sweats
- Nausea
- Vomiting
- Diarrhea
- Increased frequency or burning while passing urine
- Redness, warmth, tenderness, or swelling of skin or joint
- Cold sores
- New or worsening of pain in any location
- Weight loss
- Tiredness

It is unknown if ustekinumab may stop you from developing a fever if you do have an infection, and therefore hide that you have one.

Fungal infections have been reported in subjects taking ustekinumab. Some of these fungal infections can be serious and involve internal organs. You should find out from your study doctor which fungal infections are common where you live or travel and what symptoms they cause. Tell your study doctor and family physician right away if you develop symptoms of such illnesses.

Subjects who receive ustekinumab may also be at a greater risk for certain serious infections such as tuberculosis. Tell your study doctor if you have ever had tuberculosis or anybody in your family has ever had tuberculosis or if you come in contact with someone who has tuberculosis. Tell your study doctor if you develop:

- a cough that does not go away
- coughing up blood
- shortness of breath
- fever
- night sweats
- weight loss

<u>Cancer</u>

Cancers have been reported in subjects who have received ustekinumab but it is unknown whether taking ustekinumab has increased their risk for developing cancer. Because ustekinumab may suppress your immune system, it is possible that it may increase your risk of developing cancer, including skin cancers. Subjects who have

been diagnosed with psoriasis have a higher chance of developing skin cancers. Tell your doctor if you have any new or changing skin lesions.

It is known that people who have had inflammatory diseases (such as, Crohn's disease, Rheumatoid Arthritis, Ulcerative Colitis etc.) for a long time and who use immunosuppressive therapies (such as, azathioprine, methotrexate etc.) for a long time have a higher risk of developing cancer. These people get cancer of the lymph nodes more often than other people.

Infusion Reactions, Injection Site Reactions and Allergic Reactions

Ustekinumab may cause an allergic reaction in some people. These reactions are usually mild to moderate. Your body might have a reaction during or shortly following an infusion of Ustekinumab into the vein. This is called an infusion reaction and these reactions are usually mild to moderate. They are managed by slowing the infusion or by giving you a medication. The following can be symptoms of an infusion reaction or an allergic reaction:

- Fever
- Chills
- Hives
- Rash Swelling
- Itching
- Headache
- Nausea
- Flushing
- Light-headedness
- Chest pain or tightness
- Wheezing
- Difficulty in swallowing or breathing
- Decrease or increase in blood pressure
- Anaphylaxis (life-threatening allergic reaction)

Serious allergic reactions have been reported in subjects taking ustekinumab and can be life threatening. If this happens during the infusion, the infusion will be stopped, Signs of a serious allergic reaction include skin rash, swollen face, mouth, lips, and/or throat, and trouble breathing. Tell your doctor or get emergency medical help right away if you have an allergic reaction. If you experience a serious reaction to an injection, you will not receive any more study treatments.

If you have an infusion reaction or an allergic reaction at the doctor's office, additional necessary treatment will be provided immediately. Your study doctor may give you an antihistamine (medication used to treat allergic symptoms such as hay fever) or other medications used for treating an allergy. Antihistamines can make you sleepy, so please use caution when driving a car or operating machinery.

Another type of allergic reaction has occurred in some subjects 1-14 days after receiving similar medications. The symptoms of this type of allergic reaction may include fever, rash, muscle aches and joint pain.

Antibodies to Ustekinumab

Sometimes the body can make special antibodies that may increase the risk of an allergic reaction to either ustekinumab or other antibody medicines. If you have an allergic reaction, you may not be able to have these types of medications in the future. You should always tell your doctors that you have been treated with human antibodies in this study.

Latex Allergy

The needle cover for the prefilled syringe that contains study drug contains dry natural rubber (a form of latex). This may cause allergic reactions in people who are sensitive to latex. Please tell your study doctor if you have ever had an allergic reaction or sensitivity to latex. You will not be able to take part in this study if you have a history of a life-threatening reaction to latex.

Cardiac and Vascular

Heart attacks and strokes have been reported in subjects who have received ustekinumab. These events have rarely resulted in death. It is unknown whether taking ustekinumab increases your risk for developing these events.

