JAK Inhibition in Food Allergy

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STUDY INFORMATION:

Study Title: JAK Inhibition in Food Allergy

Study Site: Icahn School of Medicine at Mount Sinai

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to test a new medicine, abrocitinib, for its effect in people with food allergies.

The investigators are trying to learn if this drug shows an effect on food allergy; the drug was FDA approved in January 2022 for adult patients with eczema but is not FDA approved for food allergy. You should not be taking any oral steroid medicines or injectable medicines for your eczema. Research subjects will receive either 100 mg or 200 mg of abrocitinib daily for 4 months. There is a 50% chance (like a coin flip) to receive one or the other dose, but you will not be told the dose you are taking.

If you choose to participate, you will be asked to:

- Take abrocitinib daily for four months
- Have blood, urine, skin, and breathing tests at up to five visits
- There are no associated costs. The study drug, procedures and visits will be provided at no charge to you or your insurance company.
- After study tests are run, your samples can be destroyed or kept for future studies
- You will be compensated modestly for your participation in this study

If you choose to participate, the most common side effects (over 5% of people) are: nausea, headache, and common cold symptoms.

You may benefit from participation in this research if you have active atopic dermatitis or eczema (rashes on your skin might improve).

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you have a food allergy and current atopic dermatitis or a history of atopic dermatitis, also known as eczema.

Your participation in this research study is expected to last up to 26 weeks, which includes screening and follow up visits. You will need to visit the study site about 4 times during the study (after the first visit) and receive 2 telephone calls from the study team.

Up to 48 people are expected to take part in this research study at Mount Sinai.

Funds for conducting this research study are provided by Pfizer Inc.

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

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

- The study begins with a screening visit around two weeks before the initial visit to ensure that you qualify to continue in the study. At that visit, you will review and sign a consent, have a physical examination, vital signs, and medical history taken, and have urine, blood and allergy skin tests performed. You will need to stop taking antihistamine type medications (like Benadryl, Zyrtec, Allegra, Claritin and others) for a number of days prior to each visit when allergy skin tests are done. Blood tests will include screening for infections like HIV, hepatitis B and C, and tuberculosis (TB). If you have positive test results for HIV, TB, or Hepatitis B or C, we will notify you. We are required to notify state health authorities of positive results. The urine test will screen for pregnancy, if you are a female capable of having children.
- If you qualify, you will come to four additional visits at the Clinical Research Unit or another research site at Mount Sinai Hospital. You will interact with doctors, nurses, and coordinators.
- Visits will occur on the first day of the study and at week 4, 16, and 20. Visits should take less than 1 hour. There are also 2 monthly telephone calls to check how you are doing at week 8 and 12.
- At each visit, there will be a physical examination, urine, skin, and breathing tests. There will also be blood tests at screening and at the week 4, 16, and 20 visits.
- The experimental procedures will include blood and skin tests. The daily medication is also experimental. The medication that you will take is called abrocitinib. It is FDA approved for adult patients with eczema but is not FDA approved for food allergy.

- Blood draws will be approximately 2 ounces at each visit.
- Any relevant results will be disclosed to you about allergic response (after the end of the study) or blood counts.
- Because this research study involves the use of the study drug abrocitinib, a note must be included in your electronic medical record that you are taking part in the research. This way, anyone involved in your medical care will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know.

DETAILED DESCRIPTION OF VISITS

Screening Visit

After signing this consent document, the study will begin with a screening visit. The purpose of the screening visit is to find out if you meet all the requirements to take part in this study. Procedures that will be completed during the study (including screening) are described below. If you do not meet the requirements, you will not be able to take part in the study. The study doctor will explain why and will discuss other options with you, if available.

Study Drug

If you meet all the requirements and you decide to participate, you will be assigned by chance (like flipping a coin) to receive either a higher dose of abrocitinib (200 mg) or a lower dose of abrocitinib (100 mg). You will have a 50% (1 out of 2) chance of receiving the higher dose and a 50% (1 out of 2) chance of receiving the lower dose. The tablets will look alike whether it is the higher or lower dose of the study drug.

