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

Study Title:	**"A Phase I Study of Duvelisib in Combination with BMS-986345 in Lymphoid Malignancy"**
Protocol Number:	**MCC 21096**
Sponsor:	**Moffitt Cancer Center**
Principal Investigator: (Study Doctor)	**Hayder Saeed, MD**
Telephone: (24 hour number)	**(813) 745-4673 (800) 456-3434**
Address:	**Moffitt Cancer Center 12902 Magnolia Drive Tampa, FL 33612**

You are being asked to take part in a research study because you have been diagnosed with a lymphoid malignancy, a cancer that originates from immune system cells called lymphocytes. The information in this document should help you to decide if you would like to participate.

The purpose of the study is to find a safe dose and to evaluate the safety and tolerability of the drug BMS-986345, in combination with duvelisib.

About 30 participants will participate in this study. You will be asked to spend about 24 months in this study to complete study visits and procedures. It is possible the length of time you spend in the study may be longer or shorter than 24 months, depending on how you respond to the study treatment.

During the study, you will receive study treatment with BMS-986345 and duvelisib. Both drugs have been approved by the United States Food and Drug Administration (FDA) to treat certain types of cancers; however, the combination of BMS-986345 and duvelisib is experimental.

In addition to receiving the study drugs, you will come to Moffitt Cancer Center to complete study procedures such as blood tests and physical exams. More information on the study procedures can be found in the WHAT WILL HAPPEN DURING THE STUDY section of this form.

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 in this research study.

You may have problems because of the drugs used in this study. These problems are called side effects. The most common and most serious side effects that may be related to taking part in this research include diarrhea, nausea, constipation, neutropenia (a decrease in the main part of the white blood cells), thrombocytopenia (a low number of platelets in the blood) and anemia (which is usually mild, but may be serious). Additional information on the side effects of the study drugs, as well as risks of the study procedures, can be found later in this 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.

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 a lymphoid malignancy.

The purpose of this research study is to:

- Test the safety and tolerability of the study drug combination of duvelisib and BMS-986345
- Find the safe and appropriate doses of both duvelisib and BMS-986345 when used in combination
- Determine the effectiveness of the combination of duvelisib and BMS-986345

Duvelisib is FDA approved to treat relapsed or refractory chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), and relapsed or refractory follicular lymphoma (FL). BMS-986345, also known as oral azacitidine, is FDA approved to treat acute myeloid leukemia. The combination of duvelisib and BMS-986345 used in this study, however, is investigational. An investigational use is one that is not approved by the FDA.

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 if you agree to participate, 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:

- You will be asked about your medical history (including questions regarding your health problems, details of your diagnosis, and previous treatment) and what medications you are currently taking

- You will be asked to give personal information such as your name, date of birth, etc.
- You will be given a physical exam and vital signs will be taken (includes checking your heart rate, breathing, blood pressure, height, and weight)
- Bone marrow biopsy
- Electrocardiogram (ECG), a recording of your heart's rhythm
- Blood will be collected for laboratory tests to check on your health, kidney and liver function, and virus exposures (hepatitis B, hepatitis C antibodies, cytomegalovirus, Epstein-Barr virus, and HIV – the study doctor may be required by law to report the result of these tests to the local health authority)
- A pregnancy test will be conducted if you are a woman of child-bearing potential
- A positron emission tomography (PET) and computed tomography (CT) scan will be conducted

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:

There are 24 study treatment cycles in the study where you will receive the study drug combination. Each study cycle is 28 days.

For those enrolled in the first part of the study, for Cycles 1 and 2, three dose levels will be explored for the study drug duvelisib, between 15 and 75 milligrams, which you will take by mouth twice a day. In addition to this, 100 milligrams of BMS-986345 will be taken by mouth once a day from Days 1-14 for the 28 day cycle. For Cycle 3 and beyond, the dose of duvelisib will be dropped to 25 milligrams, which you will take by mouth twice a day, along with 100 milligrams of BMS-986345, which will be taken by mouth once a day, from Days 1-14 for the 28 day cycle.

If you are enrolled in the second part of the study, for Cycles 1 and 2, you will continue on 75 milligrams of duvelisib by mouth twice a day and your dose of BMS-986345 will be increased between 200 and 300 milligrams by mouth once a day from Days 1-14 of the 28 day cycle.

Dose Escalation Schedule for cycle 1-2		
Dose Level	Dose	
	Duvelisib Mg PO twice daily starting day 7 of cycle 1	BMS-986345Mg PO once daily day 1-14 of 28 days cycle
Level -1	15	100
Level 1	25	100
Level 2	50	100
Level 3	75	100
Level 4	75	200
Level 5	75	300

For Cycle 3 and beyond, you will continue on 25 milligrams of duvelisib by mouth twice a day and your dose of BMS-986345 will be increased to between 200 and 300 milligrams by mouth once a day from Days 1-14 of the 28 day cycle.

