Clinical Investigation Consent Form IRB Rev 2013

The Rockefeller University Hospital
1230 York Avenue
New York, New York 10065
Principal Investigator: Marina Caskey, MD
Phone: *212.327.7396*
Fax: *212.327.7234*
E-mail: mcaskey@rockefeller.edu

You are being asked to join a research study, which will take place at The Rockefeller University Hospital. This form tells about the research. You should ask questions of the person who is explaining this form to you. After you feel that you understand the research, if you want to be part of the study, you will be asked to sign the form. You can always ask more questions and can later change your mind about staying in the study.

If you join the research study, you will take part for a total of 62 weeks. The research study as a whole will last about 3 years.

About 15 people will take part in the research study.

Title of the research study:

An open label, phase 2 study of the safety and antiretroviral activity of 3BNC117 in HIV-infected individuals on combination antiretroviral therapy

I. What this research study is about, and the reasons for doing this research?

The research will test a study agent called 3BNC117, which is an antibody against HIV, the virus that causes AIDS (acquired immune deficiency syndrome). Antibodies are naturally made by your body and help fight diseases. The study agent we are testing in this study is an antibody made in the laboratory. This study agent attaches to HIV, and can clear HIV from your blood. In the future, this study agent may be used to treat or prevent HIV infection.

In this study we will test 3BNC117 in HIV-positive people who are on HIV medications, and have undetectable viral loads (undetectable means the amount of virus cannot be measured by a blood test). The study agent, 3BNC117, was discovered by scientists at Rockefeller University and was made at Celldex Therapeutics Inc. The United States Food and Drug Administration (FDA) has not approved this new agent for general use by the public.

This study will test if the study agent can keep the viral load low when your HIV medications are stopped for a period of time. Another reason to do this study is to find out

if the study agent does not cause significant side effects. We will also measure the time it takes for the study agent to be cleared from your body.

You are being asked to participate in this research study because you are HIV-infected and you are on HIV medications.

The study agent will be given directly into your blood stream. This means that the medicine is given into a vein. How this will be done is explained in Section II, What is going to happen in this research study?

Requirements to join this research:

- Age from 18 to 65 years old;
- HIV-1 infection confirmed by a blood test;
- Undetectable HIV viral loads for at least 12 months while taking a combination of HIV medications;
- CD4 cell count more than 500 cells/µl and lowest CD4 more than 200 cell/ µl;
- You agree to stop taking (pause) your HIV medications for 3 months after you receive the third dose of 3BNC117, and agree to return to the clinic every week for follow up visits;
- If you are a sexually active male or female, participating in sexual activity that could lead to pregnancy you must agree to use an effective method of birth control throughout the study period. You must also agree to use male or female condoms during the time of pausing your HIV medications. If you are female, you will have pregnancy tests at most study visits.
- If your HIV medications include a type of HIV medication called a Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI), for example Atripla Complera, Intelence or Sustiva, you must be willing to switch to a different HIV medication called dolutegravir (Tivicay) for a period of 4 weeks. The study team can provide Tivicay to you during this time.

You cannot join this research if you have:

- Had certain illnesses that are related to your HIV infection called AIDS-defining illnesses in the past year. The study doctor will explain to you what AIDS-defining illnesses are, and ask if you have had any of them in the past year;
- Used systemic corticosteroids, immunosuppressive anticancer (these are types of drugs that can affect how well your body fights off diseases), or other medications considered significant by the trial physician within the last 6 months;
- Any medical condition, other than HIV, that the study doctor thinks may affect your ability to be in the study;
- Chronic (ongoing) Hepatitis B or Hepatitis C infection (these are infections of the liver);
- History of heart problems or diseases, like heart attacks;
- History of diabetes and/or current use of insulin or other medications to treat high blood sugar;

- Current cigarette use of more than 1 pack per day;
- Uncontrolled high blood pressure, whether or not you are on medications for high blood pressure;
- Received a vaccine (such as the flu vaccine) within 14 days before receiving the study agent;
- Received another monoclonal antibody therapy (of any kind) in the past;
- If you are currently participating in another research study where you are getting another study agent; or you participated in another research study in the last 3 months and you received a study agent; or you plan to be in another research study that includes receiving another study agent while you are in this study;
- If you have ever become very sick, or had a bad response (like not being able to breathe) after receiving a vaccine or medicine in your vein;
- If you are pregnant or breastfeeding.

