ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORE MEDICAL CENTER

You are being asked to join this research study. The title of the study is:

"A Phase I/II study of Lenalidomide Maintenance After Autologous Stem Cell Transplant For Elderly Patients With Acute Myeloid Leukemia (AML)"

The study is being done under the supervision of:

Principal Investigator (Researcher Study Doctor): Ira Braunschweig, MD

Office Address: Montefiore-Einstein Cancer Center
Montefiore Medical Center-Moses Division
Department of Oncology, Hofheimer Pavilion, Room 100
111 East 210th Street
Bronx, New York 10467

Telephone #: 718-920-4826

Protocol #: 13-08-148

DO I HAVE TO TAKE PART IN THIS RESEARCH STUDY?

- Your participation is voluntary. This means that you decide whether or not you want to join the study after speaking with the researcher, or other member of the research team.
- If you decide to take part you will be asked to sign this consent form. Your signature means that you agree to be a subject in this research.
- After reading this form and having a discussion about what it says, you should ask all the questions you want to ask. You should take as much time as you need to make a decision.
- If you do not understand some of the terms used in this form, ask the person who is discussing the study with you to give any additional information that may make this easier to understand.
- You do not have to consent to participate in the study immediately, or ever. Take time to decide whether or not you wish to join. You may take home a copy of this consent form to think about it or discuss the information with family or friends before you decide.
- If you decide not to participate the care providers at this facility will give you all of the standard care that is appropriate for you.
- You will be given a copy of this form whether or not you agree to participate in this study. Do not sign the form unless you have had all your questions answered and understand exactly what is involved.
- If you decide to take part you are still free to withdraw at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility.

- If you decide to withdraw after receiving the study drug, you should talk with the research study doctor to see how best to complete the withdrawal process.
- The form discusses:
  WHAT THE RESEARCHERS WILL LEARN FROM THE RESEARCH
  WHAT WILL HAPPEN TO YOU DURING THE RESEARCH
  WHAT RISKS AND/OR DISCOMFORTS YOU MIGHT
  EXPECT/EXPERIENCE AS A RESEARCH SUBJECT
  IF YOU CAN EXPECT ANY BENEFITS, AND ARE THERE ANY
  ALTERNATIVES TO THIS RESEARCH FOR YOUR CONDITION.

RESEARCH STUDY SPECIFICS

- This is a clinical trial which is studying the use of a drug called lenalidomide after an autologous stem cell transplant for the treatment of AML.

- Clinical trials help to get more information about whether or not a drug used in a new way will work better than the standard treatments that are currently available for that disease. This study will help to decide whether or not lenalidomide is safe to use after transplant, and if it is, to find the best dose of lenalidomide after transplant.

- The U.S. Food and Drug Administration (FDA) has already approved lenalidomide to treat the blood cancers multiple myeloma and myelodysplastic syndrome (MDS). Lenalidomide has also been used effectively as initial therapy for AML in humans. Lenalidomide has also been used effectively in patients who have undergone a stem cell transplant for multiple myeloma. The use of lenalidomide after a stem cell transplant for AML, however, is investigational and not approved by the FDA.

WHY HAVE I BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

- You are being asked to take part in this study because you have AML and your doctor feels you may benefit from a new treatment after your stem cell transplant.

WHY IS THIS RESEARCH STUDY BEING DONE?

- The purpose of this study is to find out what effects (good and bad) treatment with lenalidomide has on you and your leukemia following an autologous stem cell transplant. Previous scientific studies suggest that lenalidomide could help AML patients. This research is being done because we do not know whether the addition of lenalidomide following autologous stem cell transplant is better than autologous stem cell transplant alone.

- We would like to find out the safest and most efficient lenalidomide dose level for patients with leukemia who underwent an autologous stem cell transplant.

- We would like to determine what effects lenalidomide will have after a stem cell transplant for AML.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

- You will be one of approximately 30 patients who will be participating in this study.

- The study will be conducted at Montefiore Medical Center.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Before you begin the study:

You will need to have the following exams, tests or procedures to find out if you can be in the study. Many of the exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your research study doctor.

- Medical history and examination, including blood pressure, heart rate, and body temperature.
- Approximately 1 tablespoon of blood will be taken for routine complete blood count
- Approximately 1-2 tablespoons of blood will be taken for tests, including tests that assess your kidneys and liver
- A bone marrow aspirate and biopsy will be done to make sure you are in remission. Approximately 2 extra teaspoons of marrow will be sent to a special laboratory for additional molecular studies.
- A saliva sample from your cheek will be obtained by using a painless cheek swab for genetic studies.

