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

Study Title:	**"A Phase 2 Study of Fedratinib in Myelodysplastic/ Myeloproliferative Neoplasms (MDS/MPNs) and Chronic Neutrophilic Leukemia (CNL)"**
Protocol Number:	**MCC 20963**
Sponsor:	**Moffitt Cancer Center**
Principal Investigator: (Study Doctor)	**Andrew Kuykendall, M.D.**
Telephone: (24-hour number)	**(813) 745-4639 (800) 456-3434**
Address:	**Moffitt Cancer Center 12902 Magnolia Drive Tampa, FL 33612**

You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate.

The purpose of the study is to evaluate the effectiveness, safety, and tolerability of a study drug called fedratinib in participants with myelodysplastic/myeloproliferative neoplasms (MDS/MPNs) and chronic neutrophilic leukemia (CNL). You will be asked to spend about 24 months, or 2 years, in this study.

Participants will undergo screening procedures that involve a routine examination, blood tests and imaging scans. After the screening visit is complete, if you qualify to continue in the study, you will undergo a baseline visit, then enter the study treatment phase, which will involve study drug administration and other clinic visits, which are covered later in this document. After study treatment, you will have one outpatient visit which involves evaluating your health condition by routine clinic examination and procedures, later described in detail.

Fedratinib will be administered as four capsules, which you will take once a day. You will take the study drug between approximately 12 and 24 months, depending on how you are responding to the study treatment.

You are being asked to take part because you have been diagnosed with myelodysplastic/myeloproliferative neoplasms (MDS/MPNs) or chronic neutrophilic leukemia (CNL).

About 25 participants will participate in this study.

Your participation is voluntary, and you may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Alternatives to participating in the study include other medical treatments or no treatment at all. Your study doctor will let you know about all options available to you.

We do not know if you will receive any benefit from your participation. The most common and most serious risks that may be related to taking part in this research include diarrhea, nausea, vomiting, and anemia (which is usually mild, but may be serious). Additional risks are described later in this consent form.

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

Some investigators on this study are being paid by Bristol-Myers Squibb, the company funding this study, for activities that are not part of the study. These activities may include, for instance, consulting, serving on advisory boards, or giving speeches. Please speak with your study doctor if you have questions about this.

If you are interested in learning more about this study, please continue reading the information below.

WHAT IS THIS STUDY ABOUT?

You are being asked to participate in this research study because you have myelodysplastic/myeloproliferative neoplasms (MDS/MPNs) or chronic neutrophilic leukemia (CNL).

The purpose of this research study is to:

- Test the safety, effectiveness, and tolerability of the study drug, fedratinib.
- Determine if fedratinib can treat your condition.

Fedratinib is a pill being studied because of the research done in myeloid malignancies. Fedratinib is also called INREBIC®. Fedratinib has been approved by the US Food and Drug Administration (FDA) for the treatment of certain types of myeloproliferative diseases, such as myelofibrosis.

The use of fedratinib in this study is investigational. An investigational use is one that is not approved by the United States Food and Drug Administration (FDA). This study is designed to test the effectiveness, safety, and tolerability of fedratinib and to see how your type of cancer responds to fedratinib study treatment.

WHAT WILL HAPPEN DURING THIS STUDY?

Before you can start the study, the study doctor and study staff will talk to you about the study. Then you will sign and date this form before the study staff can begin the first part of the study. This is called a ‘screening period’ to see if you qualify to participate in the study. A research study visit is one you have with the study doctor or study staff.

