PRINCIPAL INVESTIGATOR: [redacted]

STUDY TITLE: Phase II Study of Topical Ruxolitinib for Cutaneous Chronic Graft Versus Host Disease

STUDY SITE: The National Institutes of Health

Cohort: *Affected Patient*

Consent Version: *01/25/21*

WHO DO YOU CONTACT ABOUT THIS STUDY?

[redacted]

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

Chronic graft versus host disease (cGVHD) is reported to occur in about half of patients that have had a hematopoietic stem cell transplant using donor cells. Immune cells in the graft from the

donor may see the body tissues in the patient as "foreign" and attack causing damage. cGVHD can affect different parts of the body such as the lungs, stomach, intestines, liver, and connective tissue in the skin and joints. The skin is the most commonly affected organ. First-line therapy for cGVHD is systemic corticosteroids. The side effects of corticosteroids are significant, and can include weakening of the bones, damage of the joints, high blood sugar, high blood pressure and an increased risk of infection. Topical therapies (creams, ointments) that are available for cGVHD affecting the skin include corticosteroids and calcineurin inhibitors. Topical steroids also have significant side effects which can limit their use. These side effects include thinning of the skin, stretch marks, infection, as well as risk of systemic side effects from absorption when used over a large body surface area. These medicines also only treat the symptoms of cGVHD rather than treating the pathways that cause cGVHD.

Ruxolitinib is a medicine that inhibits the proteins JAK1 and JAK2 which are involved in communication in the immune system and are thought to play a role in cGVHD and other inflammatory diseases. Ruxolitinib has been approved by the U.S. Food and Drug Administration (FDA) to treat certain blood cancers. Oral ruxolitinib has been studied in cGVHD. One study showed that 35 out of 41 patients treated had either a partial response (32 patients) or a complete response (3 patients). Topical ruxolitinib cream has been studied in patients with plaque psoriasis, atopic dermatitis (also known as eczema) alopecia areata (hair loss due to immune dysfunction) and vitiligo (a condition where patches of skin turn white from losing pigment) and in healthy volunteers with no serious side effects such as a decrease in blood counts that were seen with the oral ruxolitinib. In this trial, we plan to test the safety and effectiveness of topical ruxolitinib 1.5% cream in patients with epidermal (outer most layer of the skin) cGVHD.

We are also studying the biology of response to the medication in cGVHD through genomic studies. We are requesting your permission to perform genome sequencing on your blood and tissue samples and link this to your cGVHD response to the medication. Your blood and tissue samples contain genes, which are made up of DNA (deoxyribonucleic acid) which serves as the "instruction book" for the cells that make up our bodies. Sequencing will determine the exact order of the base pairs (chemical letters) in your body affected by cGVHD. Your sample(s), will help us study how genes change in response to the medication.

Why are you being asked to take part in this study?

You have been invited to participate in this study because you have epidermal chronic Graft versus Host Disease (cGVHD)

How many people will take part in this study?

Up to 15 participants will take part in this study. The study will take place at the NIH.

Description of Research Study

This is a double-blinded placebo controlled study. This means that participants will receive both the topical ruxolitinib 1.5% cream and a placebo (inactive) cream to apply to two separate areas of disease (for example, an area on your right arm and an area on your left leg). Neither you nor the study team will know which tube of medicine contains the ruxolitinib 1.5% cream and which

tube contains the placebo cream. You will apply the creams to two chosen areas twice a day for 6 weeks, as long as you do not experience serious side effects. If you experience any serious side effect, you will be instructed to stop applying the creams until the side effect goes away. Your study doctor may also tell you to only apply the creams once a day. At the first visit the study team will examine you and measure your skin disease (measurements will include using a ruler or calipers, taking photographs, and tracing the outline of the skin lesions). You will be asked to complete a daily medication diary of when the creams are applied and any side effects you experience. We will also ask you to keep a list of all other medications you take. You will return to the NIH for follow-up evaluations 2 weeks after starting the topical creams. At 4 weeks, you have the option of coming to NIH for a visit or having a study team member call you at home to see how you are doing. At 6 weeks, you will return to NIH for a final evaluation to see how your skin responded to the topical creams. You will stop using the creams at this visit. A study team member will call you at home 4 weeks after you stop using the creams to see how you are doing. All the tests and procedures required in this study are outlined in detail in the "During the study" section. Following this section is a Study Chart which shows what will be done at each visit.