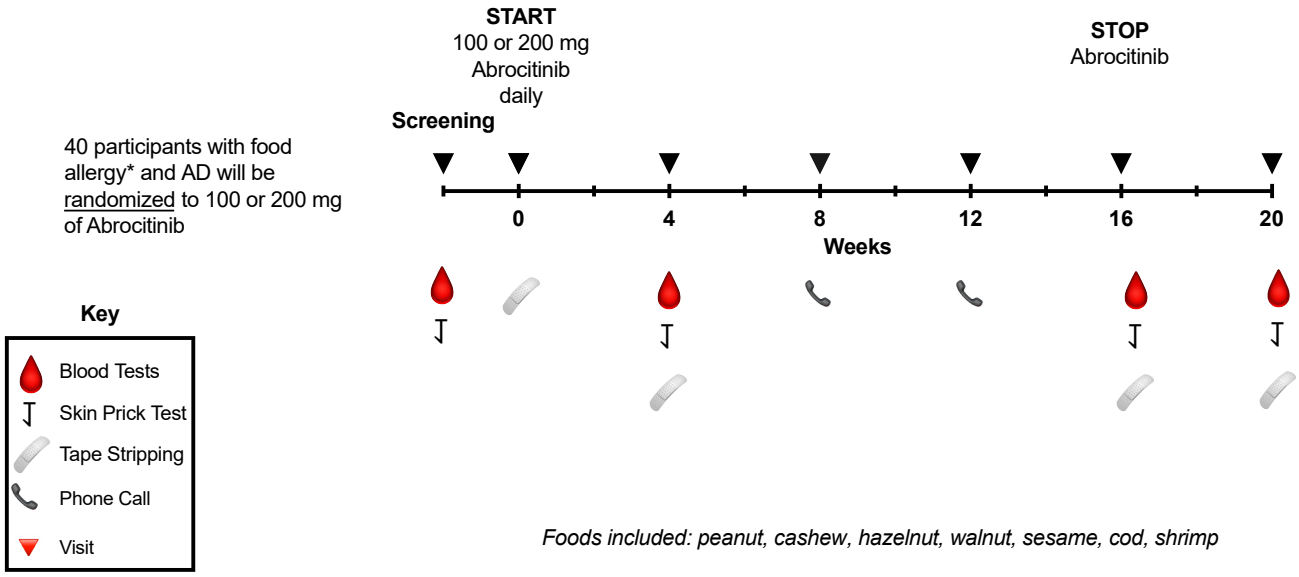
This is a double-blind research study, which means that you, your personal doctor, and the study team will not know which dose you are receiving. This is done to make sure that the study results cannot be unfairly influenced by anyone. In case of urgent need, the study doctor can learn quickly which drug dose you are receiving.

You will be provided with the study drug at study visits. You will receive detailed instructions about how to store and take the study drug. Study drug will be supplied in tablet form and is to be taken by mouth once a day for the whole study.

Bring your study drug to the study site at each visit.

Overview of visits and assessments

This timeline and table summarize the visits and assessments for the entire study. In addition to the visits listed, the study doctor may ask you to come in for extra visits if necessary to protect your well-being.



Foods included: peanut, cashew, hazelnut, walnut, sesame, cod, shrimp

	VISIT 0 (Day -7 to -14)	VISIT 1 (Day 0)	VISIT 2 (Month 1)[a]	Phone Call 1 (Month 2)[a]	Phone Call 2 (Month 3)[a]	VISIT 3 (Month 4)[a]	VISIT 4 (Month 5)[a]
Informed Consent	X						
Medical History	X	X					
Complete Physical Exam and BSA	X						
Abbreviated Physical Exam and IGA		X	X			X	X
Height and Weight		X					
Vital Signs	X	X	X			X	X
Spirometry (if feasible) and FENO		X	X			X	X
Tape Stripping		X	X			X	X
Safety Labs[b]	X		X			X	X
Pregnancy Test (Urine or Serum)	X	X	X	X	X	X	X
Total and Specific IgE	X		X			X	X
Research Blood Tests (Immunology and Proteomics) and skin prick test	X		X			X	X
Dispensing or Administration of Study Drug		X	X				
Counting of Returned Study Drug			X			X	
Adherence and Concomitant Medications Review	X	X	X	X	X	X	X
Adverse Experiences		X	X	X	X	X	X

[a] +/-7 days

[b] At Visit 0, Safety labs include lipid panel, chemistry, infectious screening, a CBC with Platelets and Diff. At Visit 2, safety labs include lipid panel, chemistry, and CBC with Platelets and Diff. At Visits 3 and 4, safety labs include chemistry, and CBC with platelets and diff.

