Washington University in St. Louis
SCHOOL OF MEDICINE

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16 March 2020

To Whom it May Concern:

Please find enclosed the protocol and informed consent form for the proof-of-concept open-label clinical trial entitled listed as “A Study Examining the Medication Apremilast as Treatment for Chronic Itch” on ClinicalTrials.gov (NCT03239106).

Please see attached/uploaded documents.

Please do not hesitate to contact me directly should anyone have questions at (314) 273-1376.

Sincerely,

Brian S. Kim, MD, MTR, FAAD
Associate Professor of Medicine (Dermatology), Anesthesiology, and Pathology and Immunology
Co-Director, Center for the Study of Itch and Sensory Disorders
Department of Medicine/Division of Dermatology
Washington University School of Medicine

Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: **An Open-Label Pilot Study of Apremilast in Chronic Idiopathic Pruritus**

Principal Investigator: **Brian S. Kim, MD**

Research Team Contact: **Nancy Bodet, RN**
(314) 273-1376

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have chronic idiopathic pruritus (CIP). CIP is an unpleasant sensation of the skin that provokes the urge to scratch, and is of unknown cause.

The purpose of this research study is to determine the effectiveness of Apremilast (the study drug) in relieving the itching associated with CIP. Apremilast is approved for treatment in other inflammatory skin conditions such as psoriasis. There is no approved treatment for CIP.

Apremilast is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration for CIP.

WHAT WILL HAPPEN DURING THIS STUDY?

You will complete a screening visit in order to assess your eligibility to take part in the study. The screening period may last up to 28 days. After your screening visit, if you are eligible to continue to take part in the study, you will start treatment with the study drug at your baseline/Day 1 visit. Study visits will take place at Weeks 2, 4, 8, 12, and 16. You will return to the clinic at Week 18 for a follow-up visit.

The assessments performed at each visit are described below:

Screening Visit

- Informed consent
- Review eligibility criteria

- Collect demographics (for example, age, race, and gender) and medical & medication history
- Measure height and body weight
- Physical examination
- Measure vital signs (pulse, respiratory rate, blood pressure)
- You will have blood drawn for laboratory assessments, including Hepatitis screening tests
- You will provide a urine sample for urinalysis
- A pregnancy test will be performed for women of childbearing potential. You will not be able to continue in the study if you are pregnant.
- Chest X-ray
- NRS itch score. You will report the intensity of your itch using a numbered scale.
- Questionnaire to measure how much your skin problem has affected your life. You are free to skip any questions you prefer not to answer.
- Review adverse (harmful) events

The screening period may last up to 28 days to allow time to review your laboratory and chest X-ray results, and to provide flexibility for scheduling your baseline visit.

Day 1/Baseline

- Review eligibility criteria
- Review medications
- Physical examination
- Measure vital signs
- A pregnancy test will be performed for women of childbearing potential.
- NRS itch score. You will report the intensity of your itch using a numbered scale.
- Questionnaire to measure how much your skin problem has affected your life. You are free to skip any questions you prefer not to answer.
- You will have a skin biopsy for bio-banking tissue. A skin biopsy is a procedure in which a sample of skin tissue is removed and examined under a microscope.
- Review adverse events
- Study drug dispensed. The study drug is taken by mouth and you will receive your first dose in the clinic. You will take the study drug at home beginning the next morning. Your dose will be increased to the maintenance dose of 30 mg twice daily as follows:
    - Day 2: 10 mg twice daily
    - Day 3: 10 mg in the morning and 20 mg in the evening
    - Day 4: 20 mg twice daily
    - Day 5: 20 mg in the morning and 30 mg in the evening
    - Day 6 – Week 16: 30 mg twice daily

Week 2

- Review medications
- Physical examination
- Measure vital signs
- A pregnancy test will be performed for women of childbearing potential
- NRS itch score. You will report the intensity of your itch using a numbered scale.

- Questionnaire to measure how much your skin problem has affected your life. You are free to skip any questions you prefer not to answer.
- Review adverse events
- Study drug collected/dispensed

Week4

- Review medications
- Physical examination
- Measure vital signs
- A pregnancy test will be performed for women of childbearing potential
- NRS itch score. You will report the intensity of your itch using a numbered scale.
- Questionnaire to measure how much your skin problem has affected your life. You are free to skip any questions you prefer not to answer.
- Review adverse events
- Study drug collected/dispensed

Week 8

- Review medications
- Physical examination
- Measure vital signs
- A pregnancy test will be performed for women of childbearing potential
- NRS itch score. You will report the intensity of your itch using a numbered scale.
- Questionnaire to measure how much your skin problem has affected your life. You are free to skip any questions you prefer not to answer.
- You will have a skin biopsy for bio-banking tissue
- Review adverse events
- Study drug collected/dispensed

