**CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY**
**AND**
**AUTHORIZATION TO DISCLOSE HEALTH INFORMATION**

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| **Study Title:** | **A Sequential Two-Stage Dose Escalation Study to Evaluate the Safety and Efficacy of Ruxolitinib for the treatment of Chronic Myelomonocytic Leukemia (CMML): A Phase 2 Expansion** |
| **Protocol Number:** | **MCC 19727** |
| **Sponsor:** | **H. Lee Moffitt Cancer Center and Research Institute** |
| **Funding:** | **Incyte Corporation** |
| **Principal Investigator: (Study Doctor)** | **Eric Padron, MD** |
| **Telephone:** | **(813) 745-3907** |
| **(24 hour number)** | **(800) 456-3434** |
| **Address:** | **H. Lee Moffitt Cancer Center and Research Institute 12902 Magnolia Dr. Tampa FL 33612** |

We (the study doctors and researchers at Moffitt Cancer Center) study diseases and other health problems people may have. Our goal is to try to find better ways to help treat these health problems. To do this, we sometimes ask people to take part in research studies. Research studies are voluntary and include only those who wish to take part.

If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. Discuss your participation with anyone you choose in order to better understand this study and your options. Do not sign and date this form unless the study doctor or study staff has answered your questions and you decide that you want to be part of this study.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. Being in this study does not replace your regular medical care.

## WHAT IS THIS STUDY ABOUT?

We are asking you to take part in this research study is to find out if treating Chronic Myelomonocytic Leukemia (CMML) with a study drug [ruxolitinib] can improve outcomes of patients with CMML. This study drug may be available for prescription for myelofibrosis (MF); however, the use of this study drug in this study is investigational. An investigational drug is one

that is not approved by the United States Food and Drug Administration (FDA) for your specific illness. The first step of the study is to learn the dose of ruxolitinib that is tolerable (bearable). It has already been studied in a number of participants with different bone marrow diseases and is approved for the treatment of a disease called Myelofibrosis; however, it is not approved for treatment of CMML. It is given orally (by mouth). Most people tolerate it well but the tolerability has not been determined in patients with CMML. We will be testing a single dose taken twice a day to determine if people can tolerate (bear it) before they develop side effects.

## HOW LONG WILL YOU BE ASKED TO STAY IN THIS STUDY?

You will be asked to spend up to 17 weeks in this study. We will follow participants for 17 weeks to determine how well they tolerate the study drug and to see if their CMML improves.

At the end of 17 weeks, if you are tolerating the study drug well and your CMML has not progressed, you may stay on the study drug. If your CMML progresses or the study drug receives FDA approval for this indication, you will be taken off study.

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 30 participants will take part in this study at Moffitt Cancer Center.

## HOW DO I KNOW IF I CAN BE IN THIS STUDY?

Before you can start the study, the study doctor or study staff will talk to you about the study. Then you have to sign and date this form before the study doctor or study staff can begin the first part of the study called a screening period to see if you qualify to be in the main part of the study.

- a complete blood count to have a baseline assessment of how well your CMML is currently controlled. This will be done with a standard blood draw (4 teaspoons) before your regular appointment.
- A chemistry profile that looks for changes in electrolytes (salts), liver, and kidney function to ensure that it is safe to start the study drug.
- Your medical history will be reviewed, along with the current medications you are taking.
- You will have a physical exam and your blood pressure, heart rate, breathing rate, temperature, height and weight will be checked.
- You will have a pregnancy test if you are a woman of child-bearing potential.
- Performance status, which evaluates how you are able to carry on with your usual activities.

Once results from these tests are finalized, you and the research team will decide if you should be in the study. After the screening tests, you will need to have a bone marrow aspirate/biopsy done to measure levels of specific factors in your bone marrow. This can be done at a time that is convenient for you; however, it must be completed before beginning the study. Bone marrow has a fluid portion and a more solid portion. In the bone marrow aspirate, your doctor uses a needle to withdraw a sample of the fluid portion. In a bone marrow biopsy, a larger needle is used to take a sample of the solid part.

## WHAT WILL HAPPEN DURING THIS STUDY?

During this study you will take 20 mg of the study drug, ruxolitinib by mouth twice per day. Every month you will come to the study clinic for an appointment and you will have your blood drawn (4 teaspoons) to look at your blood counts and to look at molecular tests to determine how well your CMML is being controlled. You should take your dose of ruxolitinib before coming to the study clinic.

