HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Protocol Title:	**A5326 FINAL Version 2.0, dated 3/26/14; Letter of Amendment 1, 10/10/14** Safety, Pharmacokinetics and Immunotherapeutic Activity of an Anti-PD-L1 Antibody (BMS-936559) in HIV-1 Infected Participants on Suppressive cART: A Phase I, Double-Blind, Placebo-Controlled, Ascending Single Dose Study
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24 hr. Emergency Contact:	Immunodeficiency Program Doctor on call (215) 662-6059

Introduction:

You are being asked to take part in this research study because you are infected with the human immunodeficiency virus (HIV-1), the virus that causes acquired immune deficiency syndrome (AIDS) and:

1. You have been taking a combination of antiretroviral drugs (cART) and you have been on the same antiretroviral medications for at least the past 3 months; and
2. Your HIV-1 RNA level (viral load, the amount of HIV in your blood) has been less than 40 copies/mL plasma, or below the limit of detection, for the past 24 months.
3. You will be able to participate in this study if you have small amounts of HIV in your blood when tested using a very sensitive test (single copy assay).

This study is sponsored by the National Institutes of Health (NIH). The doctor in charge of this study at this site is: Dr. Pablo Tebas. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

Why Is This Study Being Done?

HIV medications can reduce HIV virus to very low levels in the blood and partially repair the immune system (the way your body responds to diseases). However, these medications do not cure (remove) the HIV infection and a small amount of the virus continues to live in the body even when the viral load is very low. In most patients taking these HIV medications very sensitive tests can find small amounts of HIV virus in the blood even when regular viral load test results do not find HIV. This helps explain why the HIV virus levels come back when these medications are stopped. The reason why HIV can still be found in the body is likely because there are cells that live for a long time after becoming infected with HIV. These cells are thought to carry the HIV virus in a latent or hidden form ("non-active state"). As long as the virus exists in this non-active state, HIV medications that block only multiplying (active) virus cannot get rid of the HIV, and infected persons cannot be cured. HIV virus may come from these non-active cells that may at times produce low levels of HIV or it may come from other cells in the body. The immune system does not seem to be able to get rid of these cells that produce virus.

BMS-936559 is a drug that is not yet approved by the Food and Drug Administration (FDA) and has been tested to treat various types of cancer. BMS-936559 is an antibody that has been created to help wake up cells in the immune system that don't function well. These cells are called exhausted (tired) T-cells. One reason that the immune system does not clear the cells that produce low levels of virus is that the cells that fight HIV are exhausted and don't work well. If these cells are able to wake up, it is possible that they can help clear the infected cells. This study is being done to see if BMS-936559 is safe in HIV-infected persons and whether it can improve the HIV-specific immune response and lower the low levels of virus circulating in the blood. There will likely be no direct benefit to you from participating in this study. The overall goals of this study are:

- to find single doses of BMS-936559 that are safe and well-tolerated in HIV-infected persons on ART
- to improve the body's immune response to HIV and lower the amount of virus that is circulating in the blood
- and to see whether it can reduce latent or hidden HIV.

In this study participants will receive either the active form of BMS-936559 or placebo (a salt solution). You have 3 out of four chances to receive the active medication and one out of 4 chances to receive placebo. BMS-936559 and placebo will be provided.

The doses for this study were chosen based on studies that were done in people who did not have HIV. The most important goal of this study is to test if BMS-936559 is safe. The smallest and first dose of 0.3 mg/kg may not be active in participants with HIV as this dose is much lower than the doses used in studies against tumors and hepatitis C. The doses of 1 mg/kg and 3 mg/kg were also chosen based on their safety in a study with cancer patients. The highest dose of 10 mg/kg was chosen for this study as it showed the most activity in cancer patients. The same dose of a similar antibody had activity against hepatitis C in patients without HIV. In cancer patients, safety of BMS-936559 at this dose was not different than the lower doses except for more reactions (such as fever, chills, shakes, itching, rash, low blood pressure or shortness of breath) when the medication is being given (infusion). These reactions did not happen as often if medications such as acetaminophen (Tylenol) and diphenhydramine (Benadryl) were given before receiving BMS-936559, which are recommended and provided in this study for participants receiving the highest dose.