The photographs obtained during your visit may be used to teach a computer to identify cGVHD on the skin. These photographs will be analyzed by both a Dermatologist who will mark areas of skin affected on the photograph as well as by a computer. The photographs will be fed to the computer to train the computer to see redness in skin and to track changes in skin using the computer. This process is called machine learning. The photographs fed to the computer will be de-identified, meaning that we will not use photographs that include your face. In order to do this, the photographs and de-identified clinical information will be sent to outside experts at Vanderbilt University.

What will happen if you take part in this research study?

Before you begin the study

The study doctor will discuss with you what your responsibilities are if you decide to participate in this study. You will need certain tests before you begin the study to see if you are eligible. If you have had some of them done recently they may not need to be repeated. This will be up to your study doctor. These tests include:

- History and Physical exam (includes temperature, height, weight, respiratory rate, heart rate and blood pressure), along with past medical history and review of medications. You will not be eligible to participate in this study if you are currently taking fluconazole or some other medications that do not interact well with ruxolitinib. If you are eligible to participate in this study, we will give you an information sheet that lists medications you cannot take while you are using ruxolitinib. You also will be instructed to contact your study team physician prior to starting any new medications.

- You will be asked how well you can do daily activities.

- Routine blood tests to make sure your bone marrow, liver and kidneys are working properly, tests for certain infections including HIV and hepatitis.

- A pregnancy test if you are a female that can become pregnant.

• A skin biopsy to confirm that you have epidermal cGVHD if you have not already had one in the last 3 months. You will be asked to sign a separate consent for the biopsy at the time of the procedure.

HIV Testing

As part of this study, we will test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will not be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report HIV infection, and the importance of informing your partners at possible risk because of your HIV infection.

During the study

If it is determined that you are eligible for the study and you choose to sign this consent form, you will begin study therapy as described above and undergo the tests described below. You may not have to repeat some of the tests performed at baseline (before you start the ruxolitinib) if you have already done them as a part of screening. You may have other tests/procedures performed as needed for standard clinical care. The **Study Chart** below outlines the required visits and tests to be done at each visit.

- History and Physical exam (includes temperature, height, weight, respiratory rate, heart rate and blood pressure), along with past medical history and review of medications.

- Detailed examination of all epidermal cGVHD with selection of two target sites for medication application. Detailed measurement of the two target sites will include the physician measuring the sites with a ruler or caliper, tracing of the sites with transparency paper, taking photographs of the target sites and the physician will complete the Physician Global Assessment Form. Measurements will be done at each NIH visit.

- Total Body Photographs (Optional)-These involve taking pictures of your entire body wearing only underwear. The study doctor may ask to have these done and will discuss this with you.

- Questionnaires (Required)-

  o Visual Analog Scales: you will be asked to complete visual scales of how bad your symptoms of cGVHD are for EACH separate site chosen to receive study medication. It will take approximately 10 minutes to complete all the scales. You will be required to complete these scales at the baseline visit, the week 2 visit and the week 6 visit.

- Clinical/Safety blood tests to determine if your bone marrow, liver and kidneys are working properly.

- Blood pregnancy test for females who can become pregnant.

- Research Blood tests:

o Blood will be collected at the baseline visit and at week 6 to study how your immune system responds to the study drug. If you are 18 years of age or older, 216 ml (14.5 tablespoons) of blood will be drawn at each visit. This is a safe amount according to the NIH policy on research blood drawing limits.

o Pharmacokinetic (PK) blood samples (Required)- During the week 2 visit we will collect blood from you to measure how much of the study drug is in your body before you apply the study medication and at 1 hour, 2 hours and 4 hours after you apply the study medication. A total of 4 samples will be collected which is about 12 ml (2 tablespoons). The PK samples will be only be collected at the week 2 visit. You may have an IV (a small needle inserted into a vein in your arm) that the PK samples can be drawn from.

- Research Skin Biopsy (Optional) - If you agree, the study physician will ask to obtain a skin biopsy from each treated site (2 total) at the week 6 visit to compare changes in the skin cells. If you agree to the skin biopsies you will be asked to sign a separate consent form at the time of the procedure.