Symptoms of CMML will be assessed using The Myeloproliferative Neoplasms Symptom Assessment Form (MPN-SAF) at baseline and at best response. In addition, you will be given a hand-held electronic device (eDiary) on which to record your symptoms of CMML. The eDiary must be completed each night beginning on Day -4 or earlier of the screening phase (for example, 4 days prior to Cycle 1 Day 1) through study treatment discontinuation.

You will bring the device to the study site at each study visit so that the device charging can be verified and accumulated data can be downloaded, as applicable. The device will then be returned to you at these same visits for continued use each night. You will then return the device and the docking station for the final time at the end of study treatment (EOT) visit so that the data can be archived.

### What are Molecular Tests?

These are tests performed on blood and bone marrow biopsy tissue that may help investigators understand how the study drug affects CMML and why some participants may or may not respond to this study drug. These tests are not standard of care and are part of this clinical trial. They will not be billed to you or your insurance and will only be performed on blood and bone marrow biopsies that would have been done as part of your routine medical care.

## WHAT HAPPENS WHEN I COME FOR STUDY VISITS?

After you sign and date this form, the study doctor or study staff will do the things listed below when you come in monthly for study visits. The study team will also dispense a one month supply of study drug each monthly visit. The first visit will be longer because you will be instructed to take the study drug during the visit and asked to collect blood samples shortly after for analysis (see molecular tests). If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

A study visit is one you have with the study doctor or study staff. This visit is the same as visits with your regular doctor. In addition to your baseline visit, you will need to come for four study visits in all. This is the same number of visits that you would need to make if you were not on the study.

Most study visits will take about one hour (except for the first study visit). Some may be shorter.

At each visit, the study doctor or staff may:

- Discuss how you are feeling, and any symptoms you may be experiencing. You will go over your recent lab results as well. This will be very similar to your regular appointments that you have been going to.

- You will go to the lab before being seen in the study clinic. You will have blood drawn (4 teaspoons) in the lab in order to determine what your blood counts are at that appointment. We will be checking white blood cells, hemoglobin, platelets, electrolytes and kidney function test.
- Once you arrive in the study clinic you will have a physical exam and your blood pressure, heart rate, breathing rate and temperature will be checked.
- Discuss whether you have started any new medications since your last appointment or if you have any concerns about your treatment or disease.
- Before you begin the study you will have a bone marrow biopsy done to look at certain levels of a factor in the bone marrow. You will get another bone marrow biopsy at week 8 of the study, and again when you go off the study (week 17). This is to check if the leukemia cell levels are decreasing with the study drugs.

Not all of these procedures will be done at each visit.

**WHILE YOU ARE IN THE STUDY, YOU MUST:**

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Give correct and accurate information about your medical history and current medical condition.
- Tell the study doctor about any health problems you have during the study.
- Tell the study doctor about any new medicine or drug you take during the study.
- Not take any other drugs or remedies unless the study doctor has approved them beforehand. This includes prescription drugs and over the counter medicine (including vitamins and herbal remedies) that you buy without a prescription.
- Not participate in other medical research studies.
- Not get pregnant or cause your partner to become pregnant
- Tell the study doctor or study staff if you want to stop being in the study at any time.

**WHAT ARE MY ALTERNATIVES TO BEING IN THIS STUDY?**

If you decide not to take part in this study, that is okay. There are other choices, such as starting no therapy or starting 5-azacitidine (Vidaza), an FDA approved drug for CMML. No change to your current treatment needs to occur if you choose not to take part in this study.

Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

**WHO IS PAYING FOR THIS STUDY?**

A company called Incyte Corporation is paying for this study.

**Investigator Conflict of Interest Statement**

Dr. David Sallman, a person involved with the study has received and may receive consultant and/or speaker fees from Incyte Corporation the provider of drug for this study. This study has been carefully reviewed to help assure that the professional judgment of the Moffitt Cancer Center doctors and staff will not be compromised. The study will be monitored for your safety and for the proper analysis of data. Any questions you might have about this will be answered by the Moffitt Cancer Center Compliance Office at (813) 745-1869

Dr. Rami Komrokji, a person involved with this study, has received and may receive consultant and/or speaker fees not to exceed $10,000 in a twelve-month period from Incyte Corporation, the sponsor of the study. This study has been carefully reviewed to help assure that the professional judgment of the Moffitt Cancer Center doctors and staff will not be compromised. The study will be monitored for your safety and for the proper analysis of data. Any questions you might have about this will be answered by the Moffitt Cancer Center Compliance Office at (813) 745-1869.

