
MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient
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INSTITUTE: National Cancer Institute

STUDY NUMBER: 12-C-0192 PRINCIPAL INVESTIGATOR: Mark Roschewski, M.D.

STUDY TITLE: Lenalidomide Maintenance Therapy in Multiple Myeloma: A Phase II Clinical and Biomarker Study

Continuing Review Approved by the IRB on 03/23/15

Amendment Approved by the IRB on 06/06/14 (C)

Date posted to web: 04/18/15

Standard

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Why is this study being done?

Multiple Myeloma (MM) is rarely curable, but it is treatable. Initial therapy (also known as induction therapy) directed at controlling symptoms and reducing the myeloma cells, is generally continued until the response reaches a plateau. At that time the individual may be monitored closely with no therapy (often referred to as 'observation') or the individual may consider the use

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of maintenance therapy. The maintenance therapy is given to try to extend the response achieved by induction therapy for as long as possible. Research is showing that lenalidomide maintenance therapy may delay the time for myeloma cells to start to grow and possibly improve survival.

Lenalidomide is a drug that alters the immune system and it may also interfere with the development of tiny blood vessels that support tumor growth. It may reduce or prevent the growth of cancer cells.

The primary purpose of the current study is to evaluate the long-term effect of lenalidomide on immune cells, when given alone. This study will also look at the effects of extended treatment on your MM and your own immune system. Lenalidomide is approved by the Food and Drug Administration (FDA) for the treatment of MM in combination with dexamethasone. However, the use of lenalidomide as a single agent after induction therapy is still considered experimental.

Why are you being asked to take part in this study?

You are being asked to participate because you have newly diagnosed or relapsed multiple myeloma.

How many people will take part in this study?

About 28 patients will take part in this study.

Description of Research Study

We will test your MM response status before you enter into the study. If the disease is stable or responsive after the most recent therapy, you will receive maintenance treatment with the study drug lenalidomide. During this maintenance treatment, you will receive lenalidomide every day for 21 days of repeated 28 day cycles. You may continue to receive lenalidomide until we determine your disease has progressed, you develop intolerable side effects or you complete two years of lenalidomide treatment. At periodic time points while you are receiving lenalidomide, you will be required to provide blood samples to assess for immune cells (NK, NKT, and T cells).

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What will happen if you take part in this research study?

Before you begin the study

Before you begin the study, if you decide to take part, some procedures and tests will need to be performed to determine if you qualify for the study. Appointments for these tests will be made by your doctor. These tests 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 study doctor. You will have:

- History and physical examination
- Blood work to assess for disease status and biomarkers (immune cells)
- Urine laboratory tests
- 24 hour-urine sample may be required (you will be notified if this applies to you).
- A bone survey (series of x-rays of all of your bones)
- A bone marrow procedure to obtain aspirate and core biopsy is required for the diagnosis of MM and can provide important additional information. We will request that you undergo such a biopsy.
- Urine or blood pregnancy test

You will be asked if you would like to provide extra research samples of blood, urine and bone marrow aspirate. These studies are optional and will be used to learn more about myeloma. Whenever possible, if you have given permission, these samples will be collected at the same time as the when routine cancer care testing is done. You do not have to give these research samples in order to participate in this trial. You will not have to pay for the costs of collecting and analysis of these research samples. You will be asked at the end of this consent form to indicate your choice about giving additional research samples of blood, urine and bone marrow aspirate.

During the study

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures.

- Physical exam
- Blood work to assess for disease status and biomarkers (immune cells)
- Urine collection
- Bone marrow biopsy and aspirate to assess the status of your myeloma
- Urine or blood pregnancy tests in women of child bearing potential
- Bone series (X-rays of all of your bones)

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If you agree to donate extra blood, urine and bone marrow aspirate samples, you will be asked to give the following amounts at the time points listed in the Study Chart and the samples will be used for research purposes only.

- Research blood samples (about 3 tablespoons)
- Research urine samples (about 2 ounces)
- Research bone marrow aspirate (about 2 teaspoons)

The research blood samples, bone marrow aspirate, and urine are not mandatory. If you agree to provide research samples, they will be stored for use in research studies that may be done in the future.