How Many People Will Take Part in This Study?

About 56 men and women 18-70 years of age will take part in this study. Women who are capable of having a baby are NOT eligible for this early safety study. Only women who have had a hysterectomy

or who have gone through menopause are eligible. About 3-5 participants are expected to enroll at the University of Pennsylvania.

How Long Will I Be In This Study?

You will be in this study for about 48 weeks.

What Do I Have To Do If I Am In This Study?

Screening

If you would like to be in this study, after you have read and signed this informed consent form, you will come to the clinic for a screening visit to make sure you meet the requirements for joining the study. You will need to have had an eye exam performed by a licensed ophthalmologist within 180 days (About 6 months) of entering the study. You must provide the study staff with a copy of the results of your eye exam before you can enter the study. You will need to fast before this visit (fasting means that you have had nothing to eat or drink except plain water and required prescription medications for at least 8 hours). If you are not able to fast before this visit, you will be asked to reschedule your visit. This visit will take about 1-2 hours. At this visit:

- Your HIV infection status will be confirmed. If there is no record available, another HIV test will be done. You may have to sign a separate consent form before this is done.
- Your eye exam results (or medical records) will be reviewed.
- You will be asked questions about your medical history and any medications you are taking or haven taken in the past.
- You will have about 6 tablespoons (96 mL) of blood drawn to see if you are infected with tuberculosis or the hepatitis B and/or C virus (an infection of the liver); for metabolic tests, (to test how your body uses the food that you eat); for routine lab tests for safety; for virologic studies (to help study the virus); to measure the amount of HIV in your blood; and to measure your CD4+ and CD8+ cell counts (cells that help fight infection).
- If you are a woman and you cannot get pregnant because you have not had your period for at least 12 months), but f you do not have documentation, some of your blood will be tested for follicle-stimulating hormone (FSH). FSH is a fertility hormone. If you have documentation of an FSH test or have documentation of a hysterectomy, or removal of both your ovaries, or both your fallopian tubes; your blood will not be tested for FSH.
- You will agree to continue taking combination antiretroviral drugs as prescribed throughout the entire study

If you do not enroll into the study

If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of this screening visit, some demographic (for example, age, gender, race), clinical (for example, disease condition, diagnosis), and laboratory (for example, CD4 cell count, viral load) information is being collected from you so that the AIDS Clinical Trials Group (ACTG) researchers may help determine whether there are patterns or common reasons why people do not join a study. If you do not want this information to be recorded, you should not sign this consent form and not participate in the study. If you elect not to participate, all information collected thus far by the research team will be destroyed.

Pre-Entry

If you are eligible for the study, you will come in for a pre-entry visit. This visit will take about 1 hour. At this visit:

- You will be asked about your health and any changes in your medicines since your last visit.

- You will have about 5 tablespoons (71 mL) of blood drawn for virologic studies and for immunologic studies (to test how your body fights infection). You will be told the results of these tests when they become available. Some of the blood you provide will be stored for future protocol-required testing.
- **You will have an electrocardiogram (ECG). An ECG is a test that checks for problems with the electrical activity of your heart.**
- **You will have a complete physical exam, including vital signs (temperature, pulse, and blood pressure) and obtaining your height and weight.**

Study medication

Depending on when you enter this study, you will be assigned to one of the four groups. In Group 1, 8 participants will be enrolled: 6 will receive BMS-936559 and 2 will receive placebo salt solution that does not contain BMS-936559. In Groups 2, 3, and 4, 16 participants will be enrolled: 12 will receive BMS-936559 and 4 will receive a placebo salt solution that does not contain BMS-936559. The treatment assignment is being done at a ratio of 3:1, so of every 4 people who sign up for this study, 3 will receive the active medication and 1 will receive the placebo. You cannot choose which group you are in because you will be randomly assigned (like flipping a coin), and neither you nor the study staff will know whether you will receive BMS-936559 or the placebo. This drug is made up based on your weight. You will be weighed on the day the drug is given and the dose will be calculated by the pharmacist.