Screening:

Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- **Demographic Questions:** Ask you to give personal information, such as your name, date of birth, etc.
- **Medical History and Review of Current Medications:** Ask you to answer questions about your health, your medical history, and the medications you take.
- **Physical Exam:** You should ask the study doctor about what will happen during this exam.
- **Vital Signs:** Check your blood pressure by putting a band around your arm (this will squeeze your arm for about a minute), check your pulse, listen to you breathe in and out, and take your temperature.
- **ECOG Status:** You will be asked how well you are able to do normal activities (bathing, driving, shopping, working, etc.)
- **Blood Samples:** Take some blood to do laboratory tests.
    - Some of your blood will be used to check on your health and current condition.
    - Some of your blood will be used to check your levels of vitamin B1 (thiamine).
    - Some of your blood will be used for genetic testing to provide additional information on your disease.
- **Pregnancy Testing:** Test your blood to see if you are pregnant. You will only have pregnancy testing if you are a woman and can have children. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study.
- **Ultrasound**: You will have an ultrasound done to measure the size of your spleen. An ultrasound uses sound waves to make pictures of the inside of your body.
- **CT Scan (Optional):** If an ultrasound is not feasible, the study doctor may decide for you to have a CT scan done to measure the size of your spleen instead. A CT scan uses radiation (x-rays) to make pictures of the inside of your body. The scan can show a cross-section (a thin “slice”) of your body or can show the body tissues and structure in 3 dimensions (“3-D”). You may have to read, sign, and date a separate consent form before you can have a CT scan.
- **MRI (Optional):** If an ultrasound is not feasible, the study doctor may decide for you to have an MRI done to measure the size of your spleen instead. An MRI uses powerful magnets and radio waves to make pictures of body tissues and structure. You may have to read, sign, and date a separate consent form before you can have an MRI.
- **Bone Marrow Biopsy and Aspirate:** Take a tissue sample from your bone marrow in order to do tests. Additional bone marrow aspirate will be collected for genetic testing to provide additional information on your disease and potentially be utilized to predict which participants will respond to study therapy. You may have to read, sign, and date a separate consent form before you can have a biopsy.
- **Questionnaires:** Ask you to fill out questionnaires about your health and your current symptoms.

Review of Screening Testing:

It is possible that after these tests are reviewed, you may not be able to take part in this study. If you are not eligible, your study doctor will discuss other treatment options with you.

If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

Study Treatment:

At your Enrollment/Baseline Visit, you will be provided with the study drug, fedratinib, at no charge. You will be given bottles that contain 100 mg capsules and will be directed to take four 100 mg capsules (for a total of 400 mg), by mouth once daily. Take the capsules as directed by your study doctor. He or she will tell you if there is a change in how you take the capsules during the day.

Each study cycle is 28 days. You can take the study drug at any time during the day, but you are advised to take it at approximately the same time each day, preferably with a high fat meal. If you miss a dose by more than 8 hours from the scheduled time, the dose should not be taken, and you should take the next dose at your normally scheduled time. You will be asked to bring your study drug to each clinic visit with you.

This is an open-label study. This means that you, the study doctor, study staff and the Sponsor will know the study drugs and the doses that you are given.

The table below shows the study visits you will have and the procedures you will undergo:

Procedures	Screening	Enrollment/Baseline Cycle 1, Day 1	Cycle 1* , Day 8,15 , 22 (+/- 5 days)	Cycle 2, Day 1 (+/- 7 days)	Cycle 2, Day 15 (+/- 5 days)	Cycle 3, Day 1 ((+/- 7 days)	Cycle 4, Day 1 Week 12 Assessment (+/- 7 days)	Cycle 5, Day 1 (+/- 7 days)	Cycle 6, Day 1 (+/- 7 days)	Cycle 7, Day 1 Week 24 Assessment (+/- 14 days)	Subsequent Visits (Every 3 cycles) (+/- 14 days)	End of Treatment Visit (+/- 7 days from study drug completion)e
Informed consent	X											
Demographics	X											
Medical history	X											
Concurrent meds	X		X ----------									X
Fedratinib dispensed[d]		X	X	X	X	X	X	X	X	X	X	
Investigational Drug Diary Provided		X		X		X	X	X	X	X	X	
Physical exam	X	X	X	X	X	X	X	X	X	X	X	X
Vital signs	X	X	X	X	X	X	X	X	X	X	X	X
Weight		X										
Performance status (ECOG)	X	X										
CBC w/diff, plts	X	X	X	X	X	X	X	X	X	X	X	X
Metabolic panel [a]	X	X	X	X	X	X	X	X	X	X	X	X
Uric acid, magnesium, phosphorous	X											
Amylase, lipase	X	X	X	X		X	X			X		

