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 II study Assessing the Efficacy and Toxicity of PK-directed Intravenous Busulfan in Combination with High-Dose Melphalan and Bortezomib as Conditioning Regimen for First-line Autologous Hematopoietic Stem Cell Transplantation in Patients with Multiple Myeloma" Version 4.0

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 407
111 East 210th Street
Bronx, New York 10467

Telephone #: 718-920-4826

APPROVED
IRB
4/15/14 through 12/15/14

Protocol #: 11-12-434

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.

STUDY SPECIFICS

- This is a clinical study of a new drug combination using Busulfex™ (intravenous Busulfan) in combination with Melphalan and Bortezomib followed by a blood stem cell transplantation for the study of treatment of Multiple Myeloma.
- Clinical studies help to get more information about whether or not a new drug or drug combination will work better than the medicines that are currently available. The study will also help to see if the new drug combination is safe.
- The combination of the drugs used in this study is new and investigational, although none of the medicines itself are investigational. This means that the drugs used are already approved by the U.S. Food and Drug Administration (FDA) for use in the United States for the treatment of myeloma or other diseases.
- Busulfex™ is FDA approved for bone marrow transplantation in patients with another disease called chronic myeloid leukemia. It is also commonly used for bone marrow transplantation for patients with blood cancers, such as lymphoma. It is not FDA approved for the use in Multiple Myeloma.
- Melphalan by itself is FDA approved for the treatment of patients with myeloma and is the most commonly used drug used for bone marrow transplantation in patients with myeloma.
- Bortezomib is commonly used to treat patients with myeloma and is FDA approved for the use in myeloma.

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

- If you agree to take part in this study you will have tests and examinations to be sure that you qualify for the study.
- You are being asked to take part in this study because you have multiple myeloma and your doctor feels it is necessary to perform a bone marrow transplant

WHY IS THIS RESEARCH STUDY BEING DONE?

- The purpose of this study is to find out whether treatment with Busulfex™ combined with melphalan and bortezomib is effective and safe
- Busulfex is approved for transplant in another condition called chronic myeloid leukemia (CML). Melphalan and bortezomib are both approved for use in the treatment of myeloma, but the combination of the three drugs as used in this research study is investigational.
- We would like to determine what effects Busulfex™ in combination with melphalan and bortezomib followed by a stem cell transplant will have.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

- You will be one of approximately 28 who will be participating in this study.
- The study will be conducted at the Montefiore Medical Center, and 3 other institutions (NYU, MSKCC, UMDNJ)

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. These 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
- Approximately 1-2 tablespoons of blood for tests, including tests that assess your kidneys, liver and your myeloma
- A collection of your urine
- Tests/scans to test your heart and lung function
- A bone marrow specimen (less than 1 teaspoon of marrow taken at the same time as the specimen needed to make the treatment decisions) will be sent to a special laboratory to examine genetic defects (called cytogenetic testing) at the time you are registered on the study.
- Additional samples of blood and bone marrow will be sent to a special laboratory for additional molecular studies and banking at the time you are registered on the study. Specimens will be banked only if you separately agree to this (see "Consent Form for Use of Specimens for Research" below).
- If you are a woman capable of becoming pregnant, you will have a pregnancy test before starting the study
- Two weeks before being admitted for the bone marrow transplant you will be given a test dose of Busulfex™ in the clinic in order to determine the correct dose of the drug. On that day six blood draws will be taken at certain times after the infusion has finished (one teaspoon each time).

During the study ...

- You will be admitted for the chemotherapy and the stem cell transplantation to the hospital for the duration of about 3 weeks.