- Group 1 will enroll first to receive BMS-936559 0.3 mg/kg or placebo. If this dose is found to be safe, then
- Group 2 will enroll to receive BMS-936559 1 mg/kg or placebo. If this dose is found to be safe, then
- Group 3 will enroll to receive BMS-936559 3 mg/kg or placebo. If this dose is found to be safe, then
- Group 4 will enroll to receive BMS-936559 10 mg/kg or placebo.

Entry

After your pre-entry visit you will come in for an entry visit. This visit will take about 14 hours. At this visit:

- You will have a brief physical exam including vital signs, weight **and an eye exam performed by a licensed physician or practitioner.**
- If you are a woman and you cannot get pregnant, but you do not have documentation, some of your blood or urine will be tested for pregnancy.
- You will be asked about your health and any changes in your medicines since your last visit.
- You will have about 7 tablespoons (100 mL) of blood drawn for routine lab tests for safety; virologic, immunologic, and autoimmune (studies to see if your immune system is attacking the healthy cells in your body) studies; to measure the amount of HIV in your blood; and to measure your CD4+ and CD8+ cell counts. Some of the blood you provide will be stored for future protocol-required testing.
- You will receive BMS-936559 or placebo once during the study through a small plastic flexible tube placed into a vein in your arm (intravenous (IV) infusion). This IV infusion will take about an hour or in some cases the IV infusion may be slowed to help stop any side effects that you may have. You must stay in the clinic or clinical research center for 12 hours after the infusion so that you can be monitored. At the entry visit blood will be drawn to determine BMS-936559 amounts in your body. These blood draws will happen before the infusion, right after the infusion, and 2, 6, and 12 hours after the infusion. You may have the option to stay overnight in a hospital or the research unit to allow all the necessary testing over the estimated 14-hour study visit.
- Meals may be provided during this visit at meal times.

Study Visits

After your entry visit, you will come to the clinic at days 3, 7, 14, 28 and weeks 10, 16, 24, 36, and 48. These study visits will last about 1 hour.

During Most Study Visits

- You will be asked about your health and any changes in your medicines since your last visit.
- You will have a brief physical exam including vital signs and weight.
- You will have about 5 tablespoons (71 mL) of blood drawn to measure the amount of HIV in your blood, for future protocol-required testing, routine lab safety tests, and for immunologic and virologic studies. Some of this blood will be stored for future gene expression assays (the genetic code that is stored in your DNA will be interpreted through gene expression). Most of our cells have exactly the same genetic information (blue print) but some of the information is turned off and some is turned on depending on the type of cell. This study will test gene expression (which genes are "on" and which genes are "off") in lymphocytes (immune cells) before and after receiving the study medication.
- You will have about 1 tablespoon (18 mL) of blood drawn for metabolic studies on days 14, 28, and weeks 16, 24, 36 and 48. You will need to fast before these study visits (fasting means that you have had nothing to eat or drink except plain water and required prescription medications for at least 8 hours).
- You will have a little more than 1 teaspoon (7 mL) of blood drawn for autoimmune studies on days 14, and 28, and weeks 10, 16, 24, 36, and 48.
- You will have about 1 teaspoon (4 mL) of blood drawn to measure your CD4+ and CD8+ cell counts on days 3, 7, 14, and 28, and weeks 10, 16, 24, 36 and 48.
- You will have about half a teaspoon (2.5 mL) of blood drawn for pharmacokinetic studies on days 3, 7, 14, 28, and weeks 10, 16, 24, 36 and 48.
- On days 14, 28, and weeks 24, 36, and 48, you will be asked questions about how well you take your HIV medications.
- You will be given the results of some of the study tests as soon as they are available, including all standard viral loads, CD4+ counts, and safety blood tests.