Dr. Eric Padron, a person involved with this study, has received and may receive consultant and/or speaker fees not to exceed $10,000 in a twelve-month period from Incyte Corporation, the sponsor of the study. This study has been carefully reviewed to help assure that the professional judgment of the Moffitt Cancer Center doctors and staff will not be compromised. The study will be monitored for your safety and for the proper analysis of data. Any questions you might have about this will be answered by the Moffitt Cancer Center Compliance Office at (813) 745-1869.

**WILL IT COST ANYTHING TO BE IN THIS STUDY?**

You and/or your insurance company will be financially responsible for hospital inpatient, outpatient and follow-up visits that would normally or routinely occur in the management of your disease. Inpatient and outpatient visits could include charges for treatments, medications, physician visits, laboratory tests and procedures. You and /or your insurance company will be responsible for paying for the charges which are considered routine, since you would have received these services even if you were not participating in this study. You will be responsible for any costs not covered by your insurance company, including deductibles, co-payments and all out-of-pocket expenses. Before you agree to be in this study, you should contact your health insurer to see if your plan will cover the costs required as part of your participation.

You and/or your insurance company will not be responsible for paying for study related items and services that are specifically required for this research study and are not considered part of the routine management of your disease, if these procedures are performed at Moffitt Cancer Center.

During your participation in this study, Incyte Pharmaceuticals will be responsible for providing the study drug, Ruxolitinib, at no additional charge to you. You and/or your insurance company will be responsible for the charges related to the administration of the study drugs.

If you would like more information on the costs of being on this study or have other insurance related questions then please let your clinical trial coordinator know or contact our Business Office at 813-745-8422.

## WILL BEING IN THIS STUDY HELP ME?

You may benefit as a result of your participation in this study; however, we don't know if you will get any health benefits by taking part in this study. We don't know if ruxolitinib will help CMML. That is why we are doing this research study. This study should help us learn whether Ruxolitinib will help CMML. What we learn may help others with CMML.

## ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

### The study treatment might not help.

Right now, we don't know if it will help. If it doesn't help, your CMML may not get better.

### There may be side effects.

You may have problems because of the ruxolitinib used in this study. These problems are called side effects. Some side effects are just a bother. Others could harm you. There may be some side effects that we don't know about yet.

Here are the side effects that we know could happen with ruxolitinib:

- It may lower your blood counts and you may require a transfusion of blood or platelets. This is unlikely to be a permanent problem and would likely be reversed when the study medication is stopped.
  You also may become anemic (low red blood cell count) while you take the drug, and that may cause you to feel fatigued or short of breath.
- It may cause your white blood cells to get low which could increase your risk for an infection that requires antibiotics. If your platelet count becomes low while you take the drug, it may lead to bleeding and/or bruising. In some people taking ruxolitinib, the decreases in blood cell counts have been severe. This is unlikely to be permanent and would likely improve when the study medication is stopped.
- Dizziness, bruising, headache, weight gain, flatulence, constipation, urinary tract infections, chills, fever, and certain viral skin infections (called herpes zoster or shingles), have been reported to occur with study drug ruxolitinib. Although this happens infrequently and is usually minor, please alert your study team so that appropriate actions can be taken.
- It may damage your liver. This is also unlikely to be a permanent problem and would likely be reversed when the study medication is stopped.
- Nausea, vomiting, and diarrhea have been reported to occur. This happens infrequently and is usually minor; please alert your study team so that appropriate actions can be taken.
- Swelling in your hands and feet has been reported to occur. This happens infrequently and is usually minor; please alert your study team so that appropriate actions can be taken.
- Mild increases in cholesterol have infrequently been reported.
- Tuberculosis has occurred in a small number of patients with myelofibrosis (MF) who