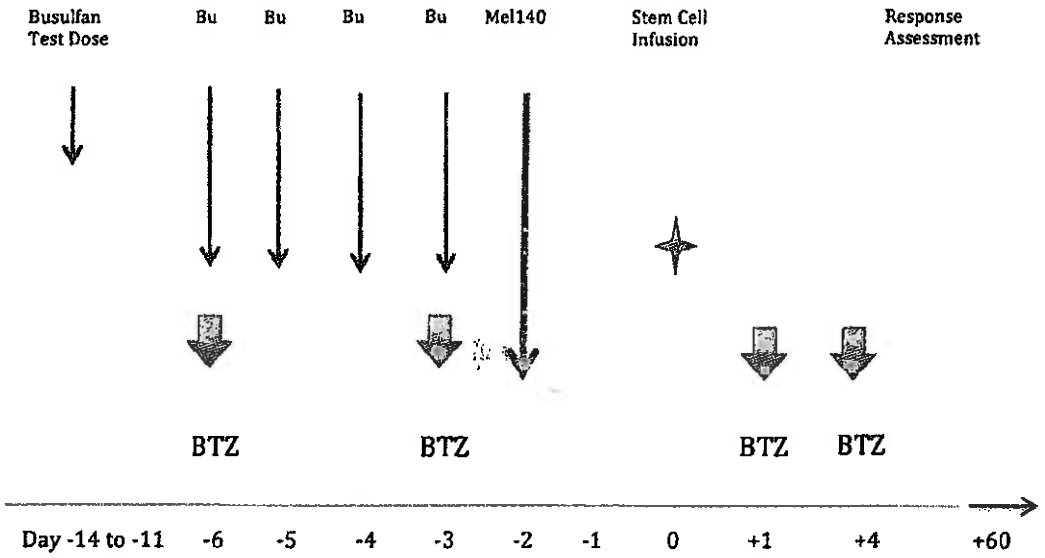
- A Central Venous Catheter will be placed unless you already have one (for example a Port-A-cath). Before you can receive treatment, your doctor will place a catheter tube into a large vein in your chest. This tube will be one of two types. 1) It can come out through the skin or 2) it can be attached to a small container with the entire device under your skin. This type of catheter has to be used because of the drugs being given to you on this study. If a regular IV was used there would be a risk that the drugs might leak from the IV into the tissues around it. If this happened, the drugs could cause damage to the tissues that were contacted. Using a central catheter, as described here, will ensure that this leakage and damage do not occur. The central venous catheter will be used throughout your treatment. This is part of standard of care for patients who are receiving this type of treatment and not part of the research. The catheter will be used in three ways:

    - To give you drugs or blood into your vein
    - To draw blood
    - To infuse stem cells

Your research study doctor will give you more information about the catheter.

- Once you have this catheter, the treatment will start. You will be given Busulfex™ as a three hour infusion daily from day minus six to day minus three before the stem cell transplant. Six days and three days before the stem cell transplant (days minus six and three) and one day one and four days after the stem cell transplant (days plus one and plus four) you will be given bortezomib as an intravenous injection. Melphalan will be given two days before the stem cell transplant (day minus two). This is also shown in the figure below (treatment Schema). In order to ensure the correct amount of the drug is given six blood draws will be taken at certain times after the infusion has finished on the first day (day minus six) and possibly on the third or fourth day (day minus four or three) if necessary (one teaspoon each time).

Treatment Schema:



Abbreviations: Bu, busulfan; Mel140; melphalan at 140mg/m^2; BTZ, bortezomib

After the transplant....

- Once you have been discharged from the hospital you will be required to come to see the researcher at least at one month, as well as three, six and twelve months after the transplant or more often if necessary; after the first year you will be seen at least once per year for up to five years. Each visit will last approximately 30 minutes to an hour. These visits will include taking a history, a complete physical examination, as well as blood and possibly urine tests in order to determine how your myeloma has responded to the therapy. This determination might include another bone marrow biopsy. All of these tests are done routinely for patients undergoing a stem cell transplant for myeloma. They are standard of care and not experimental. Additionally 1-2 teaspoons of blood (and bone marrow should you need as part of your routine care another bone marrow biopsy) will be sent once more 3 months after the transplant to a special laboratory for banking. Specimens will be banked only if you separately agree to this (see "Consent Form for Use of Specimens for Research" below).

- You will be in the study for at least one year but possibly as long as five years.

