SUMMARY OF CHANGES

A Phase II Multicenter Study of Pomalidomide Monotherapy in HIV-Positive Individuals with Kaposi Sarcoma (KS) in Sub-Saharan Africa (SSA)

Version 10.0

NCI Protocol #: AMC-100
Local Protocol #: AMC-100

NCI Version Date: 04DEC2023
Protocol Date: 04DEC2023

I. Scientific and Substantive Changes

#	Section	Comments
1.	WHAT ARE THE STUDY GROUPS?	The text was updated to reflect the expected enrollment of 26 participants instead of the originally planned 30 participants. The number of participants to be entered has been reduced from the originally planned 30 to 26 because Celgene, the donor of the study drug, requires that the last participant begin on study treatment no later than December 1, 2023. The revised sample size will provide only slightly reduced statistical power (87.5% vs 90%) to test the null hypothesis that the ORR = 10% against the alternative that it is 30% with pomalidomide monotherapy at the one-sided 10% significance level.

II. Administrative and Editorial Changes

#	Section	Description of Change
2.	Title	The National Clinical Trial number (NCT# 03601806) was added to the official study title for internet search on http://www.ClinicalTrials.gov.
3.	Global	The version number and date have been updated to version 10.0, dated 04DEC2023.

AMC-100 MODEL INFORMED CONSENT FORM

Study Title for Study Participants: Pomalidomide in HIV-positive persons with Kaposi Sarcoma in Sub-Saharan Africa

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: A Phase II Multicenter Study of Pomalidomide Monotherapy in HIV-Positive Individuals with Kaposi Sarcoma (KS) in Sub-Saharan Africa (SSA) (NCT# 03601806)

A Clinical Trial of the AIDS Malignancy Consortium (AMC)

INTRODUCTION

You are being asked to take part in this research study because you are HIV-positive (the virus that causes AIDS) and have Kaposi's sarcoma (KS). Kaposi's sarcoma (KS) is the most common cancer seen in HIV-positive patients.

WHAT IS THE USUAL APPROACH TO MY TYPE OF CANCER?

AIDS-related Kaposi's sarcoma (AIDS-KS) occurs in persons who are HIV-positive who are also infected with the Kaposi sarcoma herpesvirus (KSHV). All HIV-positive persons with Kaposi sarcoma tumors are treated with antiretroviral therapy (ART), or anti-HIV drugs. In some cases, ART alone may control KS. This study is for people whose KS has not been controlled on ART alone, even though their HIV infection is controlled.

People with KS who are not in this study are usually treated with chemotherapy (cancer fighting drugs) that are swallowed or given through a needle in a vein. Cryotherapy (freezing of the cancer), radiation, or other treatments may be used, depending on how severe the disease is. Not all of these treatments may be available where you are being treated. Sometimes combinations or sequences of these treatments are used, and your doctor can explain which may be best for you and which are available. These treatments can reduce symptoms and may stop the tumor from growing for several months or more.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above, if they are available
- you may choose to take part in a different study, if one is available, or
- you may choose not to be treated for cancer

WHY IS THIS STUDY BEING DONE?

Several anti-cancer drugs work well in treating KS, but there is no treatment that cures KSHV infection. One drug called pomalidomide has caused KS tumors to get smaller in some people in the U.S. but this drug has not been tested in Africa. The purpose of this study is to test any good and bad effects of pomalidomide. Pomalidomide is approved in the U.S. for treating KS and another type of cancer, multiple myeloma.

WHAT ARE THE STUDY GROUPS?

All study volunteers will get the same study intervention. All study volunteers will get the study drug pomalidomide.

There will be about 26 people taking part in this study.

WHAT WILL HAPPEN WHILE I AM IN THE STUDY

You will receive pomalidomide as an outpatient. The pomalidomide will be given initially as one 4 mg capsule. The dose of the pomalidomide may be lowered or even stopped if you develop certain side effects.

After starting the medication, you will be seen in the clinic about every 4 weeks. If you are a woman who could become pregnant, you will be seen more often so that pregnancy tests can be repeated. The pomalidomide will be given in cycles. Each cycle will consist of taking the pomalidomide for 21 days followed by a 7-day break when no pills will be taken. At each visit, you will need to bring back the medication container(s) and any remaining capsules.