DETAILED DESCRIPTION OF STUDY PROCEDURES AND ASSESSMENTS

Physical Examination: Physical examination, an examination of certain body systems such as the heart and lungs, will be performed at every visit. Weight and height may also be measured.

Pregnancy Testing: Pregnancy testing is a test in females of urine (each visit) to check for pregnancy. Pregnant subjects cannot participate in the study.

Skin Prick Testing: Liquid extracts of foods, and also salt water and histamine, are scratched on the surface of the skin, and any itchy bumps are measured.

Spirometry and FENO tests: You may blow into a machine to evaluate for any signs of asthma.

Vital Signs: Vital signs include blood pressure, pulse rate, respiratory rate, and temperature.

Required Biological Samples: The following biological samples will be taken in this study. You must provide these samples in order to take part in this study**.**

Blood Samples: Blood draw is the process of collecting blood from a vein through a needle. The needle is connected to a small tube in which the blood is stored until it is tested. You will need to fast (not eat or drink anything except water) for at least 8 hours prior to a blood draw on certain study visit days (screening and Week 4). The total amount of all the blood taken during the study if you complete all 20 weeks will be approximately 240 mL (about 8 ounces). Your body will easily replace this amount.

Safety Testing**:** You will be required to provide blood samples to undergo routine safety testing and testing for viral infection. Blood sample(s) will be taken and used to conduct the tests and analyses described below. You may be required to have additional blood taken to recheck blood test results.

Your blood will be collected for routine safety testing that includes:

- **Hematology Panel:** includes hemoglobin, hematocrit, red blood cell count and morphology, white blood cells (% and actual number), and platelets.
- **Chemistry Panel:** includes creatine kinase, blood urea nitrogen (BUN); serum creatinine; glucose; electrolytes [Ca++, Na+, K+, Cl-]; total CO2; aspartate aminotransferase (AST); alanine aminotransferase (ALT); gamma-glutamyl transferase (GGT); total, indirect and direct bilirubin; alkaline phosphatase; lactate dehydrogenase; uric acid; albumin; and total protein.
- **Lipid Panel:** collected on fasting days only, a lipid panel includes total cholesterol, LDL, and HDL. A minimum of 8 hours fasting is required for lipid profile evaluation.
- **Viral infections:** At the Screening visit only, your blood will be collected to test for viral infections. The study doctor might be required to disclose the results of these tests to local health authorities, depending on the country in which you live and the local laws that apply. Your blood will be taken to test for hepatitis (looking for signs of inflammation of the liver or viral infection of the liver known as Hepatitis B or C infection). Your blood will also be used to check if you have human immunodeficiency virus (HIV) infection, a condition that lowers a body's defense system to fight illnesses. The results of all of your blood tests, just like all other laboratory test results, will be provided to the Sponsor. Positive HIV and Viral Hepatitis test

results may be reportable to local health authorities according to local laws. Your blood test results must be negative for these infections to take part in this study.

- **Tuberculosis:** A 3 mL sample of your blood (less than 1 teaspoon). At the time of screening, you will undergo tuberculosis (TB) testing unless a TB test was performed within 12 weeks of Day 1. A blood test (QuantiFERON®TB Gold InTube Test) is the preferred testing method. If the QuantiFERON®TB Gold InTube test cannot be performed, or if the results cannot be determined by the reference laboratory to be either positive or negative, then subjects may be referred to their primary care doctor for a Purified Protein Derivative (PPD) Tuberculin Skin Test (Mantoux method).

***Urine Samples*:** Some of your urine will be tested at every visit, if you are a female who is capable of having a baby. Your urine will be tested at every site visit to see if you are pregnant. If you are pregnant, you will not be allowed to participate in the study.

***Total and Specific IgE Tests*:** Some of your blood will be tested for allergic antibodies to the foods included in this study (peanut, cashew, hazelnut, walnut, sesame, shrimp, cod) at screening and visits 2-4 (weeks 4, 16, and 20).

***Tape Strip Assessment*:** Adhesive pieces of tape will be applied and removed on clear areas of your skin at each visit.

Required Health and Medication Questions:

- At all study visits and during phone calls, questions will be asked about your health, medical history, medications, and methods of contraception practiced (for females who can biologically have a baby). At all study visits, your study doctor will examine your body and determine the severity and extent of your AD.
- You will need to answer questions about your food allergy called Patient Reported Outcomes (PROs). These questions are used to determine how your treatment is affecting your food allergy and your usual activities. The PROs are described below.