- You will be expected to return to the clinic for these yearly follow up visits.
- If the study is still continuing at the end of 2013, you will be asked to return yearly until the official end of the study.

WILL THIS STUDY INVOLVE GENETIC RESEARCH AND/OR TESTING?

- Genetic means having to do with information that is passed on in families from parents to their children through genes.
- **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 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.
- Tests conducted under this research study may reveal genetic information. Since the tests are being done in a research lab, the results cannot 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.

TESTING FOR HIV

- An HIV test will be performed in connection with this research. You must sign a separate consent form for HIV testing and you will be counseled before and after the test is performed by a trained counselor in the HIV clinic.
- This is part of the normal stem cell transplantation evaluation
- If as a result of participation in this study you are INITIALLY diagnosed with HIV, the results must be reported to the Commissioner of Health for contact tracing purposes.

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.
- 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.

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

Here is a list of the known risks associated with the drugs used in this study:

Possible Side Effects of Busulfex™:

MOST COMMON (>30%):

- Low white blood cell count
- Low red blood cell count (anemia)
- Low platelet count
- Nausea and vomiting
- Constipation
- Diarrhea
- Abdominal pain
- Sores in your mouth
- Abnormal liver function tests
- Fever and/or chills
- Runny nose
- Pain
- Allergic reaction
- High blood sugar
- Headaches
- Anxiety
- Sleep disturbance
- Fatigue
- Anxiety
- Cough
- Fast or irregular heart beat
- Swelling of your legs, arms or body
- Abnormal electrolyte blood levels

COMMON (5-30%):

- Bruising or bleeding
- Blood clots
- Damage to your liver
- Chest pain
- Pain at the injection site
- Dizziness
- Hot flushes
- Pain in your joints or your back
- Damage to your kidneys
- Inflammation of the lung
- Shortness of breath
- Skin rash and/or itching
- Hair loss
- Abnormally high or low blood pressure

RARE, BUT SERIOUS (<5%):

- Life-threatening bleeding
- Life-threatening infection
- Inflammation of the pancreas (pancreatitis)
- Seizures
- Changes in your mental status
- Damage to your lungs
- Fluid in your lungs and/or around your heart
- Scaling and redness of your entire skin
- Heart failure
- Slow heart rate
- Other cancers

Possible Side Effects of Bortezomib:

LIKELY (>20%):

- Low red blood cell count (anemia)
- Low platelet count
- Nausea and vomiting
- Constipation
- Diarrhea
- Fatigue
- Loss of appetite
- Swelling of your limbs
- Damage to your nerves resulting in weakness or numbness
- Infections, especially shingles

LESS LIKELY (<20%):

- Low white blood cell counts with or without fever
- Changes in your vision
- Indigestion
- Abdominal pain
- Blockage of your gut (ileus)
- Weakness
- Headaches
- Dizziness
- Fainting
- Cough
- Bleeding
- Anxiety
- Sleep disturbances
- Dizziness
- Pain in your joints, bones, your or nerves
- Infections
- Skin rash and/or itching
- Abnormally low blood pressure
- Fluid in your lungs

RARE, BUT SERIOUS (<5%):

- Severe damage to the gut
- Damage to your kidneys
- Abnormal changes in the brain that can cause a collection of symptoms including headache, confusion, seizures, and vision loss associated with MRI findings. This neurological disorder is known as Reversible posterior leukoencephalopathy syndrome (RPLS)

Possible Side Effects of Melphalan:

LIKELY (>20%):

- Low red blood cell count (anemia)
- Low platelet count
- Low white blood cell count
- Nausea and vomiting
- Diarrhea
- Loss of appetite
- Fever
- Mouth sores
- Hair loss
- New cancer – how often these occur is not clear. The frequency increases the dose and on how long people take melphalan. The estimates vary between as little as 2% to as high as 20%.

