INSTITUTE: National Cancer Institute

STUDY NUMBER: 12-C-0197 PRINCIPAL INVESTIGATOR: Steven Pavletic, MD

STUDY TITLE: A Randomized Phase 2 Single-Center Study of Pomalidomide for Chronic GvHD

Continuing Review Approved by the IRB on 10/29/18
Amendment Approved by the IRB on 10/25/18 (J) Date Posted to the Web: 11/08/18
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?

This study is being done to gain information on the use of an experimental medicine called pomalidomide (also called CC-4047) in people with chronic graft-versus-host disease (GvHD). We would like to obtain information on the efficacy of pomalidomide in people with chronic GvHD. Although pomalidomide has been already used in humans in cluding patients with chronic GvHD we will also look for any evidence of the side effects of treatment.

Pomalidomide is taken by mouth. It works by modifying the body's immune response. The effects of pomalidomide on the immune system may be beneficial in chronic GvHD. However, this has not been proven. Pomalidomide is chemically similar to the drug thalidomide, which

has been shown to have beneficial effects in some people with chronic GvHD. However, thalidomide has not been approved by the Food and Drug Administration (FDA) for treatment of chronic GvHD.

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

You are being asked to take part in this study because you have moderate or severe chronic GvHD that is not controlled by standard medicines such as corticosteroids or other treatments.

How many people will take part in this study?

We plan to enroll up to 35 subjects in this study.

Description of Research Study

In this study, we are studying the efficacy of different doses (high or low) of pomalidomide and their effect on chronic GvHD. The doses being studied are 0.5 mg and 2 mg per day. After you are accepted for this study and you choose to take part, you will be "randomized" into one of the two treatment groups (called "arms"). Randomization means that you are put into a group by chance. A computer program will place you in one of the treatment arms. Neither you nor your doctor can choose the treatment arm you will be in. All patients in the study will receive pomalidomide, just at different doses over time depending on their assigned treatment arm.

You will take pomalidomide capsules once a day in 4-week periods called cycles. All patients will start receiving the same dose of pomalidomide (0.5 mg). Patients in the 0.5 mg (low dose) treatment arm will stay at this same daily dose till the end of the study. Patients in the 2 mg treatment arm (high dose) will have their dose increased by 0.5 mg every two weeks until the 2 mg dose is reached. Pomalidomide has been given to humans at these doses before, but you will be still watched carefully for any side effects.

Pomalidomide therapy will continue for 6 cycles (6 months) unless your GvHD gets worse or you have unacceptable side effects from the pomalidomide. If your GvHD has improved at the end of the 6 cycles, you may be able to continue pomalidomide for up to 6 more cycles.

A detailed description of what will happen if you take part in this study, as well as a list of potential risks and discomforts associated with participation in the study are listed below.

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

Before you begin the study

You will need to have examinations, tests and procedures to see if you qualify for the study. Many of these tests are performed as part of your regular medical care or during the prior treatments for your GvHD. You will be asked to sign a separate consent describing the tests you will need to have done. In order for you to enroll in the Study you must follow the requirements of POMALYST REMS™ program.

After all of these examinations are performed we determine you are eligible for the trial, you will be asked to sign this informed consent agreeing to participate in this research study.

During the study

During the study, you will take pomalidomide capsules by mouth every day. Pomalidomide should be taken at about the same time each day. Pomalidomide capsules should be swallowed whole, and should not be broken, chewed or opened. Patients are instructed to fast (water or clear fluids only) for at least 2 hours prior to taking a dose to at least 1 hour post-dosing. Pomalidomide should not be swallowed concurrently with other allowed medications while on-study.

You will be asked to complete a medication diary and to return any unused study drug and empty bottles to the clinic at each visit.

If you are taking other medications that increase the risk of blood clotting or you have other risk factors for blood clotting, you will take aspirin or another medicine to reduce the chance of blood clotting. All patients taking pomalidomide must follow strict guidelines for prevention of pregnancy. This is because there is a risk of harm to a fetus if pregnancy occurs while taking pomalidomide. These guidelines are outlined in the section on birth control below.