were treated with ruxolitinib, but it is not known whether this was due to MF, ruxolitinib, or other factors that are known to increase the risk of tuberculosis (such as diabetes, bronchitis, asthma, smoking, emphysema, or steroid use).
- An increase in systolic blood pressure was noted on at least one occasion in more MF patients treated with ruxolitinib than patients treated with comparison drugs (31% vs. 20%), but the average changes in blood pressure very small, generally occurred only once over the treatment period, and their meaning was not clear.
- About one week following interruption or discontinuation of ruxolitinib, some patients with MF experienced a return of symptoms (such as fatigue, bone pain, fever, itching, night sweats, weight loss, or an enlarged spleen).
- A rare disease called progressive multifocal leukoencephalopathy (PML) has been reported during ruxolitinib treatment for MF. PML comes from a viral infection that causes brain damage and can be fatal. It is unknown whether this was due to ruxolitinib treatment since PML has occurred in patients with blood cancers, including MF, who were not treated with ruxolitinib.
- Serious bacterial, mycobacterial, fungal or viral infections may occur. Patients with chronic Hepatitis B viral (HBV) infections taking ruxolitinib have reported elevated blood markers for this infection. The effect of ruxolitinib on viral replication in patients with chronic HBV infection is unknown. Please alert your study team if you have any symptoms of these infections.
- Non-melanoma skin cancers (NMSCs) have been reported in patients with ruxolitinib. Most of these patients had histories of extended treatment with hydroxyurea and prior NMSC or pre-malignant skin lesions. A causal relationship to ruxolitinib has not been established. Please alert your study team if you discover any changes to your skin.

Tell your study doctor immediately if you have any of the following symptoms or if anyone close to you notices that you have any of these symptoms: confusion or problems thinking, loss of balance or problems walking, clumsiness, difficulty speaking, decreased strength or weakness on one side of your body, blurred and/or loss of vision.

If you have any of these problems, tell the study doctor at your next visit. If these side effects bother or worry you, or if you have other problems, call your study doctor at (813) 745-4673.

If you are not in this study, the usual treatment you might get also has risks. We want you to know what those risks might be. Then you can compare those risks with the risks of this study.

Alternate Treatments:

- 5-azacitidine (Vidaza)
  The following risks have been reported with 5-azacitidine: (1) constipation, nausea, vomiting (2) swelling in hands and feet (3) rash (4) headache and dizziness (5) lowering of blood counts (6) injection site reactions (7) muscle aches (8) cough
- Decitabine (Dacogen)
  The following risks have been reported with decitabine: (1) constipation, nausea, vomiting (2) swelling in hands and feet (3) rash (4) headache and dizziness (5) lowering of blood counts (6) injection site reactions (7) muscle aches (8) cough (9) liver damage (10) electrolyte changes
- Lenalidomide (Revlimid)

The following risks have been reported with Lenalidomide: (1) lower your blood counts (2) Rash (3) swelling of your hands and feet (4) diarrhea, nausea, vomiting (5) muscle aches

**We will tell you as soon as we can, if we find out more about the side effects from ruxolitinib.**

**We may need to stop your study treatment.**

If we find out that ruxolitinib might hurt you, we will call you and ask you to come back in to get blood drawn. If any of the results of these tests are abnormal we will have you stop taking the study drug.

## COULD I HAVE AN ALLERGIC REACTION?

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction are:

- Rash
- Having a hard time breathing
- Wheezing when you breathe
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

### What are the risks of giving blood for this study?

The study doctor or study staff will take your blood by sticking a needle in your arm. Some problems you might have from this are:

- Pain
- Bruising
- Dizziness
- Infection

### What are the risks of a bone marrow aspirate/biopsy?

Serious complications resulting from a bone marrow aspiration or biopsy are rare. Some problems you might have from this are:

- Excessive bleeding from the biopsy site. This risk is high for people with bleeding problems. If you have bleeding problems, apply pressure to the biopsy site for at least 10 minutes after the procedure.
- Discomfort or sharp pain at the biopsy site.
- Infection at the biopsy site (Osteomyelitis). Call your health professional immediately if you notice:
    - Increased tenderness, pain, redness, or swelling at the biopsy site.
    - Fever higher than 100.4 °F (38 °C).

- Excessive bleeding or drainage, such as pus, through the bandage. If excessive bleeding occurs, apply pressure to the biopsy site and contact your study doctor.

**IS THERE ANY RISK TO YOUR UNBORN CHILDREN IF YOU TAKE PART IN THIS STUDY?**
**FOR WOMEN:**

Ruxolitinib may cause side effects we do not know about. Before you begin the study, you will be asked to give a blood sample to check to see if you are pregnant.

If you take part in this study:

- Your unborn children may have problems now or in the future.
- Your breastfeeding baby may have problems.

Tell one of the study doctors right away if:

- You are pregnant.
- You get pregnant.
- You are breastfeeding.

**IF YOU ARE A MAN:**

We do not know what the ruxolitinib could do to your sperm. Should you get a woman pregnant, there could be harm to the unborn baby. You and your partner should use an effective form of birth control if your partner is a woman of childbearing potential throughout the study.