People who have certain other inflammatory diseases, have a higher risk of having heart attacks. These people have heart attacks more often than other people. You should seek medical care immediately if you develop;

- Chest pain or discomfort
- Trouble breathing
- Irregular heartbeats
- Dizziness
- Loss of balance
- New numbness or weakness
- Visual or speech changes

Vaccination

Vaccines are made to help protect people from certain illnesses. Some vaccines are made from live bacteria or live viruses. **You cannot receive most kinds of live vaccines (for example, FluMist™, varicella) during the study or for 3 months after the last study injection.** Another kind of live vaccine is BCG, which is a vaccine against tuberculosis. **You cannot receive a BCG vaccine during this study (from your first visit on) or for 12 months after the last study injection.** You could get sick from these kinds of vaccines while on ustekinumab. If you do get a live vaccination during this study, you must tell your study doctor immediately.

Tell your study doctor if anyone living in your home needs a live vaccine. Some viruses used in live vaccines can spread from a close contact (someone living in your home) to people with a weakened immune system.

Other kinds of vaccines, like tetanus and flu shots, and COVID vaccines that are not live, are allowed. It is not known if ustekinumab may interfere with them from working. Tell your study doctor before getting any vaccine while you are in this study.

Other Therapies

Tell your doctor if you are receiving treatments that weaken the immune system while using ustekinumab (For example, oral steroid medicines or biologics). These treatment combinations have not each been studied with ustekinumab, so it is unknown if they could possibly increase the risk of diseases related to a weakened immune system.

Tell your study doctor if you have ever had or are now getting allergy injections. ustekinumab may affect your response to allergy injections.

Other Drug Risk

Two cases of a very rare disease of the brain, posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical studies with Ustekinumab. PRES is generally reversible and is not caused by an infection. It is unknown whether taking Ustekinumab increases your risk of developing PRES/RPLS.Symptoms of this condition are:

- Headache
- Seizures
- Confusion
- Loss of eyesight

Tell your study doctor if you experience any of these symptoms.

There may be other discomforts or risks to you from this study that are not yet known. Your study doctor and staff will ask you about any side effects that you may have at every visit. If you have any problems, you should let your study doctor know right away.

Tell your doctors or dentist that you are or have been in a study where ustekinumab (an anti IL-12 and anti IL-23 drug) is the study drug. This is important if you have any surgery, dental procedures, or receive treatment for any other medical condition.

Other Risks of Participation

Subcutaneous Injection/ Infusion: Injection or infusion of a medication may cause temporary discomfort or pain, bleeding, bruising or phlebitis at the site. As with any insertion of a needle into the skin, there is a small risk of infection. The risks of injection will be reduced by its performance by a trained physician.

Infusion Pre-Medication: Allegra may cause drowsiness. Acetaminophen may cause liver damage in high doses. Part of the screening bloodwork includes liver function tests (AST/ALT) to exclude anyone who may have impaired liver function and might be susceptible to acetaminophen side effects.

Blood Drawing: Blood drawing may cause momentary discomfort or pain, bleeding, bruising, or phlebitis at the site. As with any insertion of a needle into the skin, there is a small risk of infection. Occasionally the subject may become dizzy or even faint. The risks of phlebotomy will be reduced by its performance by trained phlebotomists. Subjects will be seated during the blood draw to minimize dizziness and any risk of falling.

Salivary Flow: If you normally take a salivary stimulant, you will have to hold the medication for 48 hours prior to the salivary flow assessments. This may make your mouth feel drier than normal. The Pilocarpine that is given may cause flushing, sweating, or abdominal symptoms.

Schirmer's Test: If you normally take a medication for dry eyes or use lubricating eye drops, you will have to hold them prior to the Schirmer's Test. This may cause you to experience some discomfort or itchiness in your eyes or increased redness. The filter paper placed in your eye for the test may cause some mild irritation or discomfort. There is very little chance of infection.

Unknown Risks: The investigational treatments may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study. Though highly unlikely, if a previously unknown condition is discovered, you will be informed and an appropriate medical referral will be suggested.

Confidentiality: There is a risk of losing confidentiality of your information that is used in this study. However, steps have been and will be taken to help ensure that this does not occur. To protect subject health care information, each subject will be assigned a study number that will be used on all data sheets and to label all samples. The information will be de-identified and will be kept locked in an office and will only be available to the research staff. After the study is completed, the data may be placed in a central storage location or public database. This will include all of the information learned from this study and not just information specific to you. Any data will not include your name or other information that can identify you. The purpose is to make study data available to other researchers who must request permission to use it.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

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 website at any time.

