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

Study Title:	**"Reduced-Intensity Fludarabine, Melphalan, and Total Body Irradiation Conditioning for Transplantation of HLA-Haploidentical Related Hematopoietic Cells (Haplo-HCT) for Patients with Hematologic Malignancies"**
Protocol Number:	**MCC 20131**
Sponsor:	**Moffitt Cancer Center**
Principal Investigator: (Study Doctor)	**Hany Elmariah, MD, MS**
Telephone:	**813-745-7208**
(24 hour number)	**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 determine the effectiveness of HLA-haploidentical related hematopoietic cell transplant (Haplo-HCT) using a modified reduced intensity conditioning regimen (fludarabine, melphalan and total body irradiation). All drugs used in this trial are used in standard of care allogeneic transplants.. The study regimen is different from standard regimens because it uses a new strategy of combining these standard drugs and uses a lower dose of melphalan. The goal of these modifications to the conditioning regimen is to improve cure rates and reduce side effects following Haplo-HCT.

A Haplo-HCT uses hematopoietic cells from a related, partially matched donor. Your participation will involve the conditioning regimen given on Day -6 through Day -1. On Day 0, you will receive the donor cells (Haplo-HCT). After the Haplo-HCT you will receive standard post-transplant care including post-transplant cyclophosphamide (chemotherapy) given on days +3 and +4 to prevent graft-versus-host disease. You will be followed on the study for 1.5 years after your Haplo-HCT.

You are being asked to take part because you have cancer of the blood, marrow or lymph nodes and an HLA-Haploidentical transplant is a treatment option for you.

About 34 subjects 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:

- Standard of care allogeneic stem cell transplant;
- Alternative clinical study using allogeneic stem cell transplantation if eligible;
- Treatment continuation (chemotherapy without transplantation);
- Supportive/palliative care: This does not treat the blood disease, but instead tries to improve how you feel.

We do not know if you will receive any benefit from your participation more than with a standard transplant. The most common and most serious risks that may be related to taking part in this research include:

The infusion of donor cells can cause a bad taste in your mouth, nausea and vomiting, and rarely fever and chills. The risks and toxicities related to transplant: death due to infection or transplant complications; slow recovery of blood counts; study treatment failure (including graft failure or disease relapse), graft-versus-host-disease (GVHD); infections, and other cancers later in life. Risks / side effects of the conditioning regimen: decreased white blood cell count with increased risk of infection, anemia, feeling tired, nausea, vomiting, diarrhea, mucositis (painful inflammation and ulceration of the mucous membranes lining the digestive tract). Risks of radiation: fevers, joint aches, hormone abnormalities, cataracts.

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.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to take part in this study, you will need to sign and date this informed consent and research authorization form.

Before Your Study Treatment

You will need to have several check-ups and tests to see if you can be in the study. These check-ups and tests are part of your regular care. They would be done even if you were not part of this study. These tests may include:

- Medical history
- Physical exam, height, and weight
- Blood
- Heart function tests
- Lung (pulmonary) function tests; to measure how much oxygen is in your blood.
- CT scans, x-rays to measure your disease and/or evaluate for hidden infections and other cancers
- Bone marrow tests. These tests are called aspirates or biopsies. Samples of your marrow will be taken from your hip bone with a large needle.
- A pregnancy test if you are a woman and able to have children (if you are pregnant, you will not be able to join this study).

During Your Study Treatment

Almost all the aspects of your transplant will follow accepted standard practices. You will be admitted to our bone marrow transplantation unit for at least 3 to 4 weeks. During the first week, you will receive a combination of chemotherapy agents called the conditioning regimen. A small dose of radiation to your whole body may be used as well.

The following chemotherapy drugs and radiation will prepare your body for transplant:

- Fludarabine will be given to you each day for 5 days, starting 6 days before your transplant (Day -6 through Day -2). Your study doctor will give you this drug in your vein (IV).
- Melphalan will be given to you once on Day -6. Your study doctor will give you this drug in your vein (IV). During your Melphalan infusion, additional blood will be collected at various time points to measure the amount of Melphalan in your blood.
- Last, you will get a low dose of total body irradiation (TBI) the day before your transplant (Day -1)

On day 0, you will receive an infusion of cells from the partially matched donor.