Standard procedures being done because you are in this study; these may be done more often because you are in the study:

- Clinic visit, which will include a medical history, physical exam, and measurement of weight and vital signs every 2 weeks during the first 3 cycles, then at the beginning of every cycle, and when you stop taking pomalidomide
- Assessment of your GvHD, including questions about your symptoms, before you start pomalidomide, every 3 months while you are taking pomalidomide, and when you stop taking pomalidomide
- Blood draws for laboratory tests every 2 weeks during the first 3 cycles, then at the beginning of every cycle, and when you stop taking pomalidomide
- Urine tests before starting pomalidomide, every 3 months while you are taking pomalidomide, and when you stop taking pomalidomide
- Non-invasive imaging such as CT scans (a computerized x-ray examination) or MRI (an examination using magnetic field and radio waves) before starting pomalidomide and as medically necessary
- Lung function test every 3 months while you are taking pomalidomide, and when you stop taking pomalidomide
- EKG (a recording of the heart's electrical activity) and echocardiogram (an examination of your heart using sound waves) at the time of starting the study, monthy first three months, at six months and as medically necessary
- Pregnancy tests if you are a woman who is able to become pregnant, weekly during the first cycle, then every 28 days if you have regular periods or every 14 days if your

periods are irregular. We will provide a pregnancy test kit for you to use at home for the weeks you are not here at the NIH.

- As part of the evaluations for this study and of your graft-versus-host disease you will see specialists in dermatology (skin disease) and dentistry prior to study entry. You will see specialists in rehabilitation medicine, occupational therapy, ophthalmology (eyes) and gynecology (if female) up to two weeks after study entry. You will also see these specialists at 3-6 month intervals while you are on this study.

Tests and procedures that are either being tested in this study or being done to see how the drug is affecting your body:

- Blood draws to measure the levels of pomalidomide in your blood on the day you start pomalidomide, every 2 weeks for the first 3 months, then monthly until the 6-month visit. Each of these blood draws requires less than 2/3 teaspoons of blood (3 mL).
- Other blood samples will be collected for research at the same time points, about 50 mL (10 tea spoons of blood) except at the study beginning and after 3 and 6 months of therapy when a larger blood draw will be performed, about 20 teaspoons of blood (100 mL).
- You will be asked to give a sample of mouth saliva up to 10 cc (two teaspoons) before start of the therapy and at the end at six months or at permanently stopping pomalidomide therapy
- We would like your permission to collect biopsies (removal of a small bit of tissue for examination under a microscope) from your skin and mouth before starting pomalidomide and after 6 months or at permanently stopping the pomalidomide to study the effect of pomalidomide on immune response in these tissues.
- Photographs of your body cGVHD manifestations before starting the study and after 6 months or at permanently stopping pomalidomide

When you are finished taking the drugs (treatment)

When you are finished taking the drugs, we will continue to follow you for up to 2 years after you first started taking pomalidomide. The follow-up will include a clinic visit 3 months after your last dose of pomalidomide, and a phone call or visit to your regular doctor 1 and 2 years from the date you first started taking pomalidomide.

Study Chart

This chart outlines what will happen if you choose to participate:

Screening for Eligibility

- Medical history and physical exam
- Blood tests
- Chest CT scan
- Lung function test
- EKG and echocardiogram
- Pregnancy testing

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Treatment

Therapy:	Pomalidomide capsules by mouth once each day
Monitoring:	Review of side effects Medical history and physical exam Assessment of GvHD Blood and urine tests Non-invasive imaging Lung function testing EKG and echocardiogram Pregnancy testing and pregnancy prevention counseling
Research:	Blood, saliva, urine samples, Biopsies (optional)
Stop treatment:	Completion of 6 to 12 cycles of therapy Progressive GvHD Patient preference Unacceptable toxicity Other medical reasons

After Treatment

- Follow-up for up to 2 years after the first dose of

Birth Control

Pregnancy:

Pomalidomide was found to cause birth defects in an experimental study in animals. Pomalidomide is related to thalidomide. Thalidomide is known to cause severe life-threatening human birth defects. Pomalidomide is therefore considered to have the potential to cause birth defects in humans. If pomalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Females must not become pregnant while taking pomalidomide.

In order to participate in this study, you must register into and follow the requirements of the POMALYST 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, follow the pregnancy testing and birth control requirements of the program that are appropriate for you and take surveys regarding your compliance with the POMALYST REMS™ program.

In addition, all patients taking pomalidomide must follow guidelines for prevention of pregnancy. This is because there is a risk of harm to a fetus if pregnancy occurs while taking pomalidomide. These guidelines are outlined below.
Note: By signing this consent you confirm that you understand and agree to receive counseling and to comply with the pregnancy precaution requirements of the POMALYST REMS™ program.