If you take part in this study, you will need to take aspirin 75-100mg by mouth daily x 28 days for each cycle and for 30 days after the last pomalidomide dose. If the recommended dose of aspirin is not available, a dose of up to 325 mg daily is permitted. This medicine is to help prevent the risk of blood clots from pomalidomide. If you are already taking aspirin, you will keep taking your current dose if it is the same or higher.

The pomalidomide should be taken at around the same time each day.

The medication can be taken with or without food.

If you miss a dose, the pomalidomide should still be taken within 12 hours of when it would normally be taken. If more than 12 hours have passed, the dose should be skipped. If pomalidomide is skipped it should NOT be made up the next day.

If you take more than the prescribed dose you should contact the study staff immediately.

The capsules should be swallowed with whole glass of water. You should NOT bite or chew on the capsule. If you do break a capsule, you should drink an additional glass of water immediately. This is to prevent the medication from getting into your saliva, which might expose other people to the medication. If you get the powder in the capsule on your skin, you should wash it off immediately with soap and water.

If your disease is stable or does not change, you may receive up to 6 cycles of medication.

If your disease is improving, you may receive up to 12 cycles of medication.

If you miss a follow-up appointment by more than 42 days, you will be removed from study treatment.

You will be expected to complete a study diary to record the time when you took your pomalidomide for each of the cycles of your treatment.

HOW LONG WILL I BE IN THIS STUDY?

You will receive the study drug for up to 12 months depending on your response to treatment. After you finish the study drug, your doctor will continue to watch you for side effects and follow your condition every 12 weeks for up to an additional 48 weeks.

WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra examinations that you will need to have if you take part in this study.

Before you begin the study

You will need to have the following evaluations to find out if you can be in the study:

- A confirmation of your HIV infection. If there is no record available, another HIV test will be done. You may have to sign a separate consent form before this test is done.
- A medical history and a physical examination will be completed. This will include a review of all medicines that you are taking and an examination of your KS lesions.
- You will have a chest X-ray. If you have KS in your lungs, you may also have another scan called a Computed Tomography (CT) scan. A CT scan is a series of x-rays taken by a computer *(Note to site: delete if CT unavailable at institution.)*
- A skin biopsy of an area of KS will be done at this time if you have not had a biopsy of the KS in the past or if the biopsy is not available for review. A biopsy is the removal of a small piece of skin. This biopsied skin is then looked at under a microscope to show whether or not you have KS. The area of the skin that will be biopsied will be numbed with an injection of local anesthetic to prevent pain during the biopsy. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur.
- The study doctor will examine your KS lesions, will take measurements of some of the lesions, and will count them. We will also take photographs of the lesions to document their appearance. We will take more photographs during the course of the study to document any changes in your KS lesions. We will not take photos of your entire face. In the photos, we will remove any features that could be used to identify you (such as tattoos). Only your initials and subject number will be used to identify the photo.
- About 4 teaspoons of blood will be taken from a vein for routine safety tests for blood counts and liver and kidney tests.
- Pregnancy test, if applicable:

If you are a woman who is able to get pregnant, also known as 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 (FCBP) 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).

If the exams, tests, and procedures show that you can take part in the study, and you choose to take part, then you will need the following extra exams, tests, and procedures. They are not part of the usual approach for your type of cancer.

During the study

- Blood tests every month for 1 year
- 4 blood samples (about 1.5 teaspoons) for research studies
- Repeat photographs of your skin to document tumor response
- Chest X-ray or CT scan of the chest every 3 months for up to 1 year
- Repeat biopsies to review whether your tumors responded to treatment
- Counseling regarding pregnancy prevention and repeat pregnancy test if you are a female of childbearing potential

A study calendar that shows how often these exams, tests, and procedures*)* will be done is attached.

WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

If you choose to take part in this study, there is a risk that the pomalidomide (CC-4047) may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The pomalidomide (CC-4047) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important things to know about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.

- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects for Pomalidomide (CC-4047)

Table Version 2.4, May 22, 2022

COMMON, SOME MAY BE SERIOUS In 100 people receiving pomalidomide (CC-4047), more than 20 and up to 100 may have:
• Anemia which may require blood transfusion

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving pomalidomide (CC-4047), from 4 to 20 may have:
• Constipation, diarrhea • Swelling of arms, legs • Tiredness, fever • Infection • Bruising, bleeding • Pain • Numbness, tingling or pain of the arms and legs • Confusion • Kidney damage which may require dialysis • Difficulty emptying the bladder

RARE, AND SERIOUS In 100 people receiving pomalidomide (CC-4047), 3 or fewer may have:
• Heart attack • Nausea • Death • Liver damage which may cause yellowing of eyes and skin, swelling • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Loss of appetite • Second primary malignancies • A new cancer resulting from treatment of earlier cancer • Dizziness • Abnormal unpleasant sensation • Feeling of "pins and needles" in arms and legs • Damage to the brain which may cause changes in thinking and may be life-threatening • Stroke which may cause paralysis, weakness, headache • Sensing things that are not there • Cough, shortness of breath • Damage to the lungs which may cause shortness of breath • Skin rash developing 1-8 weeks after a drug is given which may be accompanied by fever, lymph node swelling and organ failure • Rash • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body • Blood clot which may cause swelling, pain, shortness of breath

Pomalidomide is in the same drug class as lenalidomide and thalidomide. While not seen in people, these other drugs are known to cause the following side effects: birth defects; damage to the brain which may cause tiredness, changes in thinking; swelling and pain in the abdomen.

Pregnancy

Pomalidomide is 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. Women are advised to not get pregnant while taking pomalidomide. You have been informed that the risk of birth defects is unknown. If you are a woman, you agree not to become pregnant while taking pomalidomide.

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:

Women

If you are a woman, 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 (FCBP), 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, including at least one of the highly effective methods listed below, or practice complete abstinence from heterosexual intercourse during the following time periods related to this study. If abstinence cannot be guaranteed, two forms of birth control must be used.

- for at least 28 days before starting pomalidomide
- while participating in this study
- during dose interruptions
- and for at least 28 days after discontinuation from the study

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, including at least one of the highly effective methods listed below.
- you must talk to your doctor before changing any birth control methods.

The following methods of birth control are considered acceptable birth control methods:

Highly Effective Methods	Additional Effective Methods
Intrauterine device (IUD)	Latex condom
Hormonal (injections, implants)	Diaphragm
Tubal ligation	Cervical Cap

Special Note: Certain HIV-protease inhibitors, griseofulvin, modafinil, penicillins, 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) 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**.

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 are discontinued from the study and at day 28 after discontinuation from the study if your menstrual cycles are regular. If your menstrual cycles are irregular, you will have pregnancy tests when you are discontinued from the study and at days 14 and 28 after discontinuation from the study.

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.

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 have been discontinued from the study. 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 and 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 have been discontinued from this study, 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). Infants will be followed through 1 year following birth.

Men

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 have been discontinued from the study, 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 have been discontinued from the study. 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.

Smoking

Smoking tobacco (cigarettes or cigars) while taking pomalidomide can increase your risk of blood clots. Do not smoke while taking pomalidomide.

Let your study doctor know of any questions you have about possible side effects. You can ask the

study doctor questions about side effects at any time.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Possible benefits to you from participating in this study are that your KS and overall physical condition may stay the same or get better, your quality of life may improve, and possibly your survival may increase. A decrease in the number and size of KS lesions may result in improvements in swelling, pain, or disfiguring skin lesions.

It is also possible that you may receive no benefit from being in this study. Information learned from this study may help others who have HIV.

CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may stop the study treatment:

- If your health changes and the study is no longer in your best interest.
- If new information becomes available.
- If you do not follow the study rules.
- If you become pregnant.
- If the study is stopped by the sponsor, IRB or FDA.

WHAT ARE MY RIGHTS IN THIS STUDY?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

WHAT ARE THE COSTS?