Confirmation of Virologic Failure

At any time during the study if the result of your viral load test shows that your HIV drugs may not be fighting your HIV infection well, you will be asked to return to the clinic. At this visit:

- You will have about 1 tablespoon (16 mL) of blood drawn to measure the amount of HIV in your blood and for an HIV resistance test (resistance means that the drugs are not likely to fight the HIV in your body).
- You will be asked questions about how well you take your HIV medications.
- You will be asked to stay on the study and complete all of the study visits.

If You Stop Taking Your HIV Drugs During the Study

If you stop taking your HIV drugs during the study:

- You will be asked to stay on the study and complete the study visits so that you can be monitored for safety. You will have all of the regularly scheduled evaluations listed above, except blood for some of the immunologic and virologic studies will not need to be taken.
- You will be given the results of some of the study tests as soon as they are available, including all standard viral loads, CD4+ counts, and safety blood tests.

If You Have to Stop the Infusion of BMS-936559 Early

If the infusion of the study medication (BMS-936559) is stopped early for any reason and cannot be completed:

- You will be asked to stay on the study and complete the study visits so that you can be monitored for safety. You will have all of the regularly scheduled evaluations listed above, except you will not be asked to have the blood draws to determine the levels of BMS-936559 in your body.
- The study team will decide whether blood for the immunologic and virologic studies will need to be taken.
- You may be asked questions about how well you take your HIV medications.
- You will be given the results of some of the study tests as soon as they are available, including all standard viral loads, CD4+ counts, and safety blood tests.

If You Have to Stop the Study Early

If you have to stop the study early, you will be asked to come to the clinic for an additional study visit. At this visit:

- You will have a brief exam physical including vital signs.
- You will have about 5 tablespoons (79 mL) of blood drawn for routine lab tests for safety; for virologic, immunologic, and autoimmune studies; to measure the amount of HIV in your blood; and to measure your CD4+ and CD8+ cell counts. Some of the blood you provide will be stored for future protocol-required testing.

Other

Some of your blood samples will be stored (with usual protectors of identity) and used for testing that is required for this study. Usual protectors of identity are defined as: All laboratory specimens, evaluation forms, reports, and other records that leave the site will be identified by coded number only to maintain participant confidentiality. All records will be kept locked. All computer entry and networking programs will be done with coded numbers only. Clinical information will not be released without your written permission, except as necessary for monitoring by the ACTG, Institutional Review Board (IRB), FDA, National Institute of Allergy and Infectious Diseases (NIAID), Office for Human Research Protections (OHRP), other government agencies as part of their duties, or the industry supporter or designee.

While you are in this research study, there will be some samples that are collected but are not used. Researchers will use these unused samples along with your associated health information for future research. This information includes your medical conditions. It may also include personal facts about you, such as your race, ethnicity, gender identity and sex at birth. You are free to ask questions at any time. You may discuss it with others. Researchers will provide you with a copy of this informed consent.

What samples will researchers collect and store?

Researchers will not collect any extra samples for future research. They will only use already collected unused samples.

Where will researchers store my information and samples?

Researchers will store your information electronically in computer databases. This information will include your associated health information and any new information learned from research done with your samples. Researchers will store your samples at the clinical research sites. To maximize research opportunities, researchers may store your samples in other storage facilities or “bio-banks.” There is a possibility that researchers may send your samples to other researchers in your country or outside of your country.

How will researchers use my information and samples?
Researchers may use your information and samples in different types of future research to fight HIV and other related diseases. Some of these research studies may include genetic testing.

What other research could researchers do with my information?
Researchers may produce a lot of new information or "data" through the research done with your samples. This new information may be placed in large databases for other researchers to use. These databases may be only for genetic information, while others may store non-genetic information or both. All these databases store the information electronically without your personal identifiers, such as your name. No one will know just from looking at the information in any of these databases that the information belongs to you.