Follow-up Procedures

After completing four months of study drug, you will enter a 4-week untreated follow up period. After this 4-week period, you will return to the study site for these follow up procedures. This is the end of study and the final safety check.

The following procedures will be performed at this visit:

- Targeted physical examination
- Vital sign collection (blood pressure, pulse rate, respiratory rate, and temperature)
- Blood samples collected for allergy tests and safety
- Urine collection for pregnancy test (if female able to conceive)
- Study doctor will assess your skin
- Skin allergy tests and tape strips
- Review medications and treatments from your last visit
- You will be asked how you are feeling

- You will be asked if you are compliant with the contraception requirements of the protocol

The study team may contact you after your last study visit to learn more about how you are doing. The study team may ask you to come back for a visit to check on your well-being. If you leave the study early, the study team may request an early termination (end) visit similar to visit 4.

Randomization

Participants in this study will receive one of two doses of study medication (100 mg or 200 mg abrocitinib). The dose you get will be chosen by chance, like flipping a coin, using a process called randomization. Neither you nor the study doctor will choose what dose/amount you get. You will have an equal chance of being given either a 100 or 200 mg daily dose of abrocitinib. Neither you nor the study doctor will know which dose you are getting; however, this information could be obtained in an emergency.

HIV/AIDS

To take part in this research study, your blood will be tested for evidence of HIV, the virus that causes AIDS. People can get HIV through unprotected sexual contact with someone who has HIV, and through contact with blood (as in sharing needles including for piercing, tattooing, and injecting drugs). People who are pregnant with HIV infections can transmit HIV to their infants during pregnancy, delivery or while breastfeeding. There are treatments for HIV/AIDS that can help people stay healthy. People with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from getting HIV or getting infected with a different strain of HIV.

By law, positive test results for HIV/AIDS (as well as other communicable diseases such as hepatitis B, hepatitis C, and syphilis) are reported to the NYS Department of Health so they can study how people get and transmit the disease and notify sexual or needle-sharing partners they may have been exposed. If you wish to be tested anonymously for HIV/AIDS, the research team can refer you to a public testing center, but you will not be able to be in this study. New York State law protects the confidentiality of HIV test results and other related information. It is illegal to discriminate against a person based on their HIV status and services are available to help if this happens. You are free to refuse to get an HIV test, but if you refuse you cannot be part of this research study.

Pregnancy

If you can possibly get pregnant, a blood or urine test for pregnancy will be done before you begin the study, and the pregnancy test will be repeated at various time points throughout the study.

You cannot be included in the study if you are or become pregnant, as the study drug could harm your fetus. You also should not be in the study if you are producing milk to feed a child as the study drug could harm your baby.

Unless you are at least one year past menopause or have had a successful operation to make pregnancy impossible, you should use effective birth control. Unless you are sexually abstinent (not having genital sex), the recommended methods of birth control are:

- The consistent use of approved hormonal birth control (pill, patches, or rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual activity),
- Sterilization (a vasectomy, getting tubes tied, or a hysterectomy).

All birth control methods (other than abstinence and sterilization) are only effective if you use them properly, start them at least one month before you begin the research study, and continue using them throughout the research study and for one month after the research study ends. If you are unsure whether the method of birth control you use is approved to use while you are in this study, you should ask the Lead Researcher before you begin the study. If you are less than one-year post-menopausal, you could still become pregnant. If you or your partner becomes pregnant, or may be pregnant, at any time during the study, you must stop the study drug and tell a person from the research team immediately. The team may refer you/your partner to an obstetrician/gynecologist for follow-up. Should you/your partner become pregnant, whether or not you/your partner have the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if you are no longer part of the study. You/your partner will be asked for additional written consent to share this information if that happens.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If “Yes”, please indicate your preferred method of contact: (initial all that apply)

_____ Email _____ Phone _____ Letter _____ Text

USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select ‘No’ each time.

(1) Will you allow the researchers to store your data and/or samples to use in future research studies?

Please initial your choice: Yes_____ No_____

If you select No, please stop here and move to the next section, '**Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

(2) The researchers can store your data and/or samples in one of two ways:

a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can't change your mind. So, if you wanted to have your data and/or samples destroyed in the future, the team could not do it as they would not know which data and/or samples were yours.
b) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

How would you like your data and/or samples stored? Please initial **ONE** choice below:

I would like my data and/or samples stored anonymously _____

I would like my data and/or samples stored with a link to my identity through the use of a code_____

(3) Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____ No_____

(4) Do you give the researchers permission to keep the data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____ No_____

(4.1) From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data and/or samples?