Week 12

- Review medications
- Physical examination
- Measure vital signs
- A pregnancy test will be performed for women of childbearing potential
- NRS itch score. You will report the intensity of your itch using a numbered scale.
- Questionnaire to measure how much your skin problem has affected your life. You are free to skip any questions you prefer not to answer.
- You will have a skin biopsy for bio-banking tissue
- Review adverse events
- Study drug collected/dispensed

Week 16

- Review medications
- Physical examination

- Measure vital signs
- A pregnancy test will be performed for women of childbearing potential
- NRS itch score. You will report the intensity of your itch using a numbered scale.
- Questionnaire to measure how much your skin problem has affected your life. You are free to skip any questions you prefer not to answer.
- You will have a skin biopsy for bio-banking tissue. A skin biopsy is a procedure in which a sample of skin tissue is removed and examined under a microscope.
- Review adverse events
- You will have blood drawn for laboratory assessments
- Study drug collected

Week 18, Follow-Up

- Review medications
- Physical examination
- Measure vital signs
- A pregnancy test will be performed for women of childbearing potential
- NRS itch score. You will report the intensity of your itch using a numbered scale.
- Questionnaire to measure how much your skin problem has affected your life. You are free to skip any questions you prefer not to answer.
- Review adverse events

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining blood, data and skin tissue from you. We would like to use this blood, data and skin tissue for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding CIP, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood and skin tissue you give up any property rights you may have in the blood and skin tissue.

Your skin tissue will be used to conduct analyses of your RNA (genetic material) and possible genomic analysis to study your response to treatment. Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes that determine things like our height or the color of our eyes. Some of these differences may make some people more or less likely to develop certain diseases or conditions or to have certain characteristics

We will share your blood, data and skin tissue with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your blood, data and skin tissue for future research you should contact the research team member identified at the top of this document. The blood, data and skin tissue will no longer be used for research purposes. However, if some research with your blood, data and skin tissue has already been completed, the information from that research may still be used. Also, if the blood and skin tissue has been shared with other researchers it might not be possible to withdraw the blood and skin tissue to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood, data and skin tissue may be stored and used for genetic/genomic research as described above.

_____ Yes **_____ No**
Initials **Initials**

My blood, data and skin tissue may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My blood, data and skin tissue may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 10 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 22 weeks. This includes the screening period which may last up to 28 days, a 16-week treatment period, and a 2 week follow-up visit. Visits can range in time from 30 minutes-2 hours.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

As of 30 Nov 2017, apremilast has been given to more than 6800 subjects (people) in studies conducted by Celgene. The following are the most commonly seen risks, discomforts and side effects in subjects who have taken apremilast: headache including tension headache, stuffiness or infections of the nose

and throat (upper respiratory tract infections including nasopharyngitis), stomach upset (nausea), vomiting and diarrhea. Most of these side effects were mild to moderate in intensity and resolved with continued treatment. Similar side effects have been observed in studies that are running now. About 8 out of every 100 subjects treated have discontinued the study drug because of side effects.

Very common:
- Diarrhea
- Nausea (stomach upset)
- Vomiting

Common:
- Upper abdominal (stomach) pain
- Indigestion
- Frequent bowel movement
- Heartburn
- Fatigue
- Bronchitis (infection of the tubes to the lungs)
- Redness/swelling/pain in the sinuses
- Inflammation or infections of the nose and throat
- Weight loss
- Decreased appetite
- Back pain
- Headache including tension and migraine
- Difficulty sleeping
- Depression
- Cough
- Rash
- Dizziness
- Weakness
- Flu
- Muscle pain
- Numbness
- Itchiness

Uncommon:
- Allergic reaction

Reports of various types of cancers, heart problems, and serious infections have been found from apremilast studies. However, these events in patients being treated with apremilast happened as often as those being treated with placebo (sugar pill).

Drugs in the same family as apremilast have been shown to produce inflammation around the vessels of the skin (vasculitis) in rats and mice. Skin vasculitis has been rarely reported equally in patient taking apremilast or placebo. If you have any unexplained swelling, pain, tenderness or redness, please tell

your study doctor.

Depression has been reported with the use of apremilast. If you have a history of depression and/or suicidal thoughts or behavior, please tell your study doctor. If you have any symptoms of depression or if your depression becomes worse, or if you have suicidal thoughts or other mood changes, contact your study doctor immediately.

In clinical studies, weight loss has been observed. If you experience unintentional or unexplained weight loss (for example, if you have weight loss without actively trying to lose weight), please notify your study doctor immediately.

Severe diarrhea, nausea, and vomiting has been reported with the use of apremilast. Some patients were hospitalized. If you are 65 years of age or older, and/or become dehydrated or experience low blood pressure, you may be at a higher risk of complications. If you experience severe diarrhea, nausea, or vomiting please notify your study doctor immediately.

Tell your study doctor if you are taking any other medication, including over-the-counter medications, since some medications could interfere with the effects of apremilast.

It is possible that the condition for which you are being treated may worsen during the study.