Reproduction

The effect of ustekinumab on human sperm or unborn babies is not known.

Pregnant women and women who are making breast milk to feed infants cannot participate in this study. Female subjects must have a blood test when beginning this study that shows they are not pregnant.

It is very important that women taking part in this study do not become pregnant while taking part in this study and for at least 15 weeks after the last dose of study drug. If is very important that men taking part in this study do not get a woman pregnant while taking part in this study or for at least 15 weeks after the last dose of study drug.

During this study and for at least 15 weeks after the last dose of study drug, women of childbearing potential and men with female partners of childbearing potential must use proven birth control methods. Your study doctor will discuss effective birth control methods with you.
If you think that you have become pregnant or may have fathered a child while taking part in the study or for 15 weeks after your last dose of study drug, tell your study doctor immediately. You should also notify your childbirth doctor that the mother/ father received an experimental drug (Ustekinumab).

If you are a female study subject and you become pregnant during your participation in this study, your treatment with study drug will be stopped and you may be withdrawn from some of the study procedures but not from follow-up with your study doctor. The study doctor will ask for your permission to stay in contact with you throughout the length of the pregnancy.

If you are a female study subject, you must not donate eggs during the study and for at least 15 weeks after your last dose of study drug.

If you are a male study subject and you father a child during your participation in this study or within 15 weeks after your last dose of study drug, you will be asked by the study doctor for your partner's permission to stay in contact with her throughout the length of the pregnancy. Your partner will be asked to sign a separate pregnant partner consent form.

If you are a male study subject, you must not donate sperm during the study and for at least 15 weeks after your last dose of study drug.

If you become pregnant or father a child during your participation in this study or during 15 weeks after your last dose of study drug, your study doctor is required to notify the drug manufacturer of the pregnancy. Your study doctor will ask you/ your partner questions about the pregnancy such as how many weeks along in the pregnancy is, when the expected due date is, and if the pregnancy is a result of birth control failure. This information will be shared with the drug manufacturer. We will ask your permission to notify the childbirth doctor that you received an investigational drug (ustekinumab). We will provide you with information about the drug manufacturer's pregnancy registry that monitors pregnancy outcomes in women that have been exposed to Ustekinumab. We will encourage you to enroll in that registry.

Within 30 days of the expected due date, a member of the study team will contact you/ your partner by telephone to collect information about the outcome of the pregnancy. Information collected may include, but is not limited to, the type of delivery, the number of weeks of pregnancy at which you/ your partner gave birth, number of fetuses, and whether or not an abnormal pregnancy outcome (i.e. spontaneous abortion, stillbirth, congenital anomaly, ectopic pregnancy etc.) occurred.

If you/ your partner experience an abnormal pregnancy outcome from a pregnancy that occurred during your participation in this study or during the 15 weeks after your last dose of study drug, you should notify your study doctor immediately. Your study doctor is required to notify the drug manufacturer of an abnormal pregnancy outcome.

Benefits of Participation

You may not benefit from participation in this research study. There is no data on the treatment of Sjogren's Syndrome with ustekinumab. The purpose of this study is to determine the safety and effect of ustekinumab on Sjogren's Syndrome.

Alternatives to Participation

Taking part in this research study is voluntary. You do not have to take part in this study. Whether or not you take part in this study, you will continue to get regular care from your doctor, including receiving standard of care medications for your SS. You may also choose to take part in another study. You are encouraged to talk with your regular doctor, as well as the study doctor about your choices including the risks and benefits, before you decide if you want to take part in this research study.

Compensation for Injury

If you are directly injured by the study drug being studied, or by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the University of Rochester, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

Costs

You will not be charged for any of the study-related treatments or procedures. The costs of the investigational drug, all tests associated with the study, and all scheduled visits will be covered by the study. You will not have to pay for parking.

If you are due to have your blood drawn for your clinical care (i.e. standard of care labs) you may be given the option to have those labs drawn at the same time as the research

blood for your convenience. The study team will inform you of what labs would be drawn standard of care. Since standard of care labs are not part of this research, you and/or your health insurance provider will be responsible for paying that cost. This will be discussed with you prior to drawing blood and you will have the option to decline.