Please initial your choice: Yes_____ No_____

a. If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done.

b. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:

I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.

II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

(5) Do you give permission to have your data and/or samples given **to other researchers,** including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

Please initial your choice: Yes_____ No_____

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: taking prescribed medications, using birth control methods as described in the Description of What's Involved section, avoiding certain medications (steroids, immunosuppressants, biologics, *environmental or food immunotherapy, anticoagulation therapy, herbal medicine, and others), and attending study visits. If you are taking antihistamines, you will need to stop these medications for a brief time for allergy skin tests.*

It is important that you:

- Continue to avoid all of the foods to which you are allergic. You must continue the avoidance previously recommended by your allergist/personal physician. You must continue to treat any allergic reactions as prescribed outside of the study, including understanding when and how to use self-injectable epinephrine.
- Tell the study doctor if you previously took part in this study, have been in any other study in the past year, or are currently involved in any other study.
- Do not take part in any other study without approval from the study doctor. Tell the study doctor immediately if you are taking part, or want to take part, in other studies while you are taking part in this study. Participating in more than one study at the same time could put your safety at risk.

- Follow the instructions you are given by the study doctor and study team. If you do not follow the instructions, your visit may have to be rescheduled and/or you may not be allowed to continue to participate in this study.
- Tell other doctors, nurses, and health care providers about your participation in this study by showing the information card provided to you by the study team.
- Tell the study doctor or the study staff about all prescription and non-prescription medications, supplements, or vaccines (*e.g.*, flu shot) before you take them.
- Notify the study team if you move and provide your new contact information.
- Do not throw the study drug in the trash or flush it down the toilet. Do not give your study drug to any other person. Keep the study drug out of the reach of children and others who cannot read the label.
- On study visits taking place at Day 1 and Week 4, ensure you do not eat or drink anything but water for at least 8 hours prior to the visit.
- On study visit days, take your prescribed, permitted, usual medication as needed, before the study visit, if it can be taken with water only. Prescribed, permitted medications that must be taken with food or after meals should not be taken until instructed to do so by the study doctor.
- On study visit day, you should not smoke or drink caffeine (e.g., tea, coffee, some soft drinks/colas/energy drinks and power bars) during the 30 minutes before blood pressure and pulse rate measurements.
- On study visit days, you can shower or bathe but should not use moisturizer or emollients until after the study visit.
- Avoid contact with body fluids from a child who has recently been vaccinated with live, attenuated vaccines. For example, you should not pick up dirty tissues, change dirty diapers, or finish the child's drink. Following these practices will minimize the chance of you getting infected. The study doctor will be able to tell you which vaccines you should avoid (specifically you cannot take live or attenuated live vaccine), what precautions you should take, and how long you need to follow these precautions after the person is vaccinated.
- You will not be able to take certain medications. You should tell the study doctor about the medications you take or are planning to take, including herbal medicines and vaccinations. The study doctor will determine whether these medications are safe to take while taking part in the study.
- It is important that you promptly discuss with the study doctor any changes or planned changes to your normal medications during the study.
- If you are considering elective surgery while you are taking part in this study, please contact the study doctor to confirm it is permitted in study.
- If applicable, talk to the study doctor about birth control and you must agree to use the right contraception methods, as necessary.
- Tell the study doctor immediately if you have any symptoms of infection such as a fever, or if you are feeling poorly.

- You must agree to avoid prolonged exposure to the sun and avoid use of tanning booths, sun lamps or other ultraviolet light sources during the study.

Tell the study doctor immediately if you have:

- A side effect or problems with your study drug (for example, lost bottles or damaged tablets)
- An injury
- Any symptom or complaint, including any allergic reaction
- Become pregnant
- Taken too much study drug
- Any changes in your physical or mental health during the study. It is your responsibility to report these to the study doctor.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

The study drug (abrocitinib), study-related procedures, and study visits will be provided at no cost to you. Additionally, if you agree to take part in this study, you will be paid $100 per visit for your time and effort by check. Payment will be provided at the end of your participation in the study.

It can take up to 6 weeks to prepare and give you a check for study participation. If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Possible benefits may be improvement in itchiness and eczema lesions on the skin and potential improvement in reaction to food allergens. However, there is no guarantee that you will benefit in any way. Your participation in this study may benefit future patients.