Blood Drawing- Blood samples will be taken by single needle-sticks. Risks associated with drawing blood from your arm include pain, bruising or bleeding from the site of the needle puncture, lightheadedness or fainting, and infection.

Skin Biopsy- A skin biopsy is a generally safe procedure, but complications can occur, including bleeding, bruising, scarring, infection, and allergic reaction to the topical antibiotic.

Local Anesthesia- The side effects of local anesthetic agents include prolonged anesthesia (numbness) and paresthesia (tingling, feeling of "pins and needles", or strange sensations). These are symptoms of localized nerve impairment or nerve damage.

Chest X-Ray- This study will expose you to radiation from chest x-ray. The amount of radiation from this, when averaged over your entire body, is 2% of the amount of radiation exposure all people in St. Louis receive each year from naturally occurring radiation sources. The risk from the radiation exposure in this study is too small to be measured. It is not a big risk when compared with other risks you take every day. If you want to know more about radiation exposure, please see the "Radiation Fact Sheet" located at http://hrpo.wustl.edu or ask the study staff for a copy

Women Capable of Becoming Pregnant- Apremilast should not be administered to pregnant or nursing women. If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods as described below and try not to become pregnant while participating in this study and for at least 28 days after your last dose of study drug. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being

studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. We would like to follow your pregnancy until its conclusion. If this happens, we will ask you to sign a separate informed consent form to permit this data collection.

Sexually Active Male- If you are a sexually active male it is important that your partner not become pregnant during your participation in this study. There may be unknown risks to the unborn child or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you believe or know that your partner has become pregnant during your participation in this study, please contact the research team member identified at the top of this document as soon as possible

Approved options for birth control are:

- Any one of the following highly effective methods: Hormonal contraception (for example, birth control pills, intravaginal ring, transdermal patch, injection, implant); intrauterine device (IUD); tubal ligation (tying your tubes); or a partner with a vasectomy. Certain drugs may reduce the effectiveness of hormonal contraceptives during and up to one month after discontinuation of these concomitant therapies. Please talk to your doctor for further information about contraceptives.

OR

- Double barrier method: Male or female condom (latex condom or any nonlatex condom NOT made out of natural [animal] membrane [for example, polyurethane]) PLUS one of the following additional barrier methods: (a) diaphragm with spermicide; (b) cervical cap with spermicide; or (c) contraceptive sponge with spermicide.

If at any time during the study your birth control method changes, or you experience a problem with your current birth control method, or your ability to become pregnant changes (for example, you have an IUD removed, accidently miss taking any of your birth control pills, or enter menopause), you must inform the study doctor and have a discussion with the study doctor or study nurse about an alternative birth control method.

Genetics- There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Breach of Confidentiality- One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of the information that is learned.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could try neuromodulators such as gabapentin or pregabalin, topical steroids, oral steroids, or other immunosuppressive agents such as cyclosporine, azathioprine, and mycophenalate mofetil. However, currently, there are no agents available for your condition that are similar to the study drug.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be paid $50 per study visit, up to $400 if you complete the study. You will only be paid for the visits you complete. A check will be mailed to you approximately 2-4 weeks after your last study visit.

WHO IS FUNDING THIS STUDY?

Celgene is funding this research study. This means that Washington University is receiving payments from Celgene to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from Celgene for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 747-6556 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives, (including the Office for Human Research Protections) to complete

federal or state responsibilities
- The U.S. Food and Drug Administration
- Celgene
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

The research team will send study results to Celgene. Information sent to Celgene will contain identifiers such as your study ID number, and date of birth. Celgene will use your data to study the effectiveness of Apremilast in relieving the itch associated with CIP. In the future, Celgene may continue to use your health information that is collected as part of this study. For example, Celgene may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study medication, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. Celgene may also share information from the study with regulatory agencies in foreign countries.

If you receive Medicare benefits, are injured as part of your participation in this research study and medical treatment relating to this injury is paid by anyone other than you or your insurance company, that payer will need to collect personal information about you. This information includes your name, date of birth, gender, social security number, Medicare identification number and information related to this research study. The payer will report this information to the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, during your participation in the study and for as long as the payer is required by CMS to report this information. If you do not want to release your personal or treatment related information you have the right to refuse reimbursement by the payer for any research injury. The payer will not use this information for any other purpose.

To help protect your confidentiality, we will store your paper study records in a locked cabinet in a locked office. Your electronic study records will be accessible only by a unique username/password given to the study team member. Biological samples will be labeled with a code. Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others. Sharing this information will allow others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/under Withdrawing from a Research Study.

If you decide to leave the study early, we will ask you to return and complete the follow-up visit.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because:

- You become pregnant
- You do not follow the study doctor's instructions
- The doctor does not feel it is safe for you to continue
- The study is ended by the sponsor or the institutional review board

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Nancy Bodet, RN at (314) 273-1376 or Brian S. Kim, MD at (314) 362-8171. If you experience a research-related injury, please contact: Brian S. Kim, MD at (314) 362-8171**.**

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 08/18/20.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)