LDH	X	X		X		X	X	X	X	X	X	X
Folic acid, Vitamin B12	X											
Thiamine	X	X		X			X			X	X	
CRP		X					X			X	X	
Serum Pregnancy test [b]	X											
Adverse event evaluation			X ---------- X									
Spleen Imaging	X						X			X	X[c]	
MPN SAF TSS	X	X		X	X	X	X	X	X	X	X	
PGIC				X	X	X	X	X	X	X	X	
MDS/MPN Response Assessment							X			X	X[c]	
Bone Marrow Biopsy/Aspirate	X									X		
Bone marrow aspirate for correlatives	X									X		
Peripheral Blood Draw for correlatives	X						X			X		
Cytogenetics	X											
Next Generation Sequencing	X											

a: Albumin, alkaline phosphatase, total bilirubin, CO2, BUN, calcium, chloride, creatinine, glucose, potassium, total protein, AST,ALT, sodium,
b: Serum pregnancy test (women of childbearing potential).
c: Spleen imaging and MDS/MPN response criteria to be performed every 24 weeks +/- 28 days (6 cycles) after week 24
d. See section 7.2.3 and 7.2.4 for details regarding specimen preparation, handling, and storage
* Cycle length = 28 days

- **Medical History and Review of Current Medications:** Ask you to answer questions about your health, your medical history, and the medications you take.
- **Physical Exam:** You should ask the study doctor about what will happen during this exam.
- **Vital Signs:** Check your blood pressure by putting a band around your arm (this will squeeze your arm for about a minute), check your pulse, listen to you breathe in and out, and take your temperature.
- **Weight:** See how much you weigh. This will only be done on your Enrollment/Baseline visit.
- **ECOG Status:** You will be asked how well you are able to do normal activities (bathing, driving, shopping, working, etc.) This will only be done on your Enrollment/Baseline visit.
- **Blood Samples:** Take some blood to do laboratory tests.
    - Some of your blood will be used to check on your health and current condition.
    - Some of your blood will be used to check your levels of vitamin B1 (thiamine).
    - Some of your blood will be used to test for any inflammation in your body.
    - Some of your blood will be used for genetic testing to provide additional information on your disease.
- **Review of Adverse Events**: You will be asked about any symptoms you may be experiencing.
- **Ultrasound**: You will have an ultrasound done to measure the size of your spleen. An ultrasound uses sound waves to make pictures of the inside of your body.

- **CT Scan (Optional):** If an ultrasound is not feasible, the study doctor may decide for you to have a CT scan done to measure the size of your spleen instead. A CT scan uses radiation (x-rays) to make pictures of the inside of your body. The scan can show a cross-section (a thin "slice") of your body or can show the body tissues and structure in 3 dimensions ("3-D"). You may have to read, sign, and date a separate consent form before you can have a CT scan.
- **MRI (Optional):** If an ultrasound is not feasible, the study doctor may decide for you to have an MRI done to measure the size of your spleen instead. An MRI uses powerful magnets and radio waves to make pictures of body tissues and structure. You may have to read, sign, and date a separate consent form before you can have an MRI.
- **Bone Marrow Biopsy and Aspirate:** Take a tissue sample from your bone marrow in order to do tests. Additional bone marrow aspirate will be collected for genetic testing to provide additional information on your disease and potentially be utilized to predict which participants will respond to study therapy. This will only be done on your Cycle 7, Day 1 visit. You may have to read, sign, and date a separate consent form before you can have a biopsy.
- **Questionnaires:** Ask you to fill out questionnaires about your health and your current symptoms.
- **Study Diary:** Give you a study diary and tell you how to use it. Ask you to bring the completed diary back to the study center at each visit.
- **Study Drug:** Give you a supply of study drug and tell you how to take it. Ask you to bring back all unused study drug to each visit.