II. What is going to happen in this research study?

Consent Process

Informed consent is a process to help you understand why we are doing this research study, what will happen in the study, possible risks and benefits, and your right to stop being a part of the study at any time. All of this information will be explained to you in detail. You should ask any questions you have until you feel that you understand what is asked of you to participate. You may then want to join the study, or you may decide not to join the study. The decision to participate is entirely up to you. Even after the study has started, you may at any time ask more questions, and decide to stop being in the study.

Pre-Screening

Before screening, you will have been able to review information about the study. You will be able to talk to the study team and ask them questions.

Initial Screening Visit

- Screening will determine whether or not you can participate in the study.
- If you agree to be screened, you will sign a copy of the Informed Consent Form confirming that you have been told about the study and voluntarily (on your own) agree to take part. You will be given a signed copy of this consent form and the original consent form will be kept in your medical record.
- You will be asked questions about your general health.
- If prior results are not available, an HIV test will be done to confirm HIV-1 infection. Before having the HIV test, you will be asked to sign a separate informed consent form.
- Up to 30 ml (2 tablespoons) of blood will be drawn to test for hepatitis B, hepatitis C, syphilis, to evaluate liver and kidney functions, for complete blood count, to see

if your blood is able to clot, for a pregnancy test, and to evaluate other health conditions.

- You will be asked to give a urine sample so that the study doctor can check that your kidneys are normal.

  All sexually active study volunteers will be asked to use a reliable form of birth control during the entire study, and to use female or male condoms while not taking the HIV medications.
- The study team will ask questions about your medical history and will do a physical exam. The exam includes checking your blood pressure, heart rate, respiration, weight, height (at screening only) and temperature.
- You may not be allowed to participate in this study if the tests indicate you have an acute or chronic infection, other than HIV, or if you are pregnant or breastfeeding.

If you are a female who can have a baby, a pregnancy test will be done.

Blood will also be taken to measure the amount of HIV in your blood (HIV viral load). We will also measure the CD4 and CD8 cell counts. CD4 cells (also called helper T cells) work for the immune system by helping other cells in the body fight infections. CD4 cell counts drop during HIV infection. Up to 15 ml (1 tablespoon) of blood will be taken for these tests.

The study doctor will review the results of these tests, your medical history and your examination. If your screening test results, medical history and examination are acceptable you may participate in the study.

With your permission, the study doctor will also speak to your primary care doctor about the study before you start. The study doctor will tell your primary care doctor what the study is about.

Study Participation

If you want to participate in the study and the study doctor agrees, you will receive a total of four doses of the study agent, given into a vein in your arm. You will be followed for 60 weeks (1 year and 3 months) after the first dose of the study agent).

Some parts of this study are experimental. Here, the word "experimental" means that the test or the study agent given is "not part of the usual routine care of patients". Research blood tests will evaluate the amount of HIV in your body after you receive the study agent and the function of your blood cells that protect you from infection. These tests are experimental.

Pre-Infusion Visit:

Before you receive the first dose of the study agent, you will have a leukapheresis procedure on the pre-infusion visit (about 2 weeks before the first dose of the study agent).

Leukapheresis is the name of a procedure commonly done in blood banks. It requires insertion of a needle into both arms similar to what you might have had if you ever donated blood. During this procedure, the blood goes through a machine. The machine filters and collects the white cells (a component of your blood), and then returns the other cells and most of the liquid (plasma) back to you. If you experience numbness of the lips or tingling in your extremities, you will be given Tums to relieve those symptoms. The procedure normally takes 2-4 hours and is performed in a hospital or outpatient setting under close supervision by experienced personnel from the New York Blood Center. The advantage of this procedure is that it allows the researchers to obtain many more white cells than can be obtained by a routine blood draw.

Eye exam:

Before you receive the first dose of the study agent, you will also be examined by an eye doctor to check the health of your eyes.

Study Agent Infusions

During the study, you will receive four doses of the study agent (30 mg/kg). The doses will be given at study day 0, week 12, week 24 and week 27. The study doctor will know how much study agent to give you based on how much you weigh. For example, if you weigh 70 kg (or 154 lbs), you will receive 2,100 mg of the study agent (30 mg of study agent for each kg of body weight).

After you receive the study agent, blood will be taken to find out how much study agent is in your blood and the effect of the study agent on blood cells and on your HIV viral load. You will also be asked questions to find out if you are having any side-effects from the study agent. Details of the study procedures are found below.