Dose Schedule for cycle 3 and afterwards		
Dose Level	Dose	
	Duvelisib Mg twice daily	BMS-986345Mg once daily day 1-14 of 28 days cycle
Level -1	15	100
Level 1	25	100
Level 2	25	100
Level 3	25	100
Level 4	25	200
Level 5	25	300

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.

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.

Study Treatment Visits:

In addition to receiving the study drugs, the following procedures will also be conducted during the study treatment phase of the study:

- Review of your prior and current medications
- Review of any symptoms you may be experiencing
- You will be given a physical exam and vital signs will be taken (includes checking your heart rate, breathing, blood pressure, and weight)
- You will complete a questionnaire where you will be asked how well you are able to do normal activities (bathing, shopping, working, etc.)
- Blood will be collected for laboratory tests to check on your health and for correlative research testing (such as seeing how much of the study drugs are in your blood and to test biomarkers to measure a side effect or condition).
- Another PET/CT and CT scan will be conducted on Day 1 (+/- 7 days) of every third cycle onward.

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

		Cycle 1				Cycle 2				Cycle 3 onward		End of therapy visit[9]
Procedures	Screening Day -28 to -1	Day 1 ±1	Day 7 ±1	Day 14 ±1	Day 21 ±1	Day 1 ±1	Day 7 ±1	Day 14 ±1	Day 21 ±1	Day 1 ±3	Day 14 ±3	Day 1 ±30
Informed consent	X											
Demographics	X											
Medical history	X											
Duvelisib[1]			X	X	X	X	X	X	X	X	X	
BMS-986345[2]		X	X			X	X			X		
Concomitant medication review	X	X----------										----------X
Physical exam	X	X	X	X	X	X	X	X	X	X		X
Vital signs	X	X	X	X	X	X	X	X	X	X		X
Height	X											
Weight	X	X				X				X		X
Performance status	X	X				X				X		
Hematology	X	X	X	X	X	X	X	X	X	X		X
serum chemistry [3]	X	X	X	X	X	X	X	X	X	X		X
Creatinine clearance	X											
HIV testing, hep panel, CMV and EBV[4]	X											
Serum B hCG	X											
Bone marrow biopsy[10,11]	X											
Pathology review[5]	X											
EKG (as indicated)	X											
Adverse event review and evaluation	X	X----------										----------X
Radiologic/Imaging assessment[6,11]	X									X		
Correlative studies[7,8]		X	X	X	X	X				X		X

End of Study Therapy Visit:

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. Within 30 days of your last dose of study drug, you will return to the study center for the End of Therapy Visit. The following procedures will also be conducted for this visit:

- Review of your prior and current medications
- Review of any symptoms you may be experiencing
- You will be given a physical exam and vital signs will be taken (includes checking your heart rate, breathing, blood pressure, and weight)
- Blood will be collected for laboratory tests to check on your health and for correlative research testing (such as seeing how much of the study drugs are in your blood and to test biomarkers to measure a side effect or condition).

ADDITIONAL INFORMATION REGARDING THE STUDY VISIT PROCEDURES CAN BE FOUND BELOW:

- **Health History and Review of Current Medications:** Ask you to answer questions about your health, your medical history, and the medications you take.
- **Demographic Questions:** Ask you to give personal information, such as your name, date of birth, race, etc.
- **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.
- **Height, Weight:** See how tall you are, and see how much you weigh.
- **Bone Marrow Biopsy:** Take a tissue sample from your bone marrow in order to do tests. You may have to read, sign and date a separate consent form before you can have a biopsy.
- **Electrocardiogram:** An electrocardiogram (ECG) measures the electrical activity of your heart.
- **Blood Testing:** Take some blood to do laboratory tests.
    - Some of your blood will be used to check on your health.
    - Some of your blood will be used to test for communicable diseases (diseases that can be spread from one person to another). Ask the study doctor which diseases your blood will be tested for. Depending on state law, you may have to sign and date a separate consent form before this testing can start. The study doctor or study staff will tell you if the test results are positive. If required by state law, the study doctor or study staff may report a positive test result to the local health department. The tests are confidential, and the study doctor or study staff will not share your results outside this study unless state law requires it. The results of these tests must be negative in order for you to be in the study.
    - Some of your blood will be used to test how much of the study drug is in your blood.

    - Some of your blood will be used to test for biomarkers, which are parts of the blood that can be used to measure efficacy or side effect.
- **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.
- **CT Scan:** 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"). The study doctor or study staff may give you a contrast dye, either by mouth or with a needle. The study doctor can tell you more about contrast dye. You may have to read, sign and date a separate consent form before you can have a CT scan.
- **Eastern Cooperative Oncology Group (ECOG) Status:** You will be asked how well you are able to do normal activities (bathing, driving, shopping, working, etc.)
- **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.