<u>After Study Treatment</u>:

Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

After your last dose of fedratinib, you will complete an End of Study Visit about 28 days after you stop taking the study drug. During this visit, the following procedures will be performed:

- **Medical History and Review of Current Medications:** Ask you to answer questions about your health, your medical history, and the medications you take.
- **Physical Exam:** You should ask the study doctor about what will happen during this exam.
- **Vital Signs:** Check your blood pressure by putting a band around your arm (this will squeeze your arm for about a minute), check your pulse, listen to you breathe in and out, and take your temperature.
- **Blood Samples:** Take some blood to do laboratory tests.
    - Some of your blood will be used to check on your health and current condition.
- **Review of Adverse Events**: You will be asked about any symptoms you may be experiencing.

HOW WILL MY BLOOD AND TISSUE SAMPLES BE USED?

In addition to the procedures outlined above, we are asking you to allow us to obtain and store samples of your blood and bone marrow, collectively referred to as "tissue", for use in future research. These samples may be used for research on your disease or condition and

others to assist in the development of new treatments. There will be no financial benefit to you.

In addition to your sample being used for this study and future research, we would like to share it with other researchers. We will code your sample so that the researcher who uses it for other purposes does not know your identity. We will not release the code that links your sample to your personal identifying information for any reason.

This study also involves genetic testing. Genes control how your body grows and changes, and how your body reacts to certain things. Genes are what we get from our parents that help make our bodies what they are. For example, eye and hair color depend on the genes we received from our parents. We want to find out how genes work in people with your condition. It may be true that some people are more likely to have your condition because of their genes and we would like to learn more about this.

As part of this study, a blood sample will be obtained and DNA from your blood sample will be purified. DNA, or deoxyribonucleic acid, stores and transmits inherited traits, such as eye color or blood type. As part of this research project, your DNA will be studied in an effort to find out if there are genes that contribute to medical conditions that are part of this study.

We will tell you what we find out about your genes. For example, we might find out that you have a mutation in a certain gene. We may know that if people have this gene mutation, they sometimes get a certain disease or do not respond to treatment. You could have a gene mutation that makes it more likely that you will have a health problem. However, that does not mean you will get that health problem. You should ask the study team or a genetic counselor if you have any questions about genetic research.

Your sample will be stored with your name or other identifying information and health information linked to it. We will not share your name or other information that identifies you unless it is required by law.

Since your genetic sample is linked to identifying information, should you choose to withdraw your consent to use the sample at a later date, please contact the study team. The study team will remove your sample from the research and immediately destroy it so that it can no longer be used. Please understand that part of your sample may have been used prior to the withdrawal of your consent.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

WHO IS PAYING FOR THIS STUDY?

A company called Bristol-Myers Squibb is paying for this study.

Dr. Andrew Kuykendall, a person involved with this study, has received and may receive compensation for service on an advisory board not to exceed $10,000 in a twelve-month period from Bristol-Myers Squibb Company, a sponsor of the study. This study has been carefully reviewed to help assure that the professional judgement 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. David Sallman, 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 Bristol-Myers Squibb, a sponsor of the study. This study has been carefully reviewed to help assure that the professional judgement 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, the company Bristol-Myers Squibb will be responsible for providing the study drug, fedratinib, at no additional charge to you.

If you would like more information on the costs of being on this study or have other insurance related questions, 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. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

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

The fedratinib might not help.

Right now, we do not know for sure if fedratinib will help. If it does not help, your condition may get worse.