How long will researchers store my samples for future research?
Researchers will store your samples indefinitely. However, you can change your mind and withdraw your permission at any time.

What are the risks of storing my samples and information for future research?
There is a small risk that someone may use your stored samples or information incorrectly. For example, someone could find out which test results are yours and use this information against you. This incorrect use of information may cause discrimination, distress or other problems to you. For this incorrect use to happen, the person would have to get into a database that links results with your name. To reduce this risk, researchers have security measures in place such as limiting access to databases, not linking names to results, and not placing results in medical records.

What are the benefits of storing my samples and information for future research?
There will be no direct benefit to you from future research using your stored samples and information. However, the information learned may help others. It may take the researchers many years to have any results. In most cases, you will not receive future research results from the researchers.

What other choices do I have?
It is your choice whether or not to give permission for the storage and use of unused samples, as described in this document. If you choose not to give permission, researchers will not store any of your unused samples.

Can I change my mind about the storage and use of my samples and information?
Yes, you can decide to withdraw your permission for the storage and use of your samples and information for future research, whenever you want. If you decide to withdraw your permission, contact the research staff. There are two ways to withdraw your permission. You could allow researchers to remove all your personal identifiers from your samples, so that they are not linked to you anymore. These samples will then become anonymous. You could also ask researchers to destroy your samples, so that they cannot be used for future research. You must make this request in writing to the Principal Investigator at Infectious Disease Division, 502 Johnson Pavilion Philadelphia PA 19104. Researchers will make reasonable efforts to obtain and destroy information and/or samples if consent is withdrawn. However, in either case, researchers will not be able to destroy samples or information from research that is already underway. If you withdraw your permission, there will be no negative consequences for you.

Your signature below confirms your voluntary decision to give permission for the collection, storage, and use of your blood samples and information in future research.

You do not have to give permission for storage of these samples. This will not affect your participation in the study and you may withdraw your permission at any time.

_____ **YES** _____ **NO**

Why Would The Doctor Take Me Off This Study Early?

The study doctor may need to take you off the study early without your permission if:

- you are not able to attend the study visits as required by the study
- the study is stopped or cancelled
- your primary care physician no longer thinks that participating in the study is in your best interest.
- A safety monitoring committee (SMC) of the ACTG, or the IRB, FDA, NIAID, OHRP, or another government agency with the duty to ensure that research participants are protected, or Bristol-Myers Squibb (the industry supporter), recommends that the study be stopped early. A SMC is an outside group of experts who monitor the study. An IRB is a committee that watches over the safety and rights of research participants.

The study doctor may also need to take you off the study drug without your permission if:

- continuing the study drug infusion may be harmful to you
- you need a treatment that you may not take while on the study
- you are not able to receive the study drug infusion as required by the study

If you must stop participating in this study before completing the study drug infusion or after receiving the study drug before the study is over, the study doctor may ask you to return for one or more study visits.

What Are The Risks Of The Study?

The drug used in this study may have side effects, some of which are listed in below. These lists include only the more serious or common side effects with a known or possible relationship. If you have questions concerning the additional study drug side effects please ask the medical staff at your site. Safety data from the lower dose level will be carefully reviewed before higher doses are administered.

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the study drug. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study and also before starting any new medications while on the study. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.

Risks of Social Harm

Although the study site will make every effort to protect your privacy and confidentiality, it is possible that your involvement in the study as a participant could become known to others if it is not already and that social harms may result (because you could become labeled as being infected with HIV). For example, you could be treated unfairly or discriminated against by family members, friends, and/or the community.

Risks of BMS-936559

Common side effects associated with the use of BMS-936559 include fatigue (tiredness), nausea, diarrhea, vomiting, dizziness, dyspnea (shortness of breath), decreased appetite, constipation, rash, pruritus (itching), coughing, arthralgia (joint pain), pyrexia (fever) and headache.