After your transplant, you will also receive medications to help prevent graft-versus-host-disease (GVHD).

- A chemotherapy drug called cyclophosphamide will be administered on Day +3 and +4. Your study doctor will give you this drug in your vein (IV).
- An immunosuppressive drug called mycophenolate mofetil (MMF) will start on Day +5 and continue for 35 days. MMF is a pill and taken 3 times a day.
- Sirolimus will also be initiated on Day +5 for and will continue for at least 90 days if tolerated. Your study doctor will give you this drug in your vein. If tolerated, sirolimus may be changed to a pill taken by mouth twice a day. The blood level of this medication will be checked once or twice a week for the first 90 days after transplant, in addition to your regular blood tests. Afterwards, it will be checked less frequently. If you have side effects from sirolimus, your study doctor may change you to a similar drug called tacrolimus. This is also a pill, usually taken twice per day. Dose is adjusted based on drug levels in the blood. Drug levels are initially checked once or twice per week until achieving a steady level and then may be checked less often.

After Your Study Treatment

<u>Health Evaluations:</u>

You will be carefully followed by your study doctor and transplant team after transplant according to standard procedures. You will be evaluated at standard time points after transplant to determine the effect of the treatment on your disease.

- Routine evaluations to assess toxicities, infections and GVHD
- Routine blood tests (cell counts and liver and kidney function)
- Blood tests to find the amount of donor cells in your body. This is called chimerism.
- Blood tests to see how well your immune system is working
- Bone marrow biopsies and/or imaging studies (PET/CTs) to evaluate disease status after transplant

HOW WILL MY 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 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.

Specifically, you would have blood samples (about 1 tablespoon of blood) taken at baseline (prior to transplant), and at days 28, 180 and 360 after your transplant.

With these blood samples, we will determine how the study therapy influences certain cells and other signals within your immune system.

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 influence the metabolism of the chemotherapy drug cyclophosphamide that is used in this regimen. It may be true that some people are more likely to have graft-versus-host disease or relapse 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 not tell you what we find out about your genes. For example, we might find out that you have a certain kind of gene. We may know that if people have this gene, they sometimes get a certain disease or do not respond to treatment. You could have a gene 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.

Genetic Information Nondiscrimination Act (GINA)

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 we 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 we 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, group health plans, and employers as outlined above must follow this law. Please note that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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.

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?

Right now, we do not know for sure if your participation in this study will help. If it does not help, your condition/disease may get worse.

You may have problems because of the study drugs 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 health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study drugs. In some cases, side effects can be serious, long lasting, or may never go away.

Risks And Toxicities Related To Transplant:

The following problems may happen because of your transplant. These risks may happen if a transplant was done as part of the study or not. The risks are:

Slow recovery of blood counts: The red blood cells, white blood cells, and platelets can be slow to recover after blood or marrow transplant. Until your blood counts recover, you will need blood and platelet transfusions, and will be at risk for bleeding and infections. You may receive filgrastim, a medicine to help speed up the recovery of white blood cells.

Graft failure: The stem cells from your donor (the "graft") may fail to grow inside your body. Past experience suggests that there can be up to a 10-15% chance of graft failure. Graft failure may cause low blood counts for a long time. If your counts do not recover, you may need to receive a second transplant. Graft failure can be fatal.

Graft-Versus-Host Disease (GVHD): GVHD happens when the donated cells see your body as foreign and attack it. GVHD can be treated, but treatment can take months to years. Sometimes GVHD is severe or difficult to treat and may lead to death. You will be watched closely for this complication and given drugs to prevent and/or treat it.

Acute GVHD may produce skin rash, nausea, vomiting, diarrhea, abdominal pain, abnormalities of liver function, and an increased risk of infection. Chronic GVHD may produce skin rashes, hair loss, thickened dry skin, dry eyes, dry mouth, liver disease, weight loss, diarrhea, and an increased risk of infection. To confirm the diagnosis of acute or chronic GVHD, you may be asked to have a biopsy (a small sample of your tissue to look at under the microscope) of your skin, gut, or, rarely, your liver.