There will be no cost to you for study-related visits, physical examinations, laboratory tests or other procedures. *(Modify the prior statement to local requirements if subjects will be expected to cover the cost of any research-related care, tests, or supplies.)* You, your insurance company, or your health care system will need to pay for the cost of anti-HIV drugs, which are not provided by the study. *(delete references to insurance company or health care system if not applicable at site)*. In some cases, it is possible that your insurance company or health care system will not pay for these costs because you are participating in a research study *(Insert site/country policy)*.

The study drug you will receive if you take part in this study, pomalidomide, is being supplied by Celgene and the AIDS Malignancy Consortium at no cost to you.

You will receive no payment for taking part in this study. *(insert information about help with transportation to and from study visits, if any)*.

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. You may/may not *(per site/country policy)* have to pay for this care. No funds have been set aside for any treatment for injuries, either through *[this institution]* or the NIH. You will not be giving up any of your legal rights by signing this consent form.

Pregnancy

If you become pregnant and your baby is injured as a result of your being in this study, your baby will be given immediate treatment for injuries, and be referred for further treatment, if necessary. However, you may/may not *(per site/country policy)* have to pay for this care.

WHO WILL SEE MY MEDICAL INFORMATION?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain laws require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The AIDS Malignancy Consortium (AMC)
- Celgene, the drug company supporting the study
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S.

WHERE CAN I GET MORE INFORMATION?

You may visit the NCI Web site at **http://cancer.gov/** for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

The following section on optional studies may be removed from the informed consent form, or placed in a separate informed consent form, as required by local policies.

OPTIONAL SAMPLE COLLECTIONS FOR LABORATORY STUDIES AND DONATION OF LEFTOVER TISSUE SAMPLES TO THE AIDS AND CANCER SPECIMEN RESOURCE (ACSR)

Researchers are trying to learn more about cancer, HIV/AIDS, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in this study, the study doctor for the main study would like to collect these specimen types:

Donation of left over study specimens to the ACSR for all study participants: If you choose to take part in this clinical trial, the researchers would like to collect unused blood and biopsy tissue left over after the study is done. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called “biobanking.” The Biobank is being run by the **AIDS and Cancer Specimen Resource** and is supported by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) **Donation of left over study specimens to the ACSR for all study participants:** Your sample and some related health information will be stored in the ACSR Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record may be updated after the study is over.
2) Qualified researchers can submit a request to use the materials stored in the ACSR. A science committee at the ACSR will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
3) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
4) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
2) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
3) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. The ACSR and AMC staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom the ACSR and the AMC send your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.

4) Information that identifies you will not be given to anyone, unless required by law.

5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no additional costs to you or your insurance for these optional studies. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option:

SAMPLES FOR FUTURE RESEARCH STUDIES

My leftover samples (blood and biopsy tissue) and related information may be donated to ACSR Biobank for use in future health research.

YES NO

I agree to have my leftover samples (blood and biopsy tissue) undergo genetic testing to learn about, prevent, diagnose, or treat HIV-related diseases and cancer.

YES NO

This is the end of the section about optional studies.

MY SIGNATURE AGREEING TO TAKE PART IN THE MAIN STUDY

I have read the consent form or had it read to me and understand the information above. I have discussed it with the study doctor and my questions have been answered I understand that I will be given a signed and dated copy of this consent form. I agree to take part in the main study and any additional studies where I circled 'yes.' My signature below indicates that I understand my rights and want to take part in this study as a research participant.

Participant's signature: _____

Date of signature: _____

Signature of person(s) conducting the informed consent discussion: _____

Date of signature: _____

ATTACHMENT 1: AMC CERTIFICATE OF CONFIDENTIALITY STATEMENT

The NIH has given the AMC a Certificate of Confidentiality. The Certificate does not mean that the NIH or the U.S. Government recommend that you take part in this study. This Certificate helps us keep your health information private.

Your records for this study will have information that may identify you. This Certificate lets us turn down legal demands for your study records. We can use the Certificate to turn down demands for records from a U.S. court. The Certificate can be used in any federal, state, or local legal matters. We will use the Certificate to turn down any demands for your study records. The cases where we cannot use the Certificate are explained below.

