OREGON HEALTH & SCIENCE UNIVERSITY

IRB#:17902

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

Clinical Research Consent Summary

TITLE: Tofacitinib Hypothesis-generating, Pilot Study for Corticosteroid-Dependent Sarcoidosis

PRINCIPAL INVESTIGATOR: James Rosenbaum, MD (503) 494-8637

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

1. The purpose of this study is to learn more about the treatment of sarcoidosis.
2. In this study, we will learn about a drug called Tofacitinib. **Tofacitinib will be called "the study drug" throughout this form.** We want to learn:
    a. We want to learn whether this study drug can be used to treat sarcoidosis in patients who are requiring treatment with corticosteroids (like prednisone).
    b. We want to learn whether this study drug allows us to lower your dose of steroids.
    c. We want to learn whether markers in the blood that are related to sarcoidosis can be reduced with the use of the study drug.
    d. We want to learn if this drug is safe in patients with sarcoidosis.
3. The study drug is produced by Pfizer. Pfizer is paying for the research study.
4. We do not know if the study drug works in sarcoidosis.
5. This study drug is approved by the Food and Drug Administration (FDA) for rheumatoid arthritis and psoriatic arthritis. It has not been approved by the FDA for sarcoidosis
6. The study drug is a tablet taken by mouth twice daily.
7. This is an open label study, meaning that every patient who enrolls gets the study drug. There is no placebo pill.
8. If you join the study, you will receive the study drug for 16 weeks. The study duration is 16 weeks. You will have 7 visits to OHSU which includes a baseline visit.

9. If by the end of 16 weeks your steroids are able to be decreased by more than half your original dose and you are not experiencing any side effects, you will have the option to continue on study drug for up to one year. This will include 2 additional visits to OHSU.

10. There are risks involved in participating in the study, some of which may be very serious.

11. Samples and information collected during the study will be saved for future research.

12. Samples collected during the study will be used for genetic research.

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Clinical Research Consent and Authorization Form

TITLE: Tofacitinib Hypothesis-generating, Pilot Study for Corticosteroid-Dependent Sarcoidosis

PRINCIPAL INVESTIGATOR: James Rosenbaum, MD (503) 494-8637

CO-INVESTIGATORS: Marcia Friedman, MD (503) 494-8637
Janelle Stevens, DO (503) 494-8637

FUNDED BY: Pfizer Inc.

OHSU is being compensated by the funder to conduct this study. This is to pay for tests performed for study purposes, and for the time involved on the part of the investigator(s) and study staff. You may freely discuss this with your physician and the investigator if you have concerns.

PURPOSE:

You have been invited to be in this research study because you have sarcoidosis that requires continued steroids. The purpose of this study is to determine whether an investigational drug may help treat sarcoidosis.

The study drug may allow us to treat sarcoidosis more effectively and be able to lower your prednisone dose.

The use of the study drug in sarcoidosis is experimental. It has been approved by the FDA for use in rheumatoid arthritis and psoriatic arthritis, but not for sarcoidosis.

Following the enrollment visit, this study requires 6 visits to the clinic and will take 16 weeks to complete.

Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female.

The blood samples provided by you will be analyzed in the laboratory to determine whether certain genes that show increased activity in sarcoidosis, reduce their activity after treatment with the study drug.

We are asking you to provide blood and information for a blood and data bank, also called a repository. These samples will be stored indefinitely and may be used and disclosed in the future for research, which will include genetic research.

This study will be conducted at OHSU and aims to enroll five patients.

PROCEDURES:

This is an open label study, meaning that there is no placebo group. If you enroll in this study you will receive the study drug.

This study will take place over 16 weeks. If you enroll in this study you will receive the study drug for 16 weeks. The study will involve 7 total visits. At the initial visit you will be asked to fill out questionnaires, have blood drawn, undergo a physical exam, and have breathing tests done (called pulmonary function tests). The second, third, fourth, fifth, and sixth visits will involve physical exams, questionnaires, brief breathing tests (called spirometry), and blood draws. At your 6th study visit you will also repeat your full pulmonary function tests. This information is detailed in the table below.

During this study we will be decreasing your steroid (also called prednisone) dose. For the first month your steroid dose will be kept the same. After the first month your steroids will be gradually decreased. If at any time during the steroid taper your disease worsens beyond the three days after the dose reduction, we will increase you to the previous dose for 2 weeks. After 2 weeks on that dose we will try to lower your dose more gradually. If you are unable to tolerate the steroid dose reduction, you will be maintained on the effective steroid dose for the duration of the study.