The treatment consists of one drug (lenalidomide) given during 28 day cycles. Lenalidomide tablets will be given from days 1-21 of every 28 day cycle. Treatment cycles will continue until your disease progresses, you develop intolerable side effects or you complete two years of lenalidomide treatment.

You will be required to take aspirin or other medication to prevent blood clots while taking lenalidomide.

Study Chart

Before Starting Treatment

Completed 4 weeks prior to starting treatment unless specified	<ul style="list-style-type: none"> • Sign informed consent • History and Physical exam • Blood work (including research blood work if you choose to donate) • 24 hour-urine sample may be required (you will be notified if this applies to you) • Bone marrow biopsy and aspirate to assess the status of your myeloma • Register for the REMS Program • Urine or blood pregnancy tests in women of child bearing potential (performed 10-14 days prior to receiving prescription for lenalidomide) • Bone series (X-rays of all of your bones) • EKG
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Cycle 1

Day 1	<ul style="list-style-type: none"> • Blood work for biomarkers and routine care • Urine for routine care • Optional research blood work/urine if you choose to donate • History and physical exam • Begin oral lenalidomide and continue from day 1-21 • Begin or stay on aspirin, or other blood thinner • Urine or blood pregnancy test in women of child bearing potential (performed within 24 hours of receiving prescription for lenalidomide)
Day 15	<ul style="list-style-type: none"> • History and physical exam • Routine blood work • Urine or blood pregnancy test in women of child bearing potential
Day 22 to 28	<ul style="list-style-type: none"> • Do not take lenalidomide
Day 28	<ul style="list-style-type: none"> • Finish Cycle 1

Cycles 2, 4, and 7; every 3 cycles thereafter

Day 1	<ul style="list-style-type: none"> • History and physical exam • Begin oral lenalidomide and continue from day 1-21 • Blood work for routine care and response • Blood work for biomarkers (immune cells) after cycle 7 will be collected every 3 cycles. • Urine for response assessment and routine care, if indicated • Optional research blood /urine for if you choose to donate • Urine or blood pregnancy test in women of child bearing potential
Days 22 to 28	<ul style="list-style-type: none"> • Do not take lenalidomide
Day 28	<ul style="list-style-type: none"> • Finish cycle
Any point that complete remission is achieved	<ul style="list-style-type: none"> • Optional research blood, urine and bone marrow biopsy and aspirate if you choose to donate • Blood work for response • Blood work for biomarkers (immune cells)
Any point that myeloma is determined to be progressive	<ul style="list-style-type: none"> • History and physical exam • Blood work for routine care and response • Blood work for biomarkers • Urine for response assessment • Optional research blood, urine and bone marrow biopsy and aspirate if you choose to donate • Bone series (X-rays of all of your bones)

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When you are finished taking the drugs (treatment)

After you complete the treatment portion of the study, you may be asked to return to the Clinical Center for follow-up visits every 3-6 months for as long as you are participating in the study. Follow-up visits will be optional and consist of routine labs and clinic visit with history and physical exam. If your disease comes back or worsens, we may ask you to have optional research blood, urine, or bone marrow biopsy.

You may have follow up visits at more frequent intervals if your doctors and the study team feel it is needed.

What does this study involve?

Pregnancy Risk:

Lenalidomide is related to thalidomide. Thalidomide is known to cause severe life-threatening human birth defects. Findings from a monkey study indicate that lenalidomide caused birth defects in the offspring of female monkeys who received the drug during pregnancy. If lenalidomide is taken during pregnancy, it may cause birth defects or death of an unborn baby. Females must not become pregnant while taking lenalidomide. You have been informed that the risk of birth defects is unknown. If you are female, you agree not to become pregnant while taking lenalidomide. 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. Because of the risk of birth defects, all patients taking lenalidomide must read the following statements that apply to them according to gender and menopausal status.

For these reasons, lenalidomide is provided to patients under a special distribution program called REMS®.

For these reasons, lenalidomide is provided to patients under a special distribution program called REMS®.