Screening:

- Pregnancy test, if applicable: 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 starting pomalidomide and the second test within 24 hours before your first dose of pomalidomide.
- For the purposes of this study, a female of childbearing potential is a sexually mature female who: 1) has not undergone a hysterectomy (the surgical removal of the uterus) or bilateral oophorectomy (the surgical removal of both ovaries) or 2) has not been naturally postmenopausal for at least 24 consecutive months (i.e., has had menses at any time during the preceding 24 consecutive months)

Pomalidomide is an analogue of thalidomide. Thalidomide is a known to cause severe life-threatening human birth defects. If pomalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Females are advised to avoid pregnancy while taking pomalidomide. You have been informed that the risk of birth defects is unknown. If you are female, you agree not to become pregnant while taking pomalidomide.

Females:
If you are a female, you must not be pregnant.
You will be considered not of child bearing potential if you meet the following criteria:

- Absence of menstrual periods (natural menopause) for the past 24 consecutive months or
- Have had a hysterectomy (the surgical removal of the uterus) or both ovaries surgically removed

If you do not meet these criteria, you will be considered a female of child bearing potential. If there is ANY chance that you can become pregnant, you must follow the guidelines below.

If you **ARE** a female of childbearing potential, you will not be able to participate in this research study unless you have had two negative pregnancy tests, one within 10-14 days and one within 24 hours of starting pomalidomide.

In addition, with your doctor's knowledge and approval, you agree to use **TWO** reliable forms of birth control or practice complete abstinence from heterosexual intercourse during the following time periods related to this study:

- For at least 28 days before starting pomalidomide
- While taking pomalidomide
- During dose interruptions
- And for at least 28 days after you stop taking pomalidomide

You agree to inform the investigator immediately if:

- You have any reason to suspect you are pregnant
- You find that circumstances have changed and that there is a risk of becoming pregnant
- You have stopped using the approved forms of **TWO** reliable birth control methods
- You must talk to your doctor before changing any birth control methods

- The following methods of birth control are considered <u>acceptable</u> birth control methods:

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

Special Note: Certain HIV-protease inhibitors, griseofulvin, modafinil, pencillins, rifampin, rifabutin, phenytoin, carbamazepine, or certain herbal supplements such as St. John's Wort may reduce the effectiveness of hormonal contraceptives during and up to one month after discontinuation of these concomitant therapies.

Therefore, females of childbearing potential requiring treatment with one or more of these drugs must choose **ONE** non-hormonal method as the highly effective method of birth control (IUD, tubal ligation, partner's vasectomy) along with **ONE** of the additional effective methods (latex

condom, diaphragm, cervical cap) or abstain from heterosexual contact while taking pomalidomide.

You must use at least one highly effective method and one additional effective method of birth control **AT THE SAME TIME**. However, your doctor may recommend that you use two barrier methods for medical reasons.

If you have sex without using **TWO** reliable methods of birth control, or if for any reason you think you may be pregnant, you must **IMMEDIATELY** stop taking pomalidomide and tell your doctor.

You will have pregnancy tests before and during treatment, even if you agree not to have reproductive heterosexual intercourse. You will have a pregnancy test done by the doctor every week during the first 28 days of this study. You will then have a pregnancy test every 28 days during your participation in this study if your menstrual cycles are regular or every 14 days if your cycles are irregular. You will also have a pregnancy test if you miss your period or have unusual menstrual bleeding. In addition, you will have pregnancy tests when you stop taking pomalidomide and at day 28 after you stop taking pomalidomide if your menstrual cycles are regular. If your menstrual cycles are irregular, you will have pregnancy tests when you stop taking pomalidomide and at days 14 and 28 after you stop taking pomalidomide.

You must not breastfeed a baby while you are participating in this study and for at least 28 days after you stop taking pomalidomide.

You must **NEVER** share pomalidomide (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 stop taking pomalidomide. You will be counseled at least every 28 days and at discontinuation from the trial about not sharing pomalidomide (and other study drugs), the potential risks of fetal exposure, and abstaining from blood donations.

If you have any reason to suspect you are pregnant, you must **IMMEDIATELY** stop taking pomalidomide and tell your doctor. If you have a positive pregnancy test while participating in this study, you must **IMMEDIATELY** stop taking pomalidomide and tell your study doctor. If you have a positive pregnancy test within 28 days after you stop taking pomalidomide, you must **IMMEDIATELY** tell your doctor.