You may have problems because of the fedratinib used in this study. These problems are called side effects. Some side effects are just bothersome. Others could harm you. There may be some side effects that we do not know about yet. The research might involve risks to you that are currently unforeseeable. Your study team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the fedratinib. In some cases, side effects can be serious, long lasting, or may never go away. There may also be the risk of death.

HERE ARE THE KNOWN SIDE EFFECTS THAT COULD HAPPEN WITH FEDRATINIB

There is always a chance that any drug may cause you some discomfort or harm and the fedratinib in this study is no different. You should talk to your study doctor if you experience any side effects that you have while taking part in the study.

Risks and side effects related to the fedratinib include those which are:

Very Common Side Effects (greater than 10% of participants):

- Nausea
- Diarrhea
- Low red blood cell count (anemia)
- Low platelet count (thrombocytopenia), which increases the risk of bleeding
- Vomiting
- Tiredness (fatigue) or weakness (asthenia)
- Muscle spasms
- Abdominal pain
- Itching (pruritus)
- Increase in lipase and amylase, which indicate damage to the pancreas

Common Side Effects (10% or less, greater than or equal to 3% of participants):

- Pain in extremities
- Constipation
- High blood levels of creatinine
- High blood levels of alanine aminotransferase, which indicates liver damage
- Headache
- Increase in weight
- Dizziness

- Bone pain
- Urinary tract infection
- Painful or difficult urination (dysuria)
- High blood levels of aspartate aminotransferase, which indicates liver damage
- High blood pressure (hypertension)
- Indigestion (dyspepsia)

Rare, but Serious Side Effects (less than 3% of participants):

- Low white blood cell count (neutropenia)
- Buildup of fluid around the heart (heart failure)
- Decreased blood flow in the heart muscle (myocardial ischemia)
- High blood levels of potassium (hyperkalemia)
- Blood infection (sepsis)
- Acute kidney injury
- Encephalopathy, including Wernicke's (disease of the brain which can cause possible confusion, balance and movement issues, and eye problems), and may be persistent. In addition, the encephalopathy may be potentially be fatal.

These side effects may be serious, may require medical care, and may cause permanent or lasting problems. If you have any of these problems, call your study doctor immediately.

Ask the study doctor or study staff if you have questions about the signs or symptoms of any side effects you read about in this consent form.

It is not uncommon for the medical treatment that you would receive as your standard of care to also cause problems.

RISKS ASSOCIATED WITH STANDARD OF CARE OR ALTERNATIVE TREATMENT:

As with any drug, there may be risks, known and unknown.

A more complete listing of side effects for other therapies may be available for you to review if you wish. Please talk with your study doctor about the risks of both this investigational drug and any alternative methods of treatment that are available.

COULD I HAVE AN ALLERGIC REACTION?

Occasionally, people have allergic reactions to drugs which may require medical treatment. A severe allergic reaction could be life-threatening. Examples of an allergic reaction include:

- Rash
- Shortness of breath
- Wheezing
- Difficulty breathing
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eye
- Fast pulse
- Sweating

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

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

FOR WOMEN:

If you are pregnant, you cannot participate in this study, because there may be risks to you and your unborn baby that are currently unforeseeable; risks that we do not know about yet. Breastfeeding (nursing) mothers will not be included in this study, since it is not known whether the study drugs in this study will be passed on to the baby in mother's milk. If you are currently breastfeeding and wish to continue breastfeeding, your study doctor may recommend another treatment.

If you are a female of childbearing potential (able to become pregnant), you will be given a pregnancy test before beginning any study drug.

Tell the study doctor right away if:

- You are pregnant
- You become pregnant
- You are planning to become pregnant
- You are breastfeeding

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 use an effective birth control method as discussed with your study doctor and continue to use it until at least 30 days after your last dose if you are a female of childbearing potential and for at least 90 days after your last dose if you are a male. Males should not donate sperm while on the study drug or within 30 days of the last dose of the study drug.