If by the end of 16 weeks, your steroids are able to be decreased by more than half the original dose at the start of the study and you are not experiencing any side effects, you will have the option to continue on study drug for up to one year. This will include labs every 2 months at OHSU, a phone call check in every 3 months and a clinic visit every 6 months until the end of the extension period.

Procedures	Baseline	Week 0*	Week 2	Week 4	Week 8	Week 12	Week 16
Informed Consent	X						
Screening Blood draw (2 teaspoons)	X						
Urine pregnancy test (women only)	X						
Start study drug		X					
End study drug							X
Start steroid taper				X			
Physical Exam	X		X	X	X	X	X
Pulmonary Function Tests	X***						X
Pulmonary Function Tests				X	X	X	
Routine Blood Draw (2-4 teaspoons)	X***		X	X	X	X	X
Genetic Blood Draw (2 teaspoons)	X						X
Questionnaires: Symptom assessment	X		X	X	X	X	X
Medication Reconciliation			X	X	X	X	X
Chest Xray	X**						X
Length of Visit	*2-4 hours*	*0-2 hours*	*1-2 hours*	*1-2 hours*	*1-2 hours*	*1-2 hours*	*1-2 hours*

* There should be no more than 4 weeks between baseline and start of study drug (week 0)
**If screening labs or a Chest Xray have been done within the past one year, they do not need to be repeated here.
***If these tests have been done within 4 weeks of baseline visit, they do not need to be repeated. If done at another institution records will be requested.

All of the above procedures, testing, and study drug will be billed to the study. Patients and their insurance will not be billed for any of the above procedures during the 16 week study. Patients continuing on to long-term follow up may have laboratory testing billed to insurance as below under "Long term follow-up".

Women who can become pregnant must have a negative pregnancy test before enrolling in the trial. For females, adequate birth control methods will be defined as: hormonal contraceptives, intrauterine device or double barrier contraception, i.e., condom + diaphragm, condom or diaphragm + spermicidal gel or foam. For males, Adequate birth control methods is defined as: use of a condom and/or female birth control methods including: hormonal contraceptives, intrauterine device or double barrier contraception, i.e., condom + diaphragm, condom or diaphragm + spermicidal gel or foam.

Spirometry or pulmonary function testing evaluates how your lungs work by measuring how much and how fast air moves out of your lungs. You will wear a nose clip and forcefully blow into a tube hooked to a machine.

Questionnaires and surveys will be used to see how you are doing. We will be asking you questions about how you have been feeling and how your illness is affecting your ability to function, questions about your physical symptoms, questions about how your medications are affecting you, and questions about medication side effects. These questionnaires should take you no more than 15 minutes to complete.

If you enroll in this study, the investigators will be reviewing your OHSU medical record. If outside records are necessary, you will be asked for written permission prior to collecting outside records.

In the future, your blood samples may be shared with other researchers for other research studies. These studies will include genetic research. The samples and information will be labeled as described in the **CONFIDENTIALITY** section.

RESEARCH REPOSITORY

Generally, a research repository collects, stores and distributes human specimens (samples of blood, tissue, or body fluids) and/or data for use in future research projects. Storing and gathering lots of specimens and data together can help to conduct future research and avoid re-collecting specimens and data over and over again. With this stored information and samples, researchers may understand better how the human body works, develop new tests to find diseases, find new ways to treat diseases, or develop new products, such as drugs.

The purpose of this repository is to learn more about sarcoidosis, and to learn more about how patients with sarcoidosis respond to tofacitinib. We will be looking at the relationship between genes, sarcoidosis, and tofacitinib.

We will collect your blood sample and information about your medical history.

At the start of the study, we will collect about 1 tablespoon of blood which will be stored in the repository. After completion of the study, we will collect another 1 tablespoon of blood which will

be stored in the repository. We will also review your medical record and collect information about your sarcoidosis (how it has affected you, how long you have had it, and what you have tried to treat it), your other medical conditions, medications you have taken, allergies, and results of your laboratory tests and imaging studies.

The blood work that we collect will be used to study genes in sarcoidosis. These genetic tests are experimental.

ACCESS TO YOUR TEST RESULTS

We will share with you the results of your non-genetic blood tests and breathing tests. The results will be placed in your medical record.

The results of the genetic tests will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

If we discover information that is important for your health care, either in this study or in the future, we will contact you and ask if you want to know the results. If you choose to receive the results, you may need to have the test repeated in a non-research laboratory. You may learn information about your health that is upsetting or that impacts your family planning, family relationships, and ability to get insurance. Because genetic information is complex and sensitive, the results should be discussed with a genetic counselor or your primary care giver who can answer your questions or discuss your concerns. You would be responsible for all costs associated with having the test repeated and visiting a doctor or genetic counselor to discuss the results.