Payments

You will be paid $75 at the end of each completed scheduled visit. You will not be paid for unscheduled visits. You will also be given a parking pass if needed for each visit. The total possible amount you can be paid is $450.00.

Payment received for participation in research is considered taxable income. If you receive payment for your participation in studies at the University of Rochester and its affiliates of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be asked to complete a copy of this form and a copy will be sent to the IRS.

We will use your information and/ or samples for research only. However, the results of this research might someday lead to the development of products (such as a drug) that could be sold by a company. You will not receive any money that may result from any commercial tests or products that are developed as a result of this study.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will assign you a study number instead of labeling the information we collect from you with your name (or medical record number). Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services The University of Rochester Janssen Scientific Affairs, Inc.

- Investigators at other collaborating institutions
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

- Your/ your partner's childbirth doctor (if applicable) *Why will this information be used and/or given to others?*
- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Future Use of Samples (optional)
If any of your samples obtained for this study remain after all the tests for this study are completed, we would like your permission to preserve and store the remaining samples in our secure lab for future research. You will be given the option at the end of this consent form to decide if you would like your samples used for future research. You can withdraw consent to have your samples stored at any time and can continue to participate in this study.

We may share some of your leftover study samples, sample data and the clinical information we have gathered about you with investigators at other collaborating institutions. All identifiers will be removed before your samples/ information are used or distributed. Your samples and information will be given a study number. The information linking this number to your name and personal information will only be accessible by the study coordinators and the Investigators at the University of Rochester. You will not be informed of the results of any such future research, nor will you benefit financially from any potential new discoveries or technological advances brought about through future research using your sample(s).

Contact for Future Research Studies (optional)

We are developing a database of individuals who have taken part in our research studies and who might be interested in participating in future studies. The database is a document in which we will store individual's personal information and medical history. We will use the database as a central resource to assist in recruiting interested subjects for future research studies. If you agree we will store your information in our Repository database. Your personal information will be stored indefinitely in our repository database. This means that we will keep your personal information in our database forever or unless you tell us to remove your information. If at some future date you no longer want us to contact you using your information in our database, you may write us to request that we stop doing so.

Circumstances for Dismissal

You may be withdrawn from the study without your consent at the discretion of the Investigator and/or Sponsor for any reason including: Positive pregnancy test

- If you do not keep appointments for study visits
- If your disease becomes worse
- If you develop another disease or serious infection that will interfere with the study
- If your doctor feels that remaining in the study is harmful to your health
- Termination of funding for the study

If you are withdrawn from the study, you will be asked to cooperate by having laboratory tests and examinations necessary to complete your participation in the study.

In addition, you will be withdrawn from the study after the screening visit if we learn anything during the screening activities that would disqualify you for the study.

Early Termination

You may withdraw from the study at any time without loss of benefit or medical care which you are entitled to. You are encouraged to contact the study doctor or clinical staff should you decide not to continue participation in the study. They will explain the best way for you to discontinue your participation in the trial. You may be asked to be seen by the study doctor for an early termination visit.

New Study Information
If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Funding and Drug Support
The University of Rochester is receiving payment from Janssen Scientific Affairs, Inc. for conducting this research study.

Return of Research Results
Subjects with autoimmune diseases have lab tests performed regularly to monitor their disease. Standard of care labs drawn during the study visit for subject convenience, will be included in your electronic medical record. Subjects with access to MyChart will receive results at the same time as the investigator.

Your research results will not be available to you. There is a remote chance that a previously unknown condition could be discovered while examining your blood sample or during clinical assessments. Although unlikely, if this was to occur the study doctor would contact you and suggest an appropriate medical referral.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact: Dr. Ummara Shah at (585) 486-0901.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process; ▯ In the event the study staff could not be reached.

Voluntary Participation
Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

CONSENT TO FUTURE USE OF INFORMATION / SAMPLES

I agree to allow my samples, health information and/or sample data to be stored and shared with other researchers for future research?

Yes [ ] No [ ]

CONSENT TO RE-CONTACT

I agree to allow my personal health information to be stored in the division of Allergy, Immunology and Rheumatology's Repository database. The storage of my information will allow me to be contacted for future research studies.

Yes [ ] No [ ]

SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date