LESS LIKELY (<20%):

- Very low white blood cell counts with or without fever
- Bleeding
- Allergic reaction
- Shortness of breath
- Swelling of your limbs or body
- Itching
- Skin rash
- Damage to your kidneys
- Reactions at the injection site
- Damage to your lungs
- Jaundice
- Damage to your ovaries or testes resulting in infertility
- Damage to your liver
- Abnormally fast heart beat
- Low blood sodium levels

RARE, BUT SERIOUS (<5%):

- Very low blood counts that might not return to normal
- Changes in your mental status
- Bleeding from your bladder
- Severe damage to your liver
- Inflammation of your gut
- Cardiac arrest
- Death

The drugs used in this study might not work against your myeloma. There might not be an improvement in your condition with this treatment.

UNFOREEN RISKS:

A previously unknown problem could result from your participation in this research. There could be an interaction between the medications used in this study or other medications you take (prescribed or over-the-counter). It is not possible to estimate the chances of such problems or how serious problems could be. Part of the purpose of this study is to evaluate those unforeseen risks.

How you can help reduce some of the risks? During your participation in this research, your study doctor will watch closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep appointments.
- Follow the study doctor's instructions.

- 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.
- Tell your regular doctor about your participation in this research.
- Talk to a family member or friend about your participation in this research.
- Carry information about the research in your purse or wallet.

Risks of Other 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 RISKS: 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 cells there (in the bone marrow). 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.

CENTRAL LINE PLACEMENT: The risk of having a central line placed includes bruising and bleeding at the site, pain, infection of the site and the blood stream as well as collapse of the lung. The central line will usually be removed three days after the transplant.

PREGNANCY AND IMPREGNATION DURING THIS STUDY

- The drugs used in this study may cause damage to the fetus.
- If you are pregnant, you may not participate in this study.
- A pregnancy test will be performed before you begin this study
- Do not become pregnant or father a baby while on this study
- You must use two effective 2 forms of birth control throughout the course of this study that includes no sexual activity.
- Acceptable forms of birth control include: hormonal methods such as the oral contraceptive pill (OCP) or injectible contraceptives (e.g. Depot Provera), barrier methods such as condoms or diaphragms, spermicides, IUD, abstinence
- A member of the study staff will counsel you on methods of birth control and the importance of preventing pregnancy while you are in this study.
- 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.
- You should not breast feed your baby while on this study because the study drug appears in the breast milk and could be a risk to the nursing infant.

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

Some tests reveal information that may affect a person's insurability. The tests done under this study may reveal an infection with HIV, which may affect your ability to get or keep medical, health or life insurance.

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 myeloma 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.

Other treatment options at this time include:

- High dose Melphalan alone followed by a stem cell transplantation (standard treatment)
- Continuing with your current or a new chemotherapy regimen
- Participation in another clinical trial
- No treatment until your myeloma comes back or causes symptoms
- 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, the company supplying the drug (Otsuka Pharmaceutical) and other institutions that might participate in this study

- As this research involves a drug, the U.S. Food and Drug Administration (FDA), the agency for regulating the drugs, may inspect your research records and medical records.
- Support for this study is provided by Otsuka Pharmaceutical
- 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 Albert Einstein College of Medicine Committee on Clinical Investigations (CCI) and the Montefiore Medical Center Institutional Review Board (IRB) may also review your research and medical records.
- The Office of Human Research Protections (OHRP) may also review your research study records.
- All of these groups have been requested to keep your name private.

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.

WILL THERE BE ANY COSTS TO ME?

- Taking part in this study may lead to added costs to you or your insurance company. There may be extra costs that may or may not be covered.

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 718-920-2006 or Dr. Ira Braunschweig at 718-920-4826.
- If you have questions regarding your rights as a research subject, you may also call the Manager of The Albert Einstein College of Medicine Committee on Clinical Investigations at (718) 430-2253, 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 researcher does 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 CCI office at 718-430-2253. Unused specimens will be destroyed.

In some research using human blood or tissue, the specimens and their parts 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?

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 become pregnant
- 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.

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.

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.

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.

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.

The signature section is specially formatted - please do not modify.

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

APPROVED
IRB
4|15|14 through 12|15|14