In order to participate in this study you must register into and follow the requirements of the REMS® 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.

Pregnancy Risk – Females:

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If you are a female of childbearing potential*, you will be required to have two negative pregnancy tests: the first test within 10-14 days before lenalidomide is prescribed and the second test within 24 hours before lenalidomide is prescribed.

You will be required to use **TWO** reliable forms of birth control, one highly effective method and one additional effective method at the same time or practice complete abstinence from heterosexual intercourse during the following time periods related to this study: 1) for at least 28 days before starting lenalidomide; 2) while participating in this study; and 3) for at least 28 days after discontinuation from the study. The following are the acceptable birth control methods:

Highly Effective Methods

- Intrauterine device (IUD)
- Hormonal (birth control pills, injections, implants)
- Tubal ligation
- Partner's vasectomy
- Additional Effective Methods
- Latex condom
- Diaphragm
- Cervical Cap

You must not breastfeed a baby while you are participating in this study and for at least 28 days after you have been discontinued from the study.

Females of childbearing potential with regular or no menstrual cycles must agree to have pregnancy tests weekly for the first 28 days of study participation and then every 28 days while on study, at study discontinuation, and at day 28 following discontinuation from the study. If menstrual cycles are irregular, the pregnancy testing must occur weekly for the first 28 days and then every 14 days while on study, at study discontinuation, and at days 14 and 28 following discontinuation from the study.

If you have any reason to suspect you are pregnant, you must IMMEDIATELY stop taking lenalidomide and tell your doctor.

Pregnancy Risk – Males:

Lenalidomide is detected in trace quantities in human semen according to a study. The risk to the fetus in females of child bearing potential whose male partner is receiving lenalidomide is unknown at this time. For these reasons 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 and for at least 28 days after 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.

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All Patients:

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 from the study. You must receive counseling and complete phone surveys as required by the **REMS®** program.

Once it is determined that you are eligible for the study and you agree to receive treatment, you will begin therapy as described below:

- 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 **REMS®** program.

Alternative Approaches or Treatments

What other choices do I have if I do not take part in this study?

Maintenance use of lenalidomide is not yet standard of care. In general, after you have completed the initial therapy (also called induction therapy), you may be monitored closely with no therapy (often referred to as "observation") or you may consider maintenance therapy.

Instead of being in this study, you have these options:

- Close observation without any treatment
- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

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Risks or Discomforts of Participation

What side effects or risks can I expect from being in this study?

Blood draws:

Side effects of drawing blood include pain and bruising in the area where the blood was drawn, lightheadedness, or rarely fainting due to transient lowering of blood pressure. If you feel dizzy, you should lie down for a few minutes to avoid hurting yourself if you fall. Infection at the blood-drawing site could also occur.

Bone marrow aspiration and biopsy:

You may feel a pulling sensation and brief discomfort as the marrow is withdrawn and a pressure sensation when the needle is being inserted. The amount of marrow taken is very small and will not change your body's ability to form blood cells. Potential complications of this procedure are local bleeding, pain at the site, and infection. Both of these are very rare. Bleeding can be stopped by applying local pressure and an infection can be treated with antibiotics.

Lenalidomide

Lenalidomide has been studied in healthy volunteers and in patients with cancer of the blood and other organs of the body and 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. Everyone taking part in the study will be watched carefully for any side effects.

Listed below are the side effects reported by approximately 6,600 patients who have participated in previous and ongoing clinical studies involving lenalidomide. These events were considered by the study doctors to be related to lenalidomide. Side effects may be mild to very severe. Side effects listed below are grouped as follows: side effects of any grade which occurred in 10% or more of patients and serious side effects that occurred in 1% or more of patients. Serious is defined as side effects that; require in-patient hospitalization, cause persistent or significant disability, are life-threatening or in some cases fatal, or important medical events.