The blood tests and breathing tests are being done to answer research questions. If we find an abnormality that requires urgent follow-up, we will contact you and your doctor (with your permission) to help answer questions and get the right follow-up care for you. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

RISKS AND DISCOMFORTS:

SIDE EFFECTS OF TOFACITINIB

Common side effects (these may affect up to 1 in 10 people, or up to 10%)	• Upper respiratory tract infection (nasopharyngitis, common cold) • lung infection (pneumonia and bronchitis) • shingles (herpes zoster) • influenza (flu) • sinusitis • urinary bladder infection (cystitis) • sore throat (pharyngitis) • increased muscle enzymes or cholesterol • weight gain • stomach (belly) pain (which may be from inflammation of the stomach lining) • vomiting, diarrhea, nausea, indigestion • pain in the joints • low red blood cell count (anemia) • fever • fatigue (tiredness) • swelling of the feet and hands • headache

	• high blood pressure (hypertension) • cough • rash
Uncommon side effects (these may affect up to 1 in 100 people, or up to 1%)	• Tuberculosis • kidney infection • viral infections • skin infection • herpes simplex or cold sores (oral herpes) • viral infections affecting the gut • increased liver enzymes • low white blood cell count • blood creatinine increased (a possible sign of decreased kidney function) • dehydration • pain in the musclesmuscle strain, tendonitis, joint swelling, ligament sprain, abnormal sensations, poor sleep • shortness of breath or difficulty breathing • sinus congestion • skin redness, itching • fatty liver • inflammation of outpouchings of your intestine (diverticulitis), tears in your stomach or intestines • some types of skin cancers (nonmelanoma-types).
Rare side effects (these may affect up to 1 in 1,000 people, or up to 0.1%)	• Blood infection (sepsis) • joint infection • tuberculosis involving the brain and spinal cord, bones and other organs • other unusual infections.

1. SERIOUS 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, 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. The risk of shingles (herpes zoster) in Asian people may be higher than for non-Asian people.

After starting tofacitinib, call your study doctor right away if you have any symptoms of an infection. Tofacitinib can make you more likely to get infections or make worse any infection that you have.

2. 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.

3. 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.

4. CHANGES IN CERTAIN LABORATORY TEST RESULTS

Your study doctor will do blood tests before you start receiving tofacitinib and while you take tofacitinib. Some changes in blood tests that can occur with tofacitinib include:

- Changes in lymphocyte counts. Lymphocytes are white blood cells that help the body fight off infections.
- Low neutrophil counts. Neutrophils are white blood cells that help the body fight off infections.
- Low red blood cell count. This may mean that you have anemia, which may make you feel weak and tired.

Your study doctor will routinely check certain liver tests as these can increase with tofacitinib treatment. You may also have changes in other laboratory tests, such as your blood cholesterol levels. Small changes in a test for muscle injury and a test for kidney function may also occur.

5. EFFECTS ON PREGNANCY

In animals, tofacitinib has been shown to have effects on fertility (the ability to become pregnant or maintain pregnancy), birth defects and delivery (delay, stillborn births or acute newborn death).

You should not take tofacitinib if:

- You plan to become pregnant during the study or are pregnant. It is not known if tofacitinib will harm an unborn baby.
- Plan to breastfeed or are breastfeeding.
- If you think you are pregnant, tell the study doctor immediately. Pregnancy will be a reason to stop study treatment.

If you are nursing an infant or you are pregnant now, you must not be in the study. This study may involve risks to an embryo, fetus, or nursing infant that are currently unknown. If you are sexually active and could become pregnant, you and your male partner(s) must use birth control that works well. or you must not have sex. For females, adequate birth control methods will be defined as: hormonal contraceptives, intrauterine device or double barrier contraception, i.e., condom + diaphragm, condom or diaphragm + spermicidal gel or foam. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell the investigator and your doctor immediately.

The drugs in this study may damage sperm or be present in seminal fluid. You should not father a child or donate sperm while you are in this study. If you are a sexually active male and could cause a pregnancy, you must be sure that your female partner(s) are using birth control that works well or you must not have sex. This study may involve risks to an embryo or fetus that are currently unknown. The investigator will talk to you about the types of birth control that are acceptable. If a sexual partner becomes pregnant during the research study, please tell the investigator and ask your partner to tell her doctor immediately that you are involved in a clinical study.

GENERAL RISKS

- You may have some side effects we do not expect because we are still learning about how the study drug works in people who have sarcoidosis. You may not have symptoms for some of these side effects, such as abnormal lab results, but you will be monitored by the investigator to check for any changes throughout the study.