If you are female, a pregnancy test is required to participate in this research study and is not a part of standard care. A urine sample will be collected for pregnancy test within 24 hours prior to prescribing the study medication, lenalidomide.

During the study:

If you agree to participate, after you have recovered fully from your transplant, and you have no evidence of leukemia, you will start the study drug, lenalidomide. You will receive lenalidomide within cycles. One cycle is four weeks. You will be asked to take lenalidomide capsules every day during the first three weeks, and not take them during the fourth week. You will be given a pill diary to record when you take the lenalidomide capsules.

- The first group of three patients will start lenalidomide at 10 mg per day. If this dose is well tolerated, the second group will be start lenalidomide at 15 mg per day. If that dose is well tolerated the next group of three patients will start at 25mg per day and that dose

(if well tolerated) will remain the dose used for the remainder of the patients. If there are significant side effects to any dose, the dose may be decreased or the drug may be stopped altogether at the discretion of you and your doctor.

- Routine physical exams, including blood pressure, heart rate, and body temperature will be done weekly during the first cycle (first four weeks), and every two weeks during the second cycle. These exams during the first two cycles are considered frequent. Frequent exams are not part of standard care, they are performed for your safety and because you are participating in this clinical research study. Physical exams will be repeated monthly after the second cycle, which are standard care.

- Routine blood work for blood count and to test your kidney and liver function will be done weekly during the first cycle (first four weeks), and every two weeks during the second cycle. Blood tests during the first two cycles are considered frequent. Each time approximately 3 tablespoons of blood will be collected. Frequent tests are not part of standard care, they are performed for your safety and because you are participating in this clinical research study. Blood tests will be repeated monthly after the second cycle, which are standard care.

- During every visit, you will be asked to report any side effects. Also, you have to notify your doctor before starting any new medication.

- A bone marrow aspirate and biopsy will be done every four cycles until the disease comes back which is standard of care. Approximately 2 extra teaspoons of marrow will be sent to a special laboratory for additional molecular studies that are for research purposes.

- You will continue the drug until the disease comes back or you develop side effects serious enough that you or your doctor thinks it is best for you to stop the drug.

At the end of the study:

The same blood tests and pregnancy test (if you are female) will be repeated at the time your study participation is over. End of study visit and tests are research related and not standard care. If the disease is not back at the time of study end, you will be asked to come to the clinic every 16 weeks to repeat a bone marrow aspiration until the disease comes back.

After the study:

You will be asked to come back to the clinic 30 days after the end of the study. Physical exam, including blood pressure, heart rate, and body temperature; blood tests and pregnancy test (if you are female) will be repeated for your safety. Approximately 3 tablespoons of blood will be collected. A urine sample will be collected for pregnancy test If there is any side effect related to lenalidomide, your doctor will schedule follow-up visits until you feel better.

A research study team member will contact you every six months to ask brief questions about your disease.

WILL THIS STUDY INVOLVE GENETIC RESEARCH AND/OR TESTING?

- This study will involve genetic testing. Genetic means having to do with information that is passed on in families from parents to their children through genes.
- Tests conducted under this research study may reveal genetic information.
- This study will involve cytogenetic testing- This means "chromosome study". Cytogenetic testing allows a scientist to look at the number or shape of chromosomes present in a patient's sample. Cytogenetic testing is useful when looking at the chromosomes as a whole, but it does not provide any information about specific genes or proteins that may be associated with a genetic disease.
- Genetic tests related to your cancer will be performed using your cheek swab and bone marrow samples.

GENETIC COUNSELING INFORMATION:

- You may wish to obtain professional genetic counseling before signing the informed consent. A genetic counselor is a person qualified to provide information about what the results of this type of test may mean to you and your family. You or your insurance company will be responsible for the cost of these services.
- Since some of the tests are research-related, the results will not be disclosed to you. No formal counseling will be provided under the research study. If you request it, you will be referred to a genetic counselor. You or your insurance carrier will be responsible for the genetic counselor's fee.