POSSIBLE RISKS AND DISCOMFORTS:

All research has some risk, which may include things that could make you feel unwell or uncomfortable, or that could harm you. You might experience these risks or discomforts while taking part in this study. The study team will monitor your health during the study, but the study team does not know all of the effects that the study drug, or your participation in this study, may have on you. These effects might be mild or serious. In some cases, these effects might be long-lasting or

permanent, and might even be life-threatening. The study team may determine that you need additional clinical procedures or medicines to help manage side effects or that you should withdraw from the study.

It is important that you report any symptoms and side effects to the study team right away. Phone numbers for the study team are listed on Page 1 of this consent document.

If you take part in this study, the most likely risks or discomforts to happen to you are discussed below.

Risks of the Study Drug (Abrocitinib)

The most commonly reported adverse reactions to abrocitinib (over 5% of people) are nausea, common cold symptoms, and headache.

Other common reported adverse reactions (more than 1 in 100 but less than 1 in 10 people):

- Vomiting
- Dizziness
- Fatigue
- Stomach pain
- Rashes
- Acne
- Laboratory abnormalities: Clinically significant increase in creatinine kinase (a muscle enzyme), low platelets (blood clotting cells)
- Infections: herpes simplex, shingles, urinary tract infection, skin infection, gastroenteritis, influenza
- High blood pressure

Uncommon adverse reactions (reported in fewer than 1 in 100 people) include low white blood cell numbers (cells that fight infections), pneumonia, and high cholesterol (blood fat).

Less common but serious reported adverse reactions to abrocitinib or medications similar to abrocitinib may include:

Serious or Unusual Infections

There may be an increased risk of serious bacterial, fungal, viral, or opportunistic infection leading to hospitalization or death, including tuberculosis (TB). Abrocitinib may lower the ability of your immune system to fight infections, leading to more serious infections or infections that usually don't occur in people with a normal immune system. You should not start taking abrocitinib if you have any kind of infection, and we will test your blood for certain infections prior to starting abrocitinib. After starting abrocitinib, call your study doctor right away if you have any symptoms of an infection. Symptoms of an infection could include fever, weight loss, excessive tiredness, or other symptoms specific to the site of infection, such as a persistent cough.

All-Cause Mortality

Higher all-cause mortality, including sudden cardiovascular death, has been seen with a medicine similar to abrocitinib (another JAK inhibitor) as compared to TNF blockers in rheumatoid arthritis (RA) patients.

Serious Heart-Related Events

Some people taking abrocitinib and similar medications have had serious heart-related problems, such as heart attack, stroke, and rare events of cardiac death. This risk appears greatest in people >50 years with a cardiovascular risk factor and/or smoking history. You should not take abrocitinib if you have heart disease or risk factors for heart disease, such as uncontrolled high blood pressure, uncontrolled high cholesterol, or current smoking.

Blood Clots in the Lungs

People taking abrocitinib and other similar medications have had blood clots in their lungs. Blood clots in the lungs can make it hard to breathe and could be life-threatening and lead to death.

You should seek medical attention immediately if you experience symptoms of a blood clot in the lungs such as new onset of:

- Sudden shortness of breath or difficulty breathing
- Chest pain or pain in the back
- Coughing up blood
- Excessive sweating
- Clammy or bluish colored skin
- Symptoms of a possible blood clot in the leg or arm (such as swelling, pain, tenderness, or red/discolored skin), which may happen before noticing symptoms of a blood clot in the lungs

Tell your study doctor and stop abrocitinib as soon as possible if you are diagnosed with a blood clot or if you experience any of the symptoms listed above during the study.

Cancer and Immune System Problems

Abrocitinib may increase the risk of certain cancers by changing the way your immune system defends against cancer. Lymphoma and other cancers, including skin cancers, could occur in patients taking abrocitinib and similar medications. Most people with a history of cancer will not be eligible for this study, except for those who have had successfully treated non-melanoma skin cancer or successfully treated early cervical cancer. Talk to the study doctor if you have had any type of cancer.

Gastrointestinal Problems

There are rare reports of patients experiencing serious gastrointestinal problems including perforation and obstruction while taking medicines similar to abrocitinib. Patients with known risk factors for perforation (example: diverticulitis or ulcers) or obstruction (known strictures or narrowing) should not start taking abrocitinib.