- Study Drug Application: At the baseline visit, 2 separate areas of disease will be selected by the study team physician. The NIH pharmacy will dispense two separate tubes of study medication. Neither you or the study team will know which tube contains the ruxolitinib, and which tube contains the placebo. Each site will be identified by photograph and each tube will contain the name of the site (i.e. right arm) where the cream should be applied. A study team member will show you how to apply the cream as a thin layer. The cream will be applied twice a day approximately 12 hours apart at least two hours before bathing or showering. If you miss a dose, you may apply it as soon as you remember up until 1 hour before the next dose is due. Care should be taken to avoid the eyes and mouth. If the study cream or placebo are ingested you should contact the study team right away. If the study cream will be applied by a pregnant or breastfeeding individual that individual will need to wear gloves and use a wooden applicator to apply the study cream.

When you are finished taking the drugs (treatment)

You will stop the study medication when you return for the week 6 visit. You will be asked to return any unused study medication at this visit. A study team member will call you at home approximately 4 weeks later to see how you are doing.

Study Chart

Study time point	What will be done
Up to 4 weeks before starting the study	• History and physical exam, review of medications • Routine blood tests • Skin biopsy to confirm cGVHD diagnosis
Start of study: Day 1 NIH Clinic visit	• Review and sign consent with study team • History and physical exam including vital signs, review of medications • Safety and research blood work

	• Measurement of skin disease/select 2 separate sites to be treated • Photographs of target treatment sites (Required) • Total Body Photographs (Optional) • Questionnaires (required)-Visual Analog Scales • Study drug administration and diary teaching • Begin topical ruxolitinib/placebo treatment
Week 2 NIH Clinic visit	• History and physical exam, including vital signs, review of medications, Diary review • Safety blood work • Research PK blood studies (Required) • Measurement of skin disease • Photographs of target treatment sites (Required) • Total Body Photographs (Optional) • Questionnaires (required)- Visual Analog Scales, • Study drug administration and Diary teaching. • Assess for study drug side effects
Week 4 NIH Clinic visit **OR** Telephone Assessment	**NIH Visit:** • History and physical exam, including vital signs, review of medications, Diary review • Safety blood work • Measurement of skin disease • Photographs of target treatment sites (Required) • Total Body Photographs (Optional) • Questionnaires (required)- Visual Analog Scales • Study drug administration and Diary teaching. • Assess for study drug side effects **Telephone Visit:** • A study team member will call you at home to ask how you are doing, review study drug application, review other medications and assess for study drug side effects.
Week 6 NIH Clinic visit	• History and physical exam, including vital signs, review of medications, Diary review • Safety and research blood work • Measurement of skin disease • Photographs of target treatment sites (Required) • Total Body Photographs (Optional) • Questionnaires (required)-Visual Analog Scales

	• Skin Biopsy (Optional): A skin biopsy for research purposes will be taken from EACH site being treated • Assess for study drug side effects • Stop study drug
Week 12 Telephone Assessment	• A study team member will call you at home to ask how you are doing, review study drug application, review other medications and assess for study drug side effects.

Birth Control

If you are a woman who is breast feeding or pregnant, you may not take part in the study because we don't know how this medicine would affect your baby or your unborn child. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice an effective form of birth control before starting study treatment, during study treatment, and for 1 month after you finish study treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once. If you are a female who become pregnant while taking the study cream you will have to stop taking the medication and will be taken off study.

Effective forms of birth control include

- abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

Risks or Discomforts of Participation

What side effects or risks can I expect from being in this study?

Risks related to the 1.5 % ruxolitinib study cream:

Topical 1.5 % ruxolitinib cream has been evaluated in over 2350 patients in 17 clinical studies. At time of review there have been no deaths and only one serious, severe and or life-threatening side effect reported that was deemed related to topical ruxolitinib. In an ongoing study of atopic dermatitits, a total of 67 pediatric participants (aged 2 to 17 years) have received ruxolitinib cream 0.5%, 1.5%, or 0.75% cream twice a day. In this study, no deaths were reported and no patient had a serious side effect or other side effect leading to discontinuation of ruxolitinib cream. In studies of ruxolitinib given by mouth to young rats, some had changes in their bones. The doses given to the young rats were significantly higher than the dose applied to the skin in this study.