HOW WILL MY BLOOD/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 tissue, 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.

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.

Your samples will be stored for up to 15 years. You may request that they be destroyed prior to 15 years by contacting your study doctor at the number listed on the first page of this form.

WHO IS PAYING FOR THIS STUDY?

A company called Secura Bio, a sponsor of the study, is paying for this study.

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, Secura Bio will be responsible for providing the study drugs, Duvelisib and BMS-986345, 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.

Medicare Advantage: If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.

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 duvelisib and BMS-986345 combination might not help.

Right now, we do not know for sure if the combination of duvelisib and BMS-986345 will help. If it does not help, your condition/disease may get worse.

You may have problems because of the 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. The study staff 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. There may also be the risk of death. The use of the combination of drugs in this study is experimental, and therefore, a list of side effects for the combination of the study drugs is not available.

HERE ARE THE KNOWN SIDE EFFECTS THAT COULD HAPPEN WITH DUVELISIB

Duvelisib is an agent involved in the inhibition of a type of enzyme called a kinase. Human cells have many different kinases, and they help control important functions like cell signaling, metabolism, division, and survival. Certain kinases are more active in some types of cancer cells and blocking them may help keep the cancer cells from growing. Kinase inhibitors may also block the growth of new blood vessels that tumors need to grow.

Side effects of duvelisib may happen anytime during study treatment or even after your study treatment has ended. Some of these problems may happen more often when duvelisib is used in combination with BMS-986345. Call or see your study doctor right away if you develop any problems listed below or the symptoms get worse.

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

Very Common Side Effects (greater than 20% of participants):

- Diarrhea or colitis (inflammation of the intestines)
- Neutropenia (low number of white blood cells with or without fever)
- Tiredness
- Rash
- Fever
- Leukopenia (low white blood cell count)
- Cough
- Nausea
- Infections, including pneumonia and upper respiratory tract infection
- Elevated liver enzymes

Common (less than 20%, greater than or equal to 1% of participants):

- Anemia (a decrease in the number of red blood cells which may make you feel weak or tired)
- Thrombocytopenia (a decrease in the number of platelets that help your blood to clot*)*
- Increase of transaminase in the blood
- Vomiting
- Mucositis (swelling or soreness in the mouth)
- Constipation
- Pain (including muscle, abdominal, and joint pain)
- Lower respiratory tract infection
- Lymphocytosis (increase in white blood cells)
- Shortness of breath
- Headache
- Hypophosphatemia (low level of phosphate in the blood)
- Leukopenia (low level of white blood cells)
- Hyponatremia (low blood sodium level)
- Decreased appetite
- Edema (swelling)
- Hypokalemia (low level of potassium in blood)
- Weight loss
- Renal insufficiency
- Hypoalbuminemia (low level of albumin in the blood)
- Elevation of markers related to the pancreas (such as lipase and serum amylase)
- Xerosis (abnormally dry skin)
- Hyperkalemia (high level of potassium in the blood)

- Increase in creatinine in the blood

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.

Additional rare but serious side effects observed when taking duvelisib, not otherwise noted above, include:

- Inflammation in the lungs, which can be life-threatening
- Skin reactions, which can include painful sores or ulcers, severe rash with blisters or peeling skin, and rash with itching or fever, which can be life-threatening

Some of those treated with duvelisib have also had severe diarrhea. If you experience any diarrhea, or loose watery stools, or notice you have more stools in a day than usual, it is important that you notify your study doctor so that he or she can give you medication to control this side effect and adjust your dose of duvelisib, if needed.

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.

Risks of BMS-986345

Azacitidine, an intravenous (IV, injected into the vein) form of BMS-986345, has been studied in participants with cancer of the blood and other organs of the body, as well as participants with other diseases. The following is a list of the most medically significant or most common side effects reported in studies considered to be related to azacitidine. This is not a complete list of all side effects that may occur. For more information about risks and side effects, please ask your study doctor. The risks and side effects related to the BMS-986345 include those which are:

<u>Very Common Side Effects (greater than 10% of participants)</u>:

- Thrombocytopenia (a decrease in the number of platelets that help your blood to clot)
- Neutropenia (low number of white blood cells with or without fever)
- Anemia (a decrease in the number of red blood cells which may make you feel weak or tired)
- Constipation
- Nausea
- Fever
- Vomiting
- Infections, including pneumonia or upper respiratory tract infection
- Stomach pain
- Feeling tired or weak
- Diarrhea
- Shortness of breath
- Headache
- Pain (including muscle, joints, and chest pain)
- Itching
- Hematoma (bruising)