Reactivation of Viruses

Certain viruses can be stored in the body, and they may reactivate (wake up) and cause negative effects. In studies with abrocitinib and other similar medications, reactivation of the chicken pox virus (herpes zoster) has caused shingles (a painful or burning skin condition) and reactivation of the

herpes simplex virus has caused cold sores/fever blisters in the mouth or genital ulcers. We don't know if abrocitinib could lead to the reactivation of hepatitis viruses. You will not be allowed to participate in the study if your blood tests show that you have active or latent hepatitis B or C. If you have any symptoms suggestive of shingles, genital ulcers, or cold sores during the study, you should inform the study team right away.

Changes in Certain Laboratory Test Results

Your study doctor will do blood tests before you start taking abrocitinib and while you participate in this trial. Some changes in blood tests have occurred with abrocitinib, so we will monitor the following tests and may ask you to discontinue the study drug for any concerning changes.

- Platelets: Platelets are blood cells that help blood to clot. If your platelet level becomes low, you might be more likely to bruise or bleed.
- Immune Cells: Neutrophils and lymphocytes are white blood cells that help the body fight off infections. If these cell numbers become low, you might be more likely to get an infection or have trouble fighting an infection.
- Creatinine Kinase/Creatinine Phosphokinase: This is a muscle enzyme. Mild elevations of this enzyme can occur in people on abrocitinib, particularly after vigorous exercise. Very high levels of this enzyme may indicate there is strain on your muscles or kidneys.

You might have other changes in laboratory tests, such as your blood cholesterol levels, so those tests and others will be checked through the study.

Other Risks

Abrocitinib is FDA approved for adults with eczema, but there may be unknown risks, and this is not a complete list of risks/discomforts. All drugs have a potential risk of allergic reaction, which could become life-threatening if not treated promptly. Get medical help right away if you have any of the following symptoms of a serious allergic reaction: trouble breathing or swelling of the face, mouth, lips, gums, tongue, or neck. Mild allergic reactions may include rash, hives, or blisters. If you think you have had an allergic reaction, do not take any further doses and inform the study team right away.

It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study medications.

Pregnancy-Related Risks; Use of Birth Control

In animals, abrocitinib did not cause birth defects but did decrease female fertility (the ability to become pregnant or maintain pregnancy). In animals, no effects on the male reproductive system have been seen. The amount of drug that could be transferred in semen to a partner would not be high enough to cause harm, so males taking abrocitinib are not required to use birth control.

If you are a female and you participate in a study involving abrocitinib, you should not take it if:

- You plan to become pregnant during the study or are pregnant. It is not known if abrocitinib will harm an unborn baby.
- You 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 female, able to have children, and have not chosen abstinence as your preferred and usual lifestyle, you will be expected to use 1 method of highly effective birth control consistently and correctly during the study and for at least 28 days after you have stopped taking the study drug. The study doctor will discuss with you the methods of birth control that you should use while you are in this study and will help you select the method(s) appropriate for you. The study doctor will also check that you understand how to use the birth control methods and will review this with you at each of your study visits.

If abstinence (not having sexual intercourse at all) is your usual and preferred lifestyle and you and your study doctor agree that it is your selected method of contraception, you must continue not to have intercourse, or you may become pregnant.

Birth control methods, even when used properly are not perfect. If you become pregnant during the study or you want to stop your required birth control during the study, you must tell the study doctor immediately. You will be withdrawn from the study if you stop using birth control or you become pregnant. There will be regular checks for pregnancy throughout the study.

Pregnancy Follow-up
If you become pregnant during the study or within 28 days after you have stopped taking the study drug, please tell the study doctor immediately. Please also tell the doctor who will be taking care of you during the pregnancy that you took part in this study. The study doctor will ask if you or your pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. If you agree, this information will be provided to the Sponsor for safety follow-up

Risks from Study Procedures

Risks and possible discomforts you might have from the study procedures include:

- Blood Draws: A blood draw may cause lightheadedness, inflammation (swelling) of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection or nerve damage.
- Tape stripping: The risk includes local skin irritation.
- Prick skin test: This should cause minimal discomfort (the sensation of a prick and an itchy bump (hive) that will go away quickly. Such tests could theoretically cause a stronger allergic reaction, but this is exceedingly rare (less than one in 1000).
- Fasting: Going without food or liquids (you may have water) for 8 hours could cause dizziness, headache, stomach discomfort, or fainting.
- Breathing tests: Blowing into a machine might cause light-headedness.
- Questionnaires: A questionnaire may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire, you should tell your study doctor.