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Likely (occurring in ≥ 10% of patients)	Less Likely (occurring in ≥ 1% of patients)	Rare
<ul style="list-style-type: none">• Fatigue or feeling tired• Anemia or a decrease in red blood cells that can cause tiredness• Neutropenia and Lymphopenia or a decrease in white blood cells that can make you more prone to infections• Thrombocytopenia or a decrease in platelets which can cause you to bruise or bleed easily• Constipation or difficulty moving your bowels• Diarrhea or loose/frequent bowel movements• Nausea• Loss of appetite• Back pain• Joint pain• Muscle cramps• Swelling of the arms and legs• Problems falling asleep or staying asleep• Fever• Cough• Shortness of breath or difficulty catching your breath• Upper respiratory infection• Rash• Itching and dry skin• Lack or loss of strength• Dizziness• Headache	<ul style="list-style-type: none">• Neutropenia associated with a fever• Atrial fibrillation or irregular heartbeat• Progression of the disease being studied including multiple myeloma• Sepsis or an infection of the blood• Dehydration• Kidney failure• Pulmonary embolism: blood clot in or around the lungs• Deep vein thrombosis: blood clot in a large blood vessel	<ul style="list-style-type: none">• Angioedema or an allergic skin disease characterized by patches of swelling involving the skin and/or the lining of your nose, mouth, and gastrointestinal tract• Stevens-Johnson syndrome and toxic epidermal necrolysis: serious allergic skin reactions that begin as a rash in one area and later cover more of the body leading to detachment of the top layer of skin (could be body-wide)• Tumor lysis syndrome: a metabolic complication that can occur during or without treatment of cancer. These complications are caused by the break-down products of dying cancer cells and include high potassium, high phosphorus, high uric acid in blood and urine, low calcium, and consequent kidney damage• Rhabdomyolysis: a serious condition involving destruction of skeletal muscle that can lead to kidney failure. Signs and symptoms include dark, red or cola colored urine, muscle tenderness and stiffness, aching (myalgia) or weakness• Occasional events such as atrial fibrillation (irregular heartbeat), myocardial infarction (heart attack), and congestive heart failure (condition where the heart becomes weak and cannot pump enough blood to the rest of the body)

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Hematological Toxicity

Lenalidomide is associated with significant neutropenia (decrease in white blood cells that help fight infection) and thrombocytopenia (decrease in platelets that help with blood clotting). You will have your blood counts checked frequently when starting treatment with lenalidomide.

Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)

Lenalidomide has demonstrated an increased risk of deep vein thrombosis (blood clots in larger blood vessels) and pulmonary embolism (a blood clot in or around the lungs) in some people with certain medical conditions. The study staff will ask you about any health conditions you may have that may increase your chance of developing blood clots. The risk of blood clots may also be increased when lenalidomide is combined with other drugs known to cause blood clots such as steroids, other forms of cancer drugs, hormone replacement therapy, birth control pills and erythropoietin (a drug given to help increase the red cell count). You should let your doctor know if you take birth control pills or hormone replacement therapy. You may be asked to take a blood thinner such as aspirin if your doctor feels that you are at increased risk for blood clots. If your platelet count becomes low, the blood thinners may need to be stopped temporarily. You will be instructed on the signs and symptoms of DVT and PE, including shortness of breath, chest pain or swelling of the arm and or leg, and if symptoms of DVT or PE occur you should contact your study doctor, healthcare provider or get emergency medical care promptly.

Second Primary Malignancies (SPM)

Higher incidences of SPM were observed in controlled trials of patients with multiple myeloma receiving lenalidomide.

Patients with multiple myeloma treated with lenalidomide in studies including melphalan and stem cell transplantation had a higher incidence of second primary malignancies, particularly acute myelogenous leukemia (AML) and Hodgkin lymphoma, compared to patients in the control arms who received similar therapy but did not receive lenalidomide. Your doctor will monitor for the development of second malignancies. You and your doctor should take into account both the potential benefit of lenalidomide and the risk of second primary malignancies when considering treatment with lenalidomide.

Other Risks

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.

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Potential Benefits of Participation

Are there benefits to taking part in this study?

The aim of this study is to see if this experimental use of lenalidomide will cause your tumors to shrink. We do not know if you will receive personal, medical benefit from taking part in this study. These potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer. Because there is not much information about the drug's effect on your cancer, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have cancer.