Other complications. Other complications may include:
Damage to the vital organs in your body. The transplant could cause problems in any body organ such as the heart, lungs, liver, gut, kidneys and bladder, or brain. The kidneys and the liver are most likely to be damaged. Some participants will experience serious lung problems from infections, chemotherapy or radiation.

Serious infections. Full and complete recovery of your immune system may take many months. During this time, there is an increased risk of infections. You will take medicines to lower your risk of infections. However, these treatments do not always work. If you have an infection, you may have to stay in the hospital longer or be re-hospitalized after transplant. Although most infections can be successfully treated, some infections may result in death.

Cytokine Release Syndrome: The transplanted cells may cause an illness called "cytokine release syndrome." This may include fevers, skin rash, blood pressure problems, shortness of breath/low oxygen, kidney problems, and other less often can affect other organs. Cytokine release syndrome can be severe and even fatal. Treatment includes a medication called tocilizumab and/or steroids. The potential side effects of tocilizumab include infections, liver injury, and allergic reactions.

Relapse of disease or a new blood cancer. Your cancer may come back even if the transplant is initially successful. In rare cases, a new blood cancer may develop from the donor cells. Cyclophosphamide can cause damage to blood cells, which may result in a blood cancer such as myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML). The blood cancer usually develops 2-10 years after treatment, or 6 years on average. The risk of developing a

new blood cancer after allogeneic blood or marrow transplant is probably less than 2%. If cancer develops in your donor's blood cells, you may require additional treatment with chemotherapy or another blood or marrow transplant.

Fludarabine

Common Side Effects

- Severe suppression of blood counts (risk of bleeding and infection)
- Diarrhea
- Anorexia (decreased appetite)
- Mucositis (mouth sores)
- Nausea/vomiting
- Stomatitis (inflammation of the mouth and lips)
- Osteoporosis (loss of bone density)
- Dysuria (pain, discomfort, or burning when urinating)

Less Common Side Effects

- Chills
- Fever
- Stomach bleeding
- Peripheral edema (accumulation of fluid causing swelling, usually in lower limbs)

Rare Side Effects

- Neurotoxicity (toxic effect on central or peripheral nervous system)
    - Agitation and confusion
    - Blurred vision
    - Peripheral neuropathy (weakness, numbness and pain in hands and feet)
    - Hearing loss
    - Headache
    - Cerebellar syndrome (unsteadiness and lack of coordination)
    - Blindness
    - Coma
    - Weakness
- Depression
- Insomnia
- Hemorrhagic cystitis (except in fa) (inflammation of the bladder)
    - Dysuria (pain, discomfort, or burning when urinating)

    - Hematuria (blood in the urine)
    - Hemorrhage
- Abnormal renal (kidney) function test
- Autoimmune hemolytic anemia (not enough red blood cells because the body produces antibodies that destroy them, leading to tiredness and weakness)
- Deep venous thrombosis (blood clot in a vein deeper in the body, usually the leg)
- Aneurysms (bulge in an artery in the brain)
- Pruritic skin rash (itchy rash)
- Abnormal liver function/liver failure
- Constipation
- Transient ischemic attack (the blood supply to part of the brain is briefly blocked, leading to a stroke that only lasts a few minutes)
- Dysphagia (difficulty swallowing)
- Myalgia (muscle pain)
- Arthralgia (joint pain)
- Renal failure (kidney failure)

Melphalan

Common Side Effects

- Nausea (at higher doses)
- Vomiting (at higher doses)
- Low white blood cell count with increased risk of infection
- Low platelet count with increased risk of bleeding
- Anemia (low red blood cell count) with symptoms such as tiredness, paleness, or trouble catching breath
- Diarrhea

Less Common Side Effects

- Short-term or long-term infertility (inability to have children)
- Weakness

Rare Side Effects

- Severe allergic reaction
- Loss of appetite
- Scarring (fibrosis) or inflammation of lungs
- Hair loss, including face and body hair

- Rash
- Itching
- Second type of cancer (may happen years after study treatment)
- Death from lung damage or other causes