We cannot use the Certificate to turn down a demand from the U.S. Government for study records. This applies to audits or reviews of the AMC. This also applies to study records that we have to report to the FDA.

The Certificate does not stop you or your family members from sharing your health information. It does not stop you from talking about taking part in this study. You may give written permission for an insurer, employer, or other person to get copies of your study records. If you give permission, we cannot use the Certificate to say no to a request for your study records.

ATTACHMENT 2: STUDY CALENDAR

You will receive pomalidomide every day for 21 out of 28 days in this study. This 28 day period of time is called a cycle. The cycle will be repeated up to 12 times. Each cycle is numbered in order. The chart below shows what will happen to you during Cycle 1 and future treatment cycles as explained previously. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Before the study

Day	What you do
Within 28 days before starting study	• Some patients may need to start two forms of birth control.
Within 21 days before starting study	• Get routine blood tests • Answer questions about your medical history and any medications that you have taken recently. • Physical exam • Review of your KS biopsies. You may have a biopsy of your KS lesions if an earlier biopsy is not available. • Chest X-ray and CT scan (if you have KS in your lungs)
Within 14 days before starting study	• Pregnancy test if you are a female who could become pregnant
Within 7 days before starting study	• Get routine blood tests. • Physical exam and review your medications • Exams to count your KS lesions and photos of KS lesions
Within 24 hours before starting pomalidomide	• Pregnancy test if you are a female who could become pregnant

Cycle 1

Day	What you do
Day 1	• Get research blood tests • Pregnancy prevention counseling with study staff • Pregnancy test if you are a female who could become pregnant • Begin taking pomalidomide once a day for 21 days, then 7 days off. Keep taking pomalidomide until Day 21 of this cycle, unless told to stop by your health care team. You will receive a diary to track when you take pomalidomide every day.

Day 8, 15 and 21	• Pregnancy test if you are a female who could become pregnant
Day 26, 27, or 28	• Get routine blood tests and exams. • Pregnancy test if you are a female who could become pregnant

Future cycles

Day	**What you do**
Days 1-28 for up to 12 cycles	• Return to the clinic with your drug diary on day 1 of each cycle • Physical exam and review of any side effects you are having • Review of your medications • Exams to count your KS lesions and photos of KS lesions if your lesions changed • Get routine blood tests every 28 days (more if your doctor tells you to). • Get routine X-rays or CT scans every 3 cycles if you have KS inside your body every 3 cycles • The study team will collect a blood sample for research studies on day 1 of cycles 2, 3, 4, 7, and 10 • Pregnancy prevention counseling with study staff • Pregnancy test if you are a female who could become pregnant every 14 or 28 days, depending on your menstrual cycle. • Keep taking pomalidomide once a day for 21 days, then 7 days off every cycle. You will keep taking pomalidomide if you have no bad side effects and cancer is not getting worse. Call the doctor at _____ *[insert phone number]* if you do not know what to do. • After 6 cycles, if your KS is not improving you will stop study treatment. If your KS is improving, you will receive up to 12 cycles of pomalidomide.

After stopping treatment

Day	What you do
Within 7 days after stopping treatment	• Return to the clinic with your drug diary • Physical exam and review of any side effects you are having • Review of your medications • Exams to count your KS lesions and photos of KS lesions, if not done recently • Pregnancy prevention counseling with study staff • Pregnancy test if you are a female who could become pregnant. This test may be repeated at 14 days after stopping. • Get routine blood tests (more if your doctor tells you to). • Get routine X-rays or CT scans if you have KS inside your body • The study team will collect a blood sample for research studies
Day 28	• Return to the clinic • Physical exam and review of any side effects you are having • Review of your medications • Exams to count your KS lesions and photos of KS lesions • Pregnancy test if you are a female who could become pregnant • Get routine blood tests (more if your doctor tells you to).

Follow-up after treatment (only for participants whose KS improved)

Day	What you do
12, 36, and 48 weeks after last cycle of pomalidomide	• Physical exam and review of any side effects you are having • Review of your medical history for conditions related to AIDS • Exams to count your KS lesions and photos of KS lesions