The following serious side effects have been associated with the use of BMS-936559 in patients with cancer:

- Upper respiratory tract infection
- Dyspnea (shortness of breath)
- Edema peripheral (swelling in the legs and ankles or the arms and hands)
- Hyperglycemia (high blood sugar)
- Pain in extremities (pain in arms, legs, wrists, ankles, shoulders, or neck)
- Musculoskeletal pain
- Insomnia (inability to sleep)
- Anemia (low red blood cell count)
- A decrease in one type of white blood cells (lymphocytes)
- Progressive cancer (abnormal growth or division of cells)
- Infusion-related reaction

Because BMS-936559 may stimulate the immune system, side effects may include symptoms of increased immune response (autoimmune reactions). These may include:

- Inflammation of the intestines (colitis) which usually includes diarrhea
- Skin rashes or hives
- Low or high thyroid levels (hypothyroidism or hyperthyroidism) which may cause fatigue, feeling hot or cold, or decreased or increase energy and may require treatment
- Low output from the adrenal gland which can cause low blood pressure or dizziness
- Inflammation of the liver (hepatitis)
- Neuropathy (tingling or numbness in the feet or hands)
- Severe pneumonitis (inflammation of the lungs) had been seen with other medications similar to BMS-936559 but not with BMS-936559. However, inflammation of the lungs is possible.
- Myocarditis (inflammation of the heart wall)
    - The risk of myocarditis is not known as the one possible case in a cancer patient after receiving 3 doses of BMS-936559 (you will receive only one dose) was not confirmed. However, development of myocarditis is possible.
- Recurrent myasthenia gravis (muscle weakness and fatigue). Symptoms consistent with myasthenia gravis are caused by antibodies to your muscles. These antibodies block signaling between your brain and muscles, and can cause weakness. One patient who had myasthenia gravis before receiving BMS 936559 had their symptoms come back when they received the medication. People with who have myasthenia gravis or a past history of this problem are not allowed in this study.
- Uveitis (inflammation of the eye) which can cause eye pain, redness, irritation, and changes in vision.

To minimize the possibility of these side effects, patients with diabetes, thyroid problems, abnormal cortisol levels (a hormone released in response to stress), or other known problems with their immune system other than HIV or abnormal results on screening for these disorders are excluded from participating in this study. During this study, you will undergo repeated testing for thyroid problems, diabetes, cortisol levels, and liver problems. In addition, you should let the study team know if you develop any symptoms while on study, so we can determine if they are possibly related to the study treatment.

Reactions (such as fever, chills, shakes, itching, rash, low or high blood pressure or shortness of breath) during the infusion have been reported. These reactions were most common at the higher dose

(10 mg/kg) and the frequency is decreased by giving acetaminophen (Tylenol) and diphenhydramine (Benadryl) prior to the infusion.

Risks of Drawing Blood or IV placement
Having blood drawn may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection. Placement of an intravenous catheter can cause bleeding, swelling or bruising where the needle enters the body.

Unknown risks
Other side effects that are not known at this time could happen during the study. There is a risk that waking up immune cells may cause immune problems (your immune cells may cause problems with the normal function of your body). We will monitor you carefully for this. All drugs have a possible risk of an allergic reaction, which if not treated right away, could become life-threatening. There is the potential for a life-threatening risk including death due to an autoimmune or infusion reaction as described above, or an unknown side effect. During the study, you will be told about any new information that may affect your decision to stay in the study. If you decide to stay in the study, you will be asked to sign an updated consent form. If you decide to leave the study early, the study staff will talk with you about your treatment options.

Pregnancy
Women of child-bearing potential are excluded from this study. The risks to a fetus are not known. However, if you think you may be pregnant you should inform study staff and you will be given a pregnancy test. If you are pregnant you may choose to stay on the study. Blood tests will be limited to safety blood tests and blood tests that measure the levels of BMS-936559 in your body. You will be asked to have an extra visit 6 months after the end of your pregnancy in order for the research team to get information on the outcome of the pregnancy.

Are There Benefits to Taking Part in This Study?
This is the first use of BMS-936559 in participants with HIV infection. This is mainly a safety study and no guarantee of any benefit can be made. You should not expect any direct benefit from being in this study. Information learned from this study may help others who have HIV.