Total Body Irradiation

Common Side Effects

- Nausea and vomiting
- Diarrhea
- Cataracts
- Sterility (inability to have children)
- Endocrinopathies (hormone imbalance due to damage to the endocrine gland)
- Stunted growth in children
- Intestinal (stomach) cramps
- Mucositis (mouth sores)

Less Common Side Effects

- Parotitis (swelling and inflammation of the parotid gland, the salivary gland on either side of the mouth and in front of both ears)
- Interstitial pneumonitis (lung disease characterized by collection of material such as pus, blood, etc. in the lungs and low levels of oxygen in the blood requiring hospitalization symptoms include a dry cough. Shortness of breath can occur either at rest or after exertion)
- Generalized mild reddening of the skin
- Veno-occlusive disease (when the small blood vessels that lead into the liver and are inside the liver become blocked)

Rare Side Effects

- Dysphagia (difficulty swallowing)
- Deformities of the backbone (vertebrae)
- Nephropathy (numbness or tingling in hands and/or feet)
- Risk of 2nd malignancy years later

Cyclophosphamide

Common Side Effects

- Nausea/vomiting
- Mucositis (mouth sores)
- Sterility (inability to have children)
- Severe suppression of blood counts with risks of bleeding and infection
- Diarrhea
- Fluid weight gain/edema
- Alopecia (hair loss)

Less Common Side Effects

- Hemorrhagic cystitis (inflammation of the bladder)
    - Dysuria (pain, discomfort, or burning when urinating)
    - Hematuria (blood in the urine)
    - Hemorrhage

Rare Side Effects

- Cardiomyopathy (disease of the heart muscle that makes it harder for your heart to pump blood to the rest of your body)
- Skin rash
- SIADH (syndrome of inappropriate anti-diuretic hormone, causing the body to retain too much water)

Sirolimus

Common Side Effects

- Kidney problems
- Pain or body aches
- Fever
- High blood pressure
- Low red blood cell count (anemia)
- Low platelets
- Unusual bleeding/bruising
- Headaches
- Ulcers of the lips/mouth

- Shortness of breath

Less Common Side Effects

- Blood clots
- High cholesterol
- Reduced number of platelets, red, and white blood cells
- Hoarse voice

Rare Side Effects, but may be serious

- Severe liver damage
- Increased risk of lymphoma or other cancers

Mycophenolate mofetil (MMF)

Common Side Effects

- Miscarriage
- Birth defects
- Diarrhea
- Damage to unborn baby
- Limited effectiveness of birth control
- Stomach pain
- Upset stomach
- Vomiting
- Headache
- Tremors
- Low white blood cell count with increased risk of infection
- Increased blood cholesterols
- Swelling of the hands, feet, ankles or lower legs

Less Common Side Effects

- Anemia
- Rash
- Difficulty falling asleep or staying asleep
- Dizziness
- Uncontrollable hand shakes

Rare, but Serious Side Effects

- Difficulty breathing
- Unusual bruising
- Fast heartbeat
- Excessive tiredness
- Weakness
- Blood in stool
- Bloody vomit
- Change in vision
- Secondary cancers, such as lymphoproliferative disease or lymphoma
- Progressive multifocal leukoencephalopathy (rare infection of the brain, symptoms include clumsiness, trouble speaking, decline in mental function, and partial blindness)

Blood Tests

Blood sampling and needle punctures carry some risk. Possible side effects include, but are not limited to: fainting, bleeding, bruising, discomfort, dizziness, infection and/or pain at the puncture site.

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 physician 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.

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:

- A 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.

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 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 after your last dose of 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 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 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 study staff about fertility preservation before you begin treatment. However, once you have started treatment you should not donate or sell your eggs or sperm.

Additional Information about MMF (Mycophenolate mofetil)

- MMF could be damaging to an unborn baby if you are pregnant or become pregnant while receiving the drug.
- MMF can make birth control pills not work well. So, you have a higher risk of becoming pregnant while you are taking it.
- If you could become pregnant, you must use 2 effective forms of birth control for 4 weeks before starting MMF, during treatment, and for one year after transplant.

If you think you might be pregnant or could become pregnant prior to enrollment, you should **not** join 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.

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

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 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 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 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 will receive a signed and dated copy of this form.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you 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.

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 Participant 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 Participant Adviser: Pro00038324.

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