WHAT ELSE DO I HAVE TO DO?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including “over-the-counter” remedies and nutritional supplements or herbs.
- In order to participate in this study you must register into and follow the requirements of the RevAssist® program of Celgene Corporation. This program provides education and counseling on the risks of fetal exposure, blood clots and reduced blood counts. You will be required to receive counseling every 28 days during treatment with lenalidomide, follow the pregnancy testing and birth control requirements of the program that are appropriate for you and take telephone surveys regarding your compliance with the program.

- If any physician other than the study doctor prescribes medication for you for another condition, or you are taking any over-the-counter medications or vitamins, you must inform your research study doctor. This is important because the interaction of some medications may cause serious side effects.

- If you do not feel well at any time, call your doctor or the research study doctor immediately.

- Drugs may cause a reaction that, if not treated promptly, could be life-threatening. It is important that you report all symptoms, reactions and other complaints to the research study doctor.

- If you think you have become pregnant, contact your research study doctor immediately.

- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.

- You may carry out all your normal daily activities.

- You must NEVER share lenalidomide (or other study drugs) with someone else.

- You must NEVER donate blood while you are participating in this study and for at least 28 days after you have been discontinued / withdrawn from the study. You must receive counseling and complete phone surveys as required by the RevAssist® program.

- You should swallow lenalidomide capsules whole with water at the same time each day. Do not break, chew or open the capsules.

- If you miss a dose of lenalidomide, take it as soon as you remember on the same day. If you miss taking your dose for the entire day, take your regular dose the next scheduled day (do NOT take double your regular dose to make up for the missed dose).

- If you take more than the prescribed dose of lenalidomide you should seek emergency medical care if needed and contact study staff immediately.

- Females of childbearing potential that might be caring for you should not touch the lenalidomide capsules or bottles unless they are wearing gloves.

- Any unused Revlimid® (lenalidomide) should be returned as instructed through the RevAssist® program.

- You should ask questions about anything you do not understand.

- You must keep appointments and follow the study doctor's instructions.

- You should let your study doctor know if your telephone number changes. Tell your study doctor before you take any new medication even if it is prescribed by another doctor for a different medical problem.

- You should tell your regular doctor about your participation in this research. You can also talk to a family member or friend about your participation in this research.

- You should carry information about the research in your purse or wallet.

WHAT ARE THE POSSIBLE SIDE EFFECTS, DISCOMFORTS, RISKS OR INCONVENIENCES I CAN EXPECT FROM BEING IN THIS RESEARCH STUDY?

Participation in this research study may involve added risks and discomforts, including possible side effects of the treatment described below.

There also may be other potentially serious side effects that are not yet known. Let your study doctor know about any side effects you are experiencing. Your study doctor may be able to give you other drugs to make side effects less serious or uncomfortable. Many side effects go away after the treatment is stopped but, in some cases, these side effects may be serious and/or long lasting. Rarely, side effects could be fatal (causing death).

RISKS ASSOCIATED WITH LENALIDOMIDE:

Lenalidomide has been studied in healthy volunteers and in patients with cancer of the blood and other organs of the body as well as in patients with other diseases. As with any other experimental treatment there may be side effects or risks associated with lenalidomide, some of which are not yet known.

The following is a list of the most medically significant or most common side effects reported in completed and ongoing studies considered to be related to lenalidomide. In some cases, side effects can be serious, long-lasting, may never go away, or can cause death. This list is not complete but your Study Doctor will answer any questions you might have and provide you with more information.

Common (between a 1-10% chance that this will happen):
Anemia (decrease in red blood cells which may cause you to feel extra tired, lightheaded, short of breath or have palpitations); decrease in cells that help your blood clot; low white blood cells with or without fever; pneumonia or other infections; fever; abnormal heart beats; shortness of breath; blood clots in lower extremities, lungs, heart, brain or other organs; abnormal kidney function; diarrhea with or without bleeding; loss of fluid; other cancers; pain including muscles, joints and non-heart pain; altered sense of taste.