Overall, there have been no deaths related to the topical ruxolitinib. There has been only one severe and or life-threatening side effect reported thought to be related to the ruxolitinib. Side

effects that were considered possibly related to the topical ruxolitinib were considered mild to moderate and went away without the need for other treatment. There may be side effects the doctors do not know about so it is important for you to tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.

Likely	Less Likely	Rare but Serious
• Irritation at the site of application • Itching • Numbness or decreased sensation in area treated • Increased sensitivity to artificial and natural sunlight • Runny nose • Upper respiratory infection • Headache • Acne	• Decrease in the number of white blood cells that help fight infection • Increase in the number of immature red blood cells • Diarrhea • Sinusitis	• Elevation of blood enzymes that indicate injury to the liver • Skin and other infections

Risks related to study procedures:

Skin biopsy (optional) Pain at the biopsy site should be minimal and bleeding and infections are rare. Biopsy wounds heal with a very small, nearly unnoticeable scar, but sometimes a raised scar (keloid) or visible lump may result. Numbing medicine is used to reduce the discomfort of the biopsies, however, there is minimal burning discomfort caused by the injection of the numbing medicine and the discomfort may not be eliminated completely. You may experience discomfort and mild tenderness at the biopsy site for up to 1 week. You may develop a bruise around the biopsy site, which usually disappears in one to two weeks. In rare cases, allergic reactions to the numbing medication have been reported. Please contact one of the investigators if you ever have had an allergic reaction to any medications or anesthetic agents in the past or after this procedure.

Blood Collection

Taking blood may cause some discomfort, bleeding or bruising where the needle enters the body, and in rare cases, it may result in fainting. There is a small risk of infection. Some people have not felt well when having their blood taken or have felt dizzy during or after. Let the person drawing your blood know if you would prefer to lie down or if you don't feel well during the blood draw.

Potential Benefits of Participation

Are there benefits to taking part in this study?

The aim of this study is to see if this experimental cream will cause your treated areas cGVHD to improve. We do not know if you will receive personal, medical benefit from taking part in this study. Potential benefits could include lessening of your symptoms, such as pain, itching that are caused by the cGVHD. Because there is not much information about the drug's effect on your GVHD, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have cGVHD.

Alternative Approaches or Treatments

What other choices do I have if I do not take part in this study?

Instead of being in this study, you have these options:

- Getting treatment or care for your GVHD without being in a study
- Taking part in another study
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, and other problems caused by cGVHD. It does not treat the cGVHD directly. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

Stopping Therapy

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease gets worse during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you
- if you do not follow the study requirements

In this case, you will be informed of the reason therapy is being stopped.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to the Sponsor or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NIH can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases cannot be recalled and destroyed.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

Cost associated with screening will not be reimbursed. Once consent is obtained, this study will assist with air or train travel through a government approved contractor. Mileage will be compensated per NIH guidelines. For long distance travelers, meals will be compensated per NIH guidelines. Lodging maybe provided through the Children's Inn or Safra Lodge, if space permits. If not available, we will provide compensation toward local lodging per NIH guidelines.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

If you choose to take part in the study, the following will apply, in keeping with the NIH policy:

- You will receive study treatment at no charge to you. This may include surgery, medicines, laboratory testing, x-rays or scans done at the Clinical Center, National Institutes of Health (NIH), or arranged for you by the research team to be done outside the Clinical Center, NIH if the study related treatment is not available at the NIH.

- There are limited funds available to cover the cost of some tests and procedures performed outside the Clinical Center, NIH. You may have to pay for these costs if they are not covered by your insurance company.

- Medicines that are not part of the study treatment will not be provided or paid for by the Clinical Center, NIH.

- Once you have completed taking part in the study, medical care will no longer be provided by the Clinical Center, NIH.

CONFLICT OF INTEREST (COI)

The NIH reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

The NIH and the research team for this study are using Ruxolitinib cream by Incyte through a collaboration between your study team and the company. The company also provides financial support for this study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

We will collect social security numbers for the purpose of reimbursement.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
  The study Sponsor, The National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the contracted monitoring company who audits the study for compliance
  Qualified representatives from Incyte, the pharmaceutical company who produces topical 1.5% ruxolitinib cream.

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, [redacted] You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.