- One risk to taking part in this study is that the study drug or the dose you receive may not be effective in helping to treat your disease. This means you may spend time in the study and experience side effects taking a drug that may not provide you with any health-related benefits but may benefit others with the disease.

- There are several drugs (prescription and non-prescription) that may cause problems when taken with the study drug. The investigator will carefully review all of the drugs you are taking before giving you the study drug. If any other health care provider prescribes any new drug(s) for you while you are in this study, please tell the investigator before you take the new drug. You could also have that provider talk to the investigator before prescribing the new drug. Do not take any new over-the-counter drugs while you are in this study unless you first check with the investigator

- A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

- Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality. If the results of these studies of your genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are certain genetic discrimination and confidentiality protections in both Oregon law and federal law, there is still a small chance that you could be harmed if a release occurred.

PROCEDURE RISKS

- We will draw blood from your arm or hand. You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting.

- Spirometry or pulmonary function testing may make you cough or feel lightheaded. This will go away shortly after the test is finished.

- Some of these questions asked in the questionnaires may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

BENEFITS:
You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

ALTERNATIVES:
You may choose not to be in this study. If you do not choose to be in this study, there are other drugs for sarcoidosis that your doctor may use to treat you.

CONFIDENTIALITY
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU will use the information we collect and create about you in order to conduct and oversee this research study. They will also store your information and blood specimens in a repository to conduct future research.

Your blood sample will be stored in a freezer in Dr. Jim Rosenbaum's laboratory. Once the study is finished, your sample will be assigned a code that does not contain any personally identifying information. Only Dr. Rosenbaum and his team will have access to the code to re-identify your sample. Your medical information will be stored on a password protected document on an encrypted OHSU drive. Only Dr. Rosenbaum and his team will have access to this information. The samples and data will be stored indefinitely.

Data/specimens from this study may be shared with other investigators for future research studies. A code number will be assigned to you, your cells and genetic information, as well as to information about you. Only the investigators and people involved in the conduct of the study will be authorized to link the code number to you. Other investigators who may receive samples of your blood/ genetic information/medical information for research will be given only the code number which will not identify you.

We will release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, Pfizer Inc., and the funder's representatives
- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records, including your medical records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

Data and specimens from this study may be shared with other investigators for future research studies. All identifying information about you will be removed from the samples before they are released to any other investigators.

Your genetic information may be shared in a public online database for future research. The database will not contain any information that directly identifies you, such as your name, address, or birth date, so it is unlikely that someone would know the genetic information came from you. In the future, people may develop ways to identify you or your blood relatives from this information, but currently, there is not a way to identify you without having additional information to compare to it, such as information from your DNA sample.

We may continue to use and disclose your information as described above indefinitely.

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

COMMERCIAL DEVELOPMENT:

Samples and information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

COSTS:

Some of the services or items in this study are part of the regular treatment for your condition. These would be performed or used even if you were not in this study. The costs for these services or items will be billed to your insurance. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company. If you are uninsured, you will be responsible for these costs.

You will not be billed for the costs of any services or procedures that are required by the study but are not considered part of your regular treatment.

If enrolled in this study, you will be compensated for participation in the study. You will receive $50 per visit that you complete via a debit card up to $400 total over the course of the study. If you withdraw before completing the study you will not receive the full amount.

You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet.

LIABILITY:

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Marcia Friedman, MD at (503) 494-8637. In the case of an emergency you should contact 911.

If you are injured or harmed by the study drug you will be treated. OHSU and the funder do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act [ORS 30.260 through 30.300]) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

PARTICIPATION:

If you have any questions, concerns, or complaints regarding this study now or in the future, contact James Rosenbaum, MD (503) 494-8637 or other members of the study team at (503) 494-8637

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Marcia Friedman, MD
3181 SW Sam Jackson Park Rd.
Mail Code OP09
Portland, OR 97239
friedmam@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If you do chose to withdraw from the study, you will be requested to answer questions regarding side-effects you may have had, and we will ask to draw your blood two weeks after you withdraw from the study to evaluate for any side effects from the study drug.

The samples and information we will collect from you will be provided to the funder (Phizer). It will be stored with a coded identifier to protect your privacy. Once provided to the funder, we will not be able to destroy your samples or data if you decide in the future you do not wish to participate in the research.

You may be removed from the study if the investigator or funder stops the study, you become pregnancy, you develop serious side effects, your disease gets worse, or you do not follow study instructions.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the subject in _____ (state language) by an individual proficient in English and _____ (state language).

If applicable:

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.