Study subjects who become pregnant will be monitored throughout the pregnancy and will continue to be monitored for 30 days after delivery (premature delivery, aborted fetus, full-term pregnancy, or no longer pregnant).

Males:
You have been informed about the risk of birth defects and you agree to use a latex condom every time you have sex with a female of childbearing potential while you are participating in this study and for at least 28 days after you stop taking pomalidomide, even if you have had a successful vasectomy. You must tell your doctor if you have sex with a female of childbearing

potential without using a latex condom or if you think for any reason your partner may be pregnant.

You must **NEVER** share pomalidomide (or other study drugs) with someone else. You must **NEVER** donate blood, sperm, or semen while you are participating in this study and for at least 28 days after you stop taking pomalidomide. You will be counseled at least every 28 days regarding abstaining from donating blood, sperm, or semen; birth control requirements; not sharing pomalidomide (and other study drugs); and the potential risks of fetal exposure.

Risks or Discomforts of Participation

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

There is always a risk involved in taking any drugs, but you will be carefully monitored for any problems and you are encouraged to report anything that is bothering you. There may be risks or side effects of the study drug that are unknown or cannot be predicted at this time. You should not hesitate to report anything that upsets you or may be troubling you to your study physician or member of the study team, even if you do not think it is connected to taking the study drug.

If you have any questions you should contact the study physician or member of the study team. You will receive any new information during the course of the study concerning significant treatment findings from this study or others (good or bad) that may affect your willingness to continue. In addition to the risks of the study drug, pomalidomide, described below, you may experience discomfort associated with blood draws and tissue biopsies (whether clinically indicated or related to research) while participating in the study.

Risks of pomalidomide:

Pomalidomide 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 pomalidomide, some of which are not yet known. As of March 1, 2011, about 517 patients participating in Celgene-sponsored studies had taken pomalidomide, and the risks below are drawn from reports from these patients.

The side effects that patients had after starting pomalidomide in completed and ongoing studies are noted below. Your health care team may give you medicines to help lessen or treat side effects. Many side effects go away soon after you stop taking the study drug. In some cases, side effects can be serious, long-lasting or may never go away, or can cause death. It is not yet possible to know for certain which of the reported side effects are directly due to pomalidomide itself. As pomalidomide is being studied as a treatment for serious diseases, some of the reported conditions could be from the disease itself, or other pre-existing diseases, or other drugs the patient may have been taking. It should not therefore be assumed that all the side effects listed below were caused by pomalidomide.

Pomalidomide can cause a decrease in the number of white blood cells, red blood cells, platelets, and/or neutrophils (a type of white blood cell). White blood cells are cells of your immune system. In some patients, a decrease in blood cells can be serious and may require you to stop treatment. A decrease in white blood cells and/or neutrophils may lead to fever and/or a life-threatening infection. The red blood cells carry oxygen to your organs. A decrease in red blood cells can lead to fatigue or feeling tired. A decrease in platelets may lead to bleeding and require stopping treatment. Other laboratory values may become abnormal, as well.

Side effects reported as serious at least once are **bolded.**

Likely (reported in more than 10% of patients)	**Less Likely** (reported in 5 to 10% of patients)	**Rare but Serious** (reported in less than 5% of patients)
• **Low white blood cell count** • Constipation • Nausea • Skin rashes • **Fatigue or tiredness** • **Shortness of breath** • **Lung infection** • Cough • Dizziness • Muscle aches or pains • Skin tingling	• **Fever** • **Low platelet count** • Inflammation of the throat • Skin itching • Swelling • **Diarrhea (loose stool)** • Muscle cramps • **Headache** • **Pain in chest, back, joints, arms or legs** • Dry skin and itch • Decreased sensitivity to touch	• **Fever and infection when the white blood cell count is low** • **Decrease in red blood cells, which carry oxygen** • **Severe infection of the bloodstream** • **Urinary tract infection** • **Dehydration (too little fluids in the body)** • **Too much calcium in the blood** • **Kidneys not working correctly** • **Cancer of the white blood cells, adrenal gland, bladder, kidney, or thyroid** • **Confusion** • **Blood clot in the veins or lung** • **Atrial fibrillation (when the top of your heart quivers instead of beating)**

Deep vein thrombosis and pulmonary embolism

Medications in the same family of medications as pomalidomide have shown an increased risk of deep vein thrombosis (blood clot in a larger blood vessel) and pulmonary embolism (a blood clot in or around the lungs) in some subjects with certain medical conditions. If you are at increased risk for blood clots due to certain medical conditions or other medications you may be taking, you will receive either aspirin or another medicine to reduce the chance of blood clotting while you are receiving pomalidomide.