Research Subject's Rights

What are the costs of taking part in this study?

If you choose to take part in the study, the following will apply, in keeping with the NIH policy:

- You will receive study treatment at no charge to you. This may include surgery, medicines, laboratory testing, x-rays or scans done at the Clinical Center, National Institutes of Health (NIH), or arranged for you by the research team to be done outside the Clinical Center, NIH if the study related treatment is not available at the NIH.
- There are limited funds available to cover the cost of some tests and procedures performed outside the Clinical Center, NIH. You may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the Clinical Center, NIH.
- Once you have completed taking part in the study, medical care will no longer be provided by the Clinical Center, NIH.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.

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- National Cancer Institute Institutional Review Board
- Qualified representatives from Celgene, the pharmaceutical company who produces lenalidomide.

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.

Stopping Therapy

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease comes back during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you

In this case, you will be informed of the reason therapy is being stopped.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to Celgene or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NCI can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases cannot be recalled and destroyed.

Conflict of Interest

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. You may ask your research team for a copy of the Protocol Review Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines but they do not need to report their personal finances to the NIH.

Members of the research team working on this study may have up to \$15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

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The National Institutes of Health and the research team for this study are using lenalidomide, a drug developed by Celgene through a joint study with your researchers and the company. The company also provides financial support for this study.

Optional Biopsy

Bone marrow biopsy procedure entails having an area in the back of your hip numbed with a local anesthetic, and a large bone marrow needle inserted into the hipbone. Bone marrow aspirate is obtained, and a core biopsy is obtained. The needle is removed. The risks of the bone marrow procedure include pain, bleeding, infection of the skin or tissues, and allergy to the local anesthetic. You may have some soreness at the site for a day or so after the procedure. You may be asked to sign a separate consent for each of the bone marrow procedures.

The biopsy to be performed is exclusively for research purposes and will not benefit you. It might help other people in the future. Even if you sign "yes" to have the biopsy you can change your mind at any time. Please read each sentence below and think about your choice. After reading each sentence, circle and initial the answer that is right for you. The decision to participate in this part of the research is optional, and no matter what you decide to do, it will not affect your care.

I agree to have the tumor biopsy for the research tests in this study.

Yes No Initials _____

Optional Studies

We would like to keep some of the specimens and data that are collected for future research. These specimens and data will be identified by a number and not your name. The use of your specimens and data will be for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you decide now that your specimens and data can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your specimens and/or data. Then any specimens that remain will be destroyed and your data will not be used for future research.

Please read each sentence below and think about your choice. After reading each sentence, circle and initial the answer that is right for you. No matter what you decide to do, it will not affect your care.

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
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MEDICAL RECORD

CONTINUATION SHEET for either:
NIH 2514-1, Consent to Participate in A Clinical Research Study
NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 12-C-0192

CONTINUATION: page 15 of 17 pages

1. My specimens and data may be kept for use in research to learn about, prevent, or treat cancer or other health problems.

Yes No Initials _____

2. Someone may contact me in the future to ask permission to use my specimens and/or data in new research not included in this consent.

Yes No Initials _____

PATIENT IDENTIFICATION

CONTINUATION SHEET for either:

NIH-2514-1 (07-09)

NIH-2514-2 (10-84)

P.A.: 09-25-0099

File in Section 4: Protocol Consent

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Mark Roschewski, M.D., Building 10, Room 3B40, Telephone: 301-451-9021. You may also call the Clinical Center Patient Representative at 301-496-2626. If you have any questions about the use of your specimens or data for future research studies, you may also contact the Office of the Clinical Director, Telephone: 301-496-4251.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

STUDY NUMBER: 12-C-0192

CONTINUATION: page 17 of 17 pages

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/
Legal Representative

Date

Print Name

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.

(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/ Guardian Date

Print Name

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian

Date

Print Name

**THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE
FROM MARCH 23, 2015 THROUGH MARCH 22, 2016.**

Signature of Investigator

Date

Signature of Witness

Date

Print Name

Print Name