- Weight loss
- Hypokalemia (low blood levels of potassium)
- Sore throat with swelling or pain of the nasal membranes or nose
- Rash
- Decreased appetite
- Skin redness
- Dizziness
- Nosebleed

Common (less than 10%, greater than or equal to 1% of participants):

- Bone marrow failure which is a severe reduction of red and white blood cells and platelets (at nearly the same time) which can cause weakness, bruising, or make infections more likely
- Sepsis (a severe infection of the blood)
- Shivering (chills)
- Indigestion or upset stomach
- Diverticulitis (a disease affecting the gut which can result in fever, vomiting, and stomach pain)
- Anxiety
- Bleeding from the gums, eye, brain, stomach, or rectum (hemorrhoids) or due to a catheter line
- Stomatitis (swelling or sores on the inside of the mouth)
- Rhinitis (stuffy nose)
- High blood pressure
- Low blood pressure
- Blood in the urine
- Sleepiness
- Fainting
- Dehydration
- Hives
- Muscle spasms
- Urinary tract infection
- Hair loss
- Fluid around the lungs

Rare, but Serious (less than 1% of participants):

- Allergic reaction (may include skin inflammation, rash, trouble breathing, trouble speaking, fever, and/or diarrhea)
- Abnormal kidney function test, kidneys not functioning properly, that has rarely led to too much acid in the blood or kidney failure (sometimes fatal)
- In participants with certain types of cancer, abnormal liver function may occur that has rarely led to decreased level of consciousness related to liver toxicity (sometimes fatal)

Additional side effects observed during post marketing surveillance of azacitidine, not otherwise noted above, include:

- Rapid death of cancer cells, where the accumulating contents of dying cancer cells cause an imbalance in the chemistry of the body which can lead to kidney damage (tumor lysis syndrome)
- Thickening, inflammation, or scarring in the lungs
- Open skin sores or tissue damage at the site of injection (if applicable)
- Infection of the deeper layers of skin, which may spread quickly, damaging the skin or tissue, which can be life-threatening
- Large plum-colored, raised painful patches on the skin with fever
- Differentiation syndrome: a condition associated with rapid worsening of shortness of breath with swelling.

Some of those taking oral azacitidine (BMS-986345) have had severe diarrhea. If you experience any diarrhea, or loose watery stools, or notice you have more stools in a day than usual, it is important that you notify your study doctor so that he or she can give you medication to control this side effect and adjust your dose of oral azacitidine (BMS-986345) if needed.

There is always a chance that any drug may cause you some discomfort or harm and the duvelisib and BMS-986345 in this study are no different. You should talk to your study doctor when you experience any side effects that you have while taking part in this study.

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 combination of duvelisib and BMS-986345 and any alternative methods of treatment that are available.

COULD I HAVE AN ALLERGIC REACTION?

Occasionally, people have allergic reactions to medications which may require medical treatment. A severe allergic reaction could be life-threatening. Examples of symptoms of an allergic reaction include: a rash; shortness of breath; wheezing; difficulty breathing; sudden drop in blood pressure; swelling around the mouth, throat, or eye; fast pulse; and 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 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 90 days after your last dose of study drug if you are a female of childbearing potential and for at least 93 days after your last dose if you are a male.

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 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. 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 inform you while still in the study.

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 study treatment. However, once you have started study treatment you should not donate

or sell your eggs or sperm.

IF I STOP TAKING MY REGULAR MEDICATION, WHAT ARE THE RISKS?

If you stop your regular medication to be in the study, your lymphoid malignancy symptoms might come back or get worse. Please tell the study doctor or study staff right away if you have any problems when you stop taking your regular medication.

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 from both the duvelisib and BMS-986345 that nobody knows about yet, which include your lymphoid malignancy getting worse, or even death. If the study doctor learns any new information about the study drugs 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 lymphoid malignancy.

It is possible that taking the study drugs with your regular medications or supplements may change how duvelisib and/or BMS-986345, 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 about 2 tablespoons when blood samples are taken during the study.

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 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.

What are the risks of other invasive study procedures?

CT Scan

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. Before or during the study, you may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs. The contrast material (dye) that is injected into your body may cause you to get a metallic taste in your mouth and to feel warm. Rarely, it causes nausea and vomiting. The dye can also cause damage to the kidneys, which may lead to kidney failure. This is a concern if you have poor kidney function. Rarely, the dye can cause a life threatening reaction. If you have any discomfort during the test or after the injection, be sure to tell the technologist.

Sedation

The risks of sedation include an allergic reaction, aspiration (fluid going into the lungs), and over-sedation. In addition, the IV 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. Secura Bio, 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. You or your insurance will be billed for any physical illness or injury resulting from this study. Likewise, Secura Bio, 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.

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.
- The company that manufactures and provides the study drug, Secura Bio.
- 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 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: Pro00050513.

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