- Risk of loss of private information: this risk always exists, but there are procedures in place to minimize the risk.
- Group Risks: Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.
- Privacy Risks: Your name and other information that could directly identify you (such as address, date of birth, or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.
- Testing of DNA and/or RNA: Genes are pieces of DNA that, through material called RNA, give instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code. This is the code that you inherit from your parents and that you pass on to your children. DNA, RNA, and proteins can be studied as part of genetic research. This study may involve studying your biology and whether a particular biological feature (including genes) is related to the effects or action of the study drug or to a disease. This may include analyzing all of your genetic information (called “whole genome sequencing”). Sequencing a gene is like reading a book one letter at a time. This is a very thorough way to learn about genes. The genetic analysis is for research purposes only and is not a medical test. This means that the medical importance of the results may not be known or that they may not be related to any medical condition. The results of tests on your sample will not be given to you, the study doctor, any insurance company, your employer, your family, or any physician who treats you. If you do not want genetic testing to be done on your samples, you should not agree to participate in the research described in this document. The Sponsor and researchers will put measures in place to minimize the possibility for the results from this research being linked to you, but there is always the remote possibility that information from your participation in the research may be disclosed.
- To take part in this research project we will have to test your blood for evidence of HIV infection. HIV is the virus that causes AIDS. It can be transmitted through unprotected sex (vaginal, anal, or oral sex) with someone who has HIV and through contact with blood, as in sharing needles (piercing, tattooing, drug equipment including needles used to inject drugs). HIV-infected pregnant women can transmit to their infants during pregnancy or delivery or while breast feeding. There are treatments for HIV/AIDS that can help an individual stay healthy. Individuals with HIV/AIDS can adopt safe practices to protect uninfected and infected

people in their lives from becoming infected or being infected themselves with different strains of HIV.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Instead of being in this research study, your choices may include:

- *Continuing your current approaches to food allergy*
- Continuing your current approaches to treatment of eczema (atopic dermatitis), if active

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you are injured or made sick from taking part in this research study, you will get medical care. Generally, it will be billed to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, copayments, and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

If you are injured or get sick because of being in this research, call the study doctor immediately. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not a research injury. There are no plans to offer you payment for such things as lost wages, expenses other than medical care, or pain and suffering. To help avoid injury, it is very important to follow all study directions.

This study involves HIV-related information. The release of any HIV-related information to Pfizer does not permit Pfizer to re-disclose such information without your consent, unless permitted to do so under applicable state law. If you receive Medicare, by signing this consent, you specifically authorize Pfizer and its representatives to disclose your HIV-related health information to CMS for the purpose of complying with reporting requirements.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted. If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you stop being in the research study, the research team may not remove information they have already placed in the study database and may continue to use that data as part of this study. The research team may ask you whether they can continue to collect information from your medical record.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

While you are participating, the study team will tell you in a timely manner if new information is learned during the course of the study that could change your mind about continuing in this study. If you decide to withdraw from the study, you may be asked to continue to participate in the study procedures even though you would no longer take the study drug.

Withdrawal without your consent: The Lead Researcher, the funder, or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 212-241-5548.

If there is an emergency, please call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

The company sponsoring this research study makes the drug being tested and has a financial interest that could be affected by the outcome of this research study.

Dr. Emma Guttman (a Principal investigators in this study) receives financial compensation as a consultant for Pfizer, the study sponsor and developer of the study drug (abrocitinib). In addition, Dr. Guttman receives financial compensation as a consultant from other companies that research and develop treatment for dermatological diseases.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this research project, the research team will collect your name, address, telephone/fax numbers, birthdate, e-mail address, and medical record number.

The researchers will also get information from your medical record at Mount Sinai, including skin testing and allergy blood test results.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature.
- Completing the tests, procedures, questionnaires, and interviews explained in the description section of this consent.

- Reviewing HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- Other collaborating research center(s) and their associated research/clinical staff who are working with the researchers on this project: Dr. Cecilia Berin, who is an Adjunct Professor at Mount Sinai but located at Northwestern University, will continue to analyze blood samples obtained for this research study.
- The commercial sponsor and/or their representative [who will use the results for submissions to the Food and Drug Administration (the government organization that approves drugs or devices for medical use)]: Pfizer Inc.
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.

- The United States Food and Drug Administration.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:
Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:
My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time