Reproductive Risks

As indicated in the section on birth control, pomalidomide is related to thalidomide, a drug known to cause severe life-threatening human birth defects. If pomalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby.

Additional precautions

Other than the patient, women who are able to become pregnant and men who are able to father a child should not touch or handle the pomalidomide capsules.

While in this study, if any physician or healthcare provider, other than your study physician, prescribes medication(s) for you for another condition or reason, or you are taking any over-the-counter medications, vitamins, herbal, holistic or homeopathic remedies, please tell the study doctor or a member of the research team immediately. Please also let your study doctor know all of your present and past diseases and allergies. This is important because a possible interaction with some medications, vitamins, and remedies may cause serious side effects, and/or may still be unknown.

Biopsies

Optional punch skin and oral biopsies will be performed. Prior to the biopsy, you will receive local anesthesia through a small injection into the area of skin or mouth mucosa surrounding the biopsy site. Samples will be removed with a needle during the biopsy (size of the pencil eraser). You may require a stitch after the biopsy. Risks of the biopsy include local oozing of blood or discomfort. Infection is a rare complication of skin/oral biopsies. The biopsies to be performed are exclusively for research purposes and will not benefit you. They might help other people in the future. 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. Your permission for this will be obtained at the time of the biopsy.

Potential Benefits of Participation

Are there benefits to taking part in this study?

No benefit can be promised to you for your participation in this study. We do not know if you will receive personal medical benefit directly from taking part in this study, although the knowledge gained from this study may help others in the future who have chronic GvHD. This study may lead to an increase in understanding of pomalidomide as therapy for chronic GvHD, and possibly better treatments based on results from this study for patients in the future. Potential benefits to you could include improvement in your GvHD or lessening of your symptoms that are caused by your GvHD. However, it is possible that you will not receive any benefit from participating.

Alternative Approaches or Treatments

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

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

- Getting treatment or care for GvHD 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 GvHD. It does not treat the GvHD 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.

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 worsens or 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
- if you do not follow the treatment plan, including steps to prevent getting pregnant and protecting others from pomalidomide

If this occurs, 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 until 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 can**not** be recalled and destroyed.

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 my medical information be kept private?

We will do our best to make sure that the personal information in you medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. 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), involved in keeping research safe for people.
- Regulatory agencies in the United States
- NCI Institutional Review Board
- Qualified representatives from Celgene, the pharmaceutical company who produces pomalidomide.
- In order to obtain pomalidomide free of charge from Celgene, your name, address, phone, date of birth and the fact that you are participating in this trial will be disclosed to Celgene and its agents or vendors that supply pomalidomide and administer the POMALYST REMS™ program. By signing this consent form you agree to this disclosure.

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.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should also know that there are several circumstances in which the Certificate does not provide coverage. These include when information:

- will be used for auditing or program evaluation internally by the NIH; or
- must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA).
- is necessary for your medical treatment and you have consented to this disclosure;
- is for other research.

In addition, identifiable, sensitive information protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

Conflict of Interest

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a Protocol Review Guide. 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.

The National Institutes of Health and the research team for this study are using pomalidomide, developed by Celgene. This means it is possible that the results of this study could lead to payments to NIH scientists and to the NIH. By law, government scientists are required to receive such payments for their inventions. You will not receive any money from the development of pomalidomide.

Use of Specimens and Data for Future Research

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your specimens and data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that it may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used 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 do not want your stored specimens and data used for future research, please contact us in writing and let us know that you do not want us to use your specimens and/or data. Then any specimens that have not already been used or shared will be destroyed and your data will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

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, Steven Pavletic, M.D., Building 10, Room 4-3130, Telephone: 240-760-6174. You may also call the Clinical Center Patient Representative at (301) 496-2626. If you have any questions about the use of your specimens and data for future research studies, you may also contact the Office of the Clinical Director, Telephone: 240-760-6070.

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

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 OCTOBER 29, 2018 THROUGH NOVEMBER 12, 2019. _____ _____ _____ _____ Signature of Investigator Date Signature of Witness Date _____ _____ Print Name Print Name	