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 (tubes tied) or vasectomy
- Abstinence (no sexual intercourse)

You should discuss the method of birth control which is best for you to use both during study treatment and for a period of time after study 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 during the study or withing 4 months after the study. 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).

The long-term effects of the study drug on fertility are unknown. This means that it is unknown if the study drug will affect your ability to have children in the future. If we find out that the study drug might harm your fertility, we will notify you immediately and you may stop the study.

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

COULD I HAVE ANY OTHER PROBLEMS WITH MY HEALTH IF I DO THIS RESEARCH STUDY?

It is possible that you could have problems and side effects of fedratinib that nobody knows about yet, which include your condition getting worse, or even death. If the study doctor learns any new information about fedratinib that might change your mind about continuing in the study, the study doctor or study staff will tell you about it. The study doctor will also tell you if new treatments become available for your condition.

It is possible that taking fedratinib with your regular medications or supplements may change how fedratinib, your regular medications, or your regular supplements work. It is very important that you tell the study doctor about all medications or supplements you are taking during the study.

What are the risks of giving blood for this study?

Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

You will give between 10 mL and 18 mL, or between 0.5 and 1 tablespoons of blood, when blood samples are taken during the study, depending on the visit.

During your screening visit, Week 12 assessment, and Week 24 assessment, you will also have a total of about 70 mL, or 5 tablespoons of additional blood drawn.

What are the risks of having a biopsy done for this study?

Bone Marrow Aspiration and Biopsy

A bone marrow aspiration and biopsy is a procedure done in the clinic in which an area of the hip (either one hip or both hips) is numbed and a small sample of bone marrow is withdrawn. When the local anesthesia (numbing medication) is given, you may initially feel a burning sensation in your skin and bone surface for several seconds. During the procedure, you may temporarily feel pressure and/or pain of varying degrees. If necessary, you may ask your study doctor for additional local anesthesia or a medication to ease your stress. You also may experience minimal bleeding, and/or bruising after the procedure is completed and you may experience soreness in the area for a few days afterwards. Rarely, infection can develop.

What are the risks of other invasive study procedures?

MRI (Optional)

Magnetic resonance imaging (MRI) uses a magnet and radio waves to make diagnostic medical images of the body. There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. However, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body, including medical implants, devices such as pacemakers and internal defibrillators, or certain dyes found in tattoos. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner.

If there is any question about potentially hazardous metal within your body, you will not undergo the MRI. This may exclude you from participation in this research study. The MRI involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the MRI. During the MRI, you can have voice contact and physical contact with someone in attendance if you desire. Let the study doctor know if you have a fear of enclosed spaces.

CT Scan (Optional)

Computed Tomography (CT) is a way to make x-ray images of the inside of the body. The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures that show structures inside your body more clearly than regular x-ray pictures.

During the procedure, a technologist will take you into the CT scan room where you will lie down on the table (usually on your back) inside of the CT machine. You should get comfortable because it is very important that you not move during certain parts of the test.

CT examinations differ depending on the part of your body being studied. For example, if your abdomen is being studied, a series of pictures will be taken from your lower chest to your lower pelvis. During the study, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. Also, you may receive signals from the technologist or from the machine about your breathing. If you have any discomfort during the test, be sure to tell the technologist.

Sedation (Optional)

The risks of sedation include an allergic reaction, aspiration (fluid going into the lungs), and over-sedation. In addition, the intravenous (IV) line used may cause a bruise. Occasionally, an infection develops at the IV site.

Questionnaires

Filling out the questionnaires could cause you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while filling out a questionnaire.

Confidentiality

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

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 and dating 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 813-745-7882. 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.

WILL I GET PAID?

You will not get paid for being in this study.

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.

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 and study materials.

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 and dating 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.

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed

consent.

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: Moffitt Cancer Center
- 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), and the 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 and dating 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 do not need to sign this form, but if you do not, you cannot participate in this study.

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 study doctor 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
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00050052.

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 AND AUTHORIZATION

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 | Time

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 | Time