Uncommon (between a 0.1-1% chance that this will happen):
Heart attack; heart and lungs stop working; bleeding including bleeding in individual organs; stroke; seizure; dizziness; fainting; diabetes; depression; confusion; worsening of general

condition/ disease; feeling tired, weak and unwell; chills; constipation; blockage of intestine; nausea; vomiting; decreased appetite; weight loss; swelling including swelling of individual organs; gall bladder problem; chemical imbalance; abnormal liver lab tests; allergic reactions including serious allergic skin reactions including involvement of the lining of the nose, mouth, stomach and intestines or rash leading to the separation of the top layer of skin; skin irritation; fracture; problems urinating; cough; breathing disorder; abnormal blood pressure; low oxygen to tissues of the body including heart; absence of blood cells due to defective development; 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; sudden increase in tumor size

Rare (less than a 0.1% chance that this will happen):
Abnormal lymph gland; heart pain; shock; weak heart muscle; deafness; blindness; abnormal eye pressure; vision changes; tear in intestine; decreased action of intestine; food poisoning; indigestion; stomach ulcer with or without bleeding; problem with thyroid; problem with adrenal gland; liver failure; abnormal liver function; destruction of red blood cells; abnormal bone marrow test result; blood vessel narrowing; lack of blood supply leading to tissue damage; arthritis with infection; worsening of chronic lung disease with infection; too much fluid in body; trouble speaking; trouble walking; muscular inflammation/swelling; coma; abnormal sense of touch; lowered level of consciousness, with drowsiness, listlessness and apathy; headache; neurologic problems; pain and decreased sensation in nerves; parkinson's disease; repetitive speech; sleepiness; shaking; irritability; excited; hallucination; not able to sleep; moody; fluid in lungs; runny nose; sore throat; blister; change in skin color; skin ulcer; blood not getting to extremities; itching; destruction of muscle that can lead to kidney damage.

Other risks related to lenalidomide:

Lenalidomide has been shown to increase the level of digoxin in the blood in some patients; please tell your doctor if you are taking digoxin.

According to researchers, patients with cancer have a higher risk of developing a second new cancer when compared to people without cancer. In clinical studies of newly diagnosed multiple myeloma, a higher number of second cancers were reported in patients treated with induction therapy (treatment as first step to reducing number of cancer cells) and/or bone marrow transplant then lenalidomide for a long period of time compared to patients treated with induction therapy and/or bone marrow transplant then placebo (a capsule containing no lenalidomide). Patients should make their doctors aware of their medical history and any concerns they may have regarding their own increased risk of other cancers.

Your condition may not get better or may become worse while you are in this study. For more information about risks and side effects, ask your study doctor.

RISKS OF STUDY PROCEDURES:

Blood Draws:

The risk of having blood drawn through a vein includes pain, bruising, irritation at the site of the blood draw, and rarely an infection could develop at the site of the blood draw. Rarely a person might faint.

Bone Marrow Biopsy / Aspirate:
The bone marrow biopsy is a procedure that requires the removal of a small piece of bone by a special needle which is usually inserted in the back of the hip bone. The bone marrow aspiration is also done at the same time and it means that blood is sucked out of the middle of the bone to examine the cells there (in the bone marrow). Approximately 1-2 tablespoons of additional blood will be obtained for research. This procedure is usually done under local anesthesia, usually with mild pain at the site of the biopsy which can be controlled with pain medication which usually does not last longer than 24 hours. Rare risks are infection and bleeding at biopsy site which can be treated with medications.

REPRODUCTIVE RISKS:

For Males:
Do not father a baby while on this study. Lenalidomide is present at very low levels in human semen of healthy men for three days after stopping the drug according to a study. For some men, such as men with kidney problems, lenalidomide may be present in semen for more than three days. For these reasons, to be safe, all male patients receiving lenalidomide must use a latex condom during any sexual contact with a pregnant female or with a female of childbearing potential while you are participating in this study, including during times when lenalidomide is temporarily stopped, and for at least 28 days after permanently stopping therapy, even if you have had a successful vasectomy. You must NEVER donate blood, sperm, or semen while you are participating in this study and for at least 28 days after you have stopped therapy.

For Females - Risks Associated with Pregnancy:
Lenalidomide is related to thalidomide. Thalidomide is known to cause severe life-threatening human birth defects. If lenalidomide is taken during pregnancy, it may cause birth defects or death to any unborn baby. Females must not become pregnant while taking lenalidomide. You have been informed that the risk of birth defects is unknown.

A pregnancy test will be performed before you begin this study. Do not become pregnant while on this study. Depending on your menopausal status, you might need to use an effective form (or 2 forms) of birth control throughout the course of this study that includes no sexual activity. You should discuss birth control options with your research study doctor.

If you do become pregnant, you are to inform your research study doctor immediately, and you will be removed from the study and be referred for care for your pregnancy.