What Other Choices Do I Have Besides This Study?

Instead of being in this study you have the choice of:
- treatment with prescription drugs available to you
- treatment with experimental drugs, if you qualify
- no treatment

Please talk to your doctor about these and other choices available to you. Your doctor will explain the risks and benefits of these choices.

What About Confidentiality?
We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally. Further, the Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects individuals from genetic

discrimination in health insurance and employment. Genetic discrimination is the misuse of genetic information.

People who may review your records include the ACTG, Office for Human Research Protections (OHRP), other government agencies with the duty to ensure that research subjects are protected, University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), Food and Drug Administration study staff, study monitors, Bristol-Myers Squibb (the drug company supporting this study) and their designees. If you are a woman and you become pregnant while on this study, your pregnancy will be reported to the Antiretroviral Pregnancy Registry. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

Your personal information may be given out if required by law. If you test positive for HIV or if a CD4 or viral load is done at a study visit, by law we have to report the result to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government. If hepatitis B and hepatitis C tests are positive, they will be reported to the local department of health.

HIPAA AUTHORIZATION

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might also be disclosed?
The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, email address, dates directly related to you such as date of birth and clinic visits.
- Personal and family medical history
- Current and past medications or therapies
- Information from questionnaires administered in the study and from the other HIV studies in which you have participated.
- Results of tests and procedures you will undergo during this research
- Social Security Number, Medical record number

Why is your personal contact and health information being used?
Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?
The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?
As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- ACTG Data Coordinating Center, Frontier Science Technology Research Foundation (FSTRF): Data for this study will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be cleaned and stored at this facility until it is ready to be analyzed.
- Statistical Data Analysis Center (SDAC): Approved data will be downloaded from FSTRF to the statistical data center for the AACTG at the Harvard School of Public Health. Specific study reports will be periodically provided to the study team and data safety review board to monitor if the trial is safe.
- Bristol-Myers Squibb: The pharmaceutical company that is supplying the drug for this study.
- Contract Research Organization (PPD, Inc): Monitors from PPD will visit the AACTG on a quarterly basis to review data and correct mistakes before the data are sent to SDAC for analysis.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration and to the National Institutes of Health/Division of AIDS (DAIDS)/National Institute for Allergy and Infectious Disease (NIAID), for them to evaluate the safety and efficacy of the treatments being used in this study.

Regulatory and safety oversight organizations

- The Office of Human Research Protections
- Food and Drug Administration

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at Infectious Disease Division, 502 Johnson Pavilion Philadelphia PA 19104. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What Are the Costs To Me?
There will be no cost to you for the study drug, BMS-936559 or placebo, study-related visits, physical examinations, required laboratory tests or other procedures. This study will not provide you with antiretroviral drugs. You, your insurance company, or your health care system may need to assume the cost of drugs not provided by the study. In some cases, it is possible that your insurance company or health care system will not pay for these costs because you are taking part in a research study.

Will I Receive Any Payment?
You will be compensated $50 for most study visits (screen, pre-entry, Days 3, 7, 14, 28 and Weeks 10,16,24,36 and 48 you attend. At entry (Day 0) (Infusion and 14 hr stay in the CTRC) you will be compensated $150. Compensation will be given as cash, except for the entry visit which will be a check from the University that can take 4-6 weeks to process. The maximum amount of compensation for the study is $700 if all study required visits are completed and attended. If you are required to come to the clinic for any additional visits, you will be compensated $35. There is no other form of compensation available such as reimbursements for parking, tokens or child care. In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note

that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

What Happens If I Am Injured?

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the National Institutes of Health. You will not be giving up any of your legal rights by signing this consent form.

What Are My Rights As a Research Subject?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

What Do I Do If I Have Questions Or Problems?

If you have questions about this study or a research-related injury, please contact the research team listed on page 1 of this consent form.

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

CONSENT

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date