**FOR MEN AND WOMEN:**

Whether you are a man or a woman, there may be risks to your unborn children that we don't know about ahead of time; they are unforeseeable.

If you take part in this study, you must agree to use two reliable forms of birth control simultaneously or to practice complete abstinence from heterosexual intercourse 1) for at least 28 days before starting study drug; 2) while participating in the study; and 3) for at least 28 days after discontinuation from the study. The two methods of reliable birth control must include one highly effective method (For example, intrauterine device [IUD], birth control pills, injections, implants, tubal ligation, and partner's vasectomy) and one additional effective (barrier) method (for example, latex condom, diaphragm, cervical cap). Examples of birth control methods include:

- Oral birth control pills
- Birth control patch
- Implanted (injectable contraceptive hormones or mechanical products such as intrauterine device)
- Barrier methods (such as: diaphragm, condoms, or spermicides)
- Tubal ligation or vasectomy
- Abstinence (no sexual intercourse)

You should discuss with your study doctor the method of birth control which is best for you to use both during study treatment and for a period of time after treatment.

Whether you are a woman or a man, you should tell your study doctor immediately if you become pregnant or if your partner becomes pregnant. Women who become pregnant during the study will have to leave the study. The study doctor or study staff may ask for information about the pregnancy and the birth of the baby. The study doctor or study staff may share this information with the sponsor and Advarra IRB (a group of people who review research studies to protect the rights and welfare of research participants).

Cancer treatment can affect fertility in both men and women, and it is important to understand the risks before starting therapy. Ask your staff about fertility preservation before you begin treatment. However, once you have started treatment you should not donate or sell your eggs or sperm.

## WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

**If you need emergency care:**

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

**If you do NOT need emergency care:**

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If you experience a side effect or a change in the way that you feel, call the study doctor at the telephone number listed on the first page of this form.

By signing this informed consent and research authorization form, you have not given up any legal rights to seek compensation for injuries from the sponsor**.**

## MOFFITT CANCER CENTER INJURY STATEMENT

If you believe you have been injured as a result of your participation in this study or if you have questions about your rights as a person who is taking part in a research study, you may call the Moffitt Cancer Center Risk Manager at 813-745-4219. Moffitt Cancer Center and its investigators have made no provision for monetary compensation in the event of physical illness or injury resulting from this study. Likewise, Moffitt Cancer Center and its investigators have made no provision for payment of lost wages, disability, or discomfort in the event of physical illness or injury resulting from this study. Florida law (Statute 768.28) limits the liability of Moffitt Cancer Center. This statute provides that damages are available only to the extent that negligent conduct of a Moffitt Cancer Center employee caused your injuries, and are limited by law. A copy of this statute is available upon request at 813-745-1869.

## WILL I GET PAID?

You will not get paid for being in this study. You will not be reimbursed for expenses for travel and/or lodging while taking part in this study.

## NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

## DO I HAVE TO REMAIN ON THIS STUDY ONCE I JOIN?

If you want to stop being in the study, tell the study doctor or study staff and return all unused study drug. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in more tests or return for a final study visit.

## ARE THERE REASONS THE STUDY DOCTOR OR SPONSOR MIGHT TAKE ME OUT OF THE STUDY LATER?

Even if you want to stay in the study, there may be reasons the study doctor or study staff will need to take you out of it. Your study doctor has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons, including the following:

- If the study doctor believes, for any reason, that it is in your best interest.
- If at any time while you are taking the study drug the study doctor discovers that your disease has worsened.
- If you develop side effects that the study doctor considers unacceptable.
- If you refuse to take the study drug or return for follow-up as recommended by your study doctor, or do not follow the study doctor's instructions.
- If you refuse to have tests that are needed to determine whether the study drug is safe and effective.
- If you require treatment with drugs that are not allowed on this study.
- If other causes prevent you from continuing in this study.
- If the Sponsor decides to end the study.

## HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing this form, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

**WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?**

Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: Incyte Corporation
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

## WHAT INFORMATION WILL BE USED OR DISCLOSED?

By signing below, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study doctor listed on the first page of this form.

Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You will receive a signed and dated copy of this form.

## WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00030294.

## WHERE CAN I GET MORE INFORMATION?

You may call the National Cancer Institute's (NCI) Information Service at:

1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

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.

**STATEMENT OF CONSENT**

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

**STATEMENT OF PERSON OBTAINING INFORMED CONSENT/RESEARCH AUTHORIZATION**

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____

Printed Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date