WILL THE RESULTS OF THIS STUDY OR ANY OF THE PROCEDURES AFFECT MY INSURABILITY?

No.

ARE THERE LIKELY TO BE ANY BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

- There may or may not be direct medical benefit to you from being in this research study.
- Possible benefits are that the leukemia might disappear for a long period of time and that the symptoms of your cancer might improve.
- In addition, the information learned from this study may, in the future, benefit other people with the same medical condition.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS RESEARCH STUDY?

Before agreeing to join the study and before signing this consent form your personal doctor should have discussed with you what, and if, standard treatments are available and/or other research protocols. Current standard care for your condition is observation without any treatment.

Other treatment options at this time include:

- Participation in another clinical trial
- No further treatment until your leukemia comes back or causes symptoms
- Receiving no treatment and only comfort care
- You may choose not to participate in this study.

WILL I BE PAID FOR BEING IN THE STUDY?

There will be no reimbursement for your participation in the study.

WHO MAY SEE MY RECORDS?

- The research records will be kept private and your name will not be used in any written or verbal reports.

- Your research records and medical records may be inspected by members of the research team, designated employees of Montefiore Medical Center, the company conducting the study and supplying the drug (Celgene Corporation), and other institutions that participate in this study.

- Support for this study is provided by Celgene Corporation. In order to obtain lenalidomide at no cost from Celgene Corporation, your name, address, phone numbers, date of birth and the fact that you are participating in this trial will be disclosed to

Celgene Corporation and its agents or vendors that supply lenalidomide and administer the RevAssist® program. By signing this consent form you agree to this disclosure.

- As this research involves a drug, the U.S. Food and Drug Administration (FDA), the agency responsible for regulating drugs, may inspect your research records and medical records.

- The researcher and research staff will review your medical records and will keep the information private. The research records will be kept in a secured manner and computer records will be password protected.

- The people who reviewed this research study as members of the Institutional Review Board of The Albert Einstein College of Medicine may also review your research and medical records.

- The Office of Human Research Protections (OHRP) may also review your research study records.
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- All of these groups have been requested to keep your name private.

A description of this clinical will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time

WILL THERE BE ANY COSTS TO ME?

- Research related tests, procedures and exams will not be billed to you or your insurance (those are the routine physical exams and routine blood work during the first two cycles of the study). You and/or your insurance will only be responsible for tests, procedures, and exams that you would have needed even if you were not on study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If there is a physical injury as a result of this research, only immediate, essential, short term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document

- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Ira Braunschweig, MD, telephone 718-920-4826.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

Researcher's Name: Dr. Ira Braunschweig
Office Address: Montefiore Medical Center
Department of Oncology
111 East 210th Street, Bronx, NY 10467
Office Phone: 718-920-4826

- If any questions arise related to this research project, or you believe you have any injury related to this study, you can call the researcher above.

- You may also call Lawrence Almanzar at 718-920-6642.

- If you have questions regarding your rights as a research subject, you may also call the Administrator of The Albert Einstein College of Medicine Institutional Review Board at 718-798-0406 Monday through Friday between 9 AM and 5 PM.

WILL ANY OF THE SAMPLES (BLOOD, TISSUE, DNA) TAKEN FROM ME BE USED FOR FUTURE RESEARCH STUDIES?

In addition to the research you are consenting to under this research study, Dr. Braunschweig or other researchers at this or other institutions may wish to study the samples in future research, including genetic analysis. These samples, taken from your body, would be able to be linked back to you. Information about you may be shared with other researchers who will keep the information confidential. However, it is possible that information about you may become known to people other than the researchers.

At this time, the researchers do not know what the future studies will be. Your specimens may also be submitted to a tissue/cell/DNA bank. The specimens may be kept for a long time and may exceed 50 years. You have the right to withdraw consent to use of the tissue for future use at any time by contacting the supervisor of the study named on the first page of the consent or the IRB office at 718-798-0406. Unused specimens will be destroyed.

In some research using human blood or tissue, the specimens may enable researchers to develop medical tests or treatments that have commercial value. You will not receive any money that may result from any such commercial tests or treatments.

Your specimens may be used for future research, even though the purpose of the future research is not known at this time.

PARTICIPANT:
PLEASE INDICATE YOUR CHOICE BY INITIALING ONE (1) OF THE FOLLOWING OPTIONS

___ I consent to have my specimens used for future research studies.

___ I consent to have my specimens used for future research studies only for the study of

_____.

___ I do NOT consent to have my specimens used for future research studies. The specimens will be destroyed at the end of the study.

PARTICIPANT:
FOR FUTURE CONTACT, PLEASE INITIAL YOUR CHOICES BELOW

I consent to be contacted in the future to learn about:

_____ New research protocols that I may wish to join.

_____ General information about research findings.

_____ Information about the test on my sample that may benefit me or my family members in relation to choices regarding preventive or clinical care.

_____ I DO NOT AGREE TO BE CONTACTED IN THE FUTURE, EVEN IF THE RESULTS MAY BE IMPORTANT TO MY HEALTH OR MY FAMILY'S HEALTH.

Your wish does not constitute a guarantee that you will be contacted.

CAN I BE ASKED TO STOP PARTICIPATING IN THIS STUDY BEFORE THE STUDY IS FINISHED?

You may take the study drug indefinitely unless removed or withdrawn from the study. Sometimes the researcher may stop the study for the following reasons:

- You fail to follow instructions given to you by the research study doctor.
- New information about important medical risks and benefits become available.
- You are unable to keep appointments
- You are taking part in another study

- Your study doctor feels that participation in the study is no longer beneficial for you
- Your study doctor believes that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- You become pregnant during the course of the study

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

- If the research study doctor obtains new information that might lead you to change your mind about continuing in this study, the research study doctor will tell you about it.

- If you decide to withdraw, the research study doctor and your personal doctor will make arrangements for your care to continue.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS RESEARCH STUDY?

- Your participation in this study is voluntary.
- You do not waive any of your legal rights by participating in this research study.
- Your treatment by doctors and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you refuse to participate or if you enter the study and withdraw later.

MAY I STOP THE STUDY AT ANY TIME?

- Your participation in this study is voluntary, and you may withdraw from the study at any time without giving a reason.
- If you decide to withdraw after receiving the study drug, you should talk with the research study doctor (Ira Braunschweig, MD; telephone 718-920-4826) to see how best to complete the withdrawal process.
- If you agree to participate and withdraw at a later time, some of your information may have already been entered into the study and that will not be removed.
- In addition, you may be asked to return to the research study doctor again for any final tests in order to close the record and tests or monitoring that are necessary for your health as a result of your participation. These results may be recorded.
- Your treatment by doctors and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you agree to participate and withdraw later.

Informed Consent Signature Page

The following is a list of items we discussed about this research study. If you have any questions about any of these items, please ask the person who is discussing the study with you for more information before agreeing to participate.

- What the study is about.
- What I must do when I am in the study.
- The possible risks and benefits to me.
- Who to contact if I have questions or if there is a research related injury.
- Any costs and payments.
- I can discontinue participating in the study at any time without penalty.
- Other choices.
- All written and published information will be reported as group data with no reference to my name.
- If there is a schedule explaining how the study medicines are to be taken, I will be given the time schedule.
- I have been given the name of the researcher and others to contact.
- I have the right to ask any questions.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person conducting the Informed Consent Process	Signature of Person conducting the Informed Consent Process	Date

Study Calendar

	Screening	Cycle 1 (Weeks)				Cycle 2 (Weeks)			Cycle 3	Cycle 4 & onward	End of Study [5]	Follow up Visits [7]	Phone Follow-up [8]
		W1	W2	W3	W4	W1	W2	W3					
Informed Consent	X												
Demographic Information	X												
Medical History	X												
Physical Examination	X	X	X	X	X	X		X	X	X	X	X	
Performance Status (KPS)	X	X	X	X	X	X		X	X	X	X	X	
Vital Signs	X	X	X	X	X	X		X	X	X	X	X	
CBC with differential [1]	X	X[4]	X	X	X	X		X	X	X	X	X	
Serum chemistry [1]	X	X[4]	X	X	X	X		X	X	X	X	X	
Concomitant Medications [2]	X	←									→	X	
Adverse Event Assessment [2]	X	←									→	X	
Buccal Swab	X												
Bone Marrow Aspiration Biopsy [3]	X									X[3]			
Lenalidomide Treatment		X	X	X		X	X	X	X	X			
Review of pill diary			X	X	X	X		X	X	X	X		
Urine β-hCG [6]	X										X		
Instructions for restricted drugs [2]	X	←									→	X	
Secondary malignancy reporting												X	X
Survival Information												X	X