Infusion Visits:

- On the days you receive the study agent you will be monitored in the inpatient unit of the Rockefeller University Hospital for 4 hours after the study agent is given.

During these visits, before you get the study agent, the following things will happen:

  - You will have a chance to talk to the study team and ask any questions;
  - A physical examination will be done, and your vital signs will be checked;
  - You will be asked questions about your health and medications;
  - Up to 10 ml (2 teaspoons) of blood will be drawn to evaluate liver and kidney functions, for complete blood count, to see if your blood is able to clot, and for a pregnancy test;
  - Additional blood samples will be collected for research purposes. At week 12 you will have a large blood draw of about 250 ml (about 17 tablespoons or half-pint of blood).

- A urine sample will be collected;

- The study agent will be given directly into your blood stream through a vein in your arm (an IV). This means a small, plastic tube will be placed into a vein in your arm and the study agent will be given through the plastic tube. It will take about 60 minutes to give the study agent. The IV will be removed after the study agent is given and a blood sample is collected.

- On the day following each dose of the study agent, you will return to the study clinic. During these visits, your vital signs will be checked, you will be examined and the study team will ask you about any new complaints.

ART Discontinuation (Pausing your HIV Medications)

You will stop taking your HIV medications two days after the third dose of the study agent (week 24 of the study). The study team will see you and check your viral load every week while you are off your HIV medications. You may also return to clinic between scheduled visits for additional viral load measurements, if you desire to do so.

If your HIV medications include a type of HIV medication called a Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI), for example Atripla Complera, Intelence, you will be switched to a medication called dolutegravir (Tivicay). This switch will happen at week 20 of the study, which is 4 weeks before you pause all of your HIV medications. The study team will call you at week 20 to remind you about the switch in medication. The study doctor will give you the Tivicay to take for those 4 weeks. The study doctor will also talk to your primary care doctor about the change in your HIV medications, so your primary care doctor will know.

Restarting your HIV Medications

You will start taking your HIV medications again 3 months after you stopped them (which will be week 36 of the study). You may have to restart your HIV medications before week 36 and the reasons to do that are listed below:

- You become pregnant;
- Your HIV viral load is more than or equal to 200 copies/ml, and a second test 1 week later shows the same or higher viral load;
- Your CD4+ count drops below 350 cells/μl, and a second test 2 weeks later shows the same or lower CD4 count;
- If your HIV viral load is more than 1,000 copies/ml, you will be asked to return to the study clinic before the next scheduled visit for a second measurement. If the second test shows a viral load of 200 copies/ml or more, you will be asked to restart your HIV medications;
- If you start to feel like you have a fever, rash, swollen glands, headache, sore throat, nausea or vomiting, you will be asked to come in to the study clinic for a visit. Your

HIV medications will be started again if the study team finds that you are feeling sick because the amount of HIV in your blood has gone up (increased viral load).

If you need to restart your HIV medications within 3 weeks after you stop them, you will not receive the fourth dose of the study agent at week 27.

If you did not need to restart your HIV medications by week 36, your study doctor will ask if you would like to stay off your HIV medications while in the study. If you choose to stay off your HIV medicationss after week 36, your HIV viral load will be checked every week. You may continue off HIV medications until the end of the study at week 60. However, you may have to restart taking your HIV medications sooner for the same reasons listed above.

Follow-up visits:

You will be asked to return to the study clinic for a total of 24 visits. These visits will be at 1 day, 1 and 4 weeks after each dose of the study agent, weekly while you are off your HIV medications from weeks 24 through 36, and at weeks 40, 48, 56 and 60.

If you did not have to restart your medications by week 36 and you choose to remain off your HIV medications, you will return to the clinic for extra weekly visits.

During these follow up visits, vital signs will be taken, you will be asked about any new complaints and any changes in your medications. In addition, the study doctor may examine you.

A pregnancy test will be done at most study visits (except at 1 day after each dose of the study agent and at week 23).

At week 48, an eye doctor will examine your eyes. The eye doctor will compare this exam to the first exam you received before receiving the study agent.

Depending on the specific study visit, approximately 3-8 tablespoons of blood will be drawn to study any effect of the study agent on your blood cells.
In addition, your blood counts, liver and kidney functions will be checked many times during the study: at 1 and 4 weeks after each dose of the study agent and every 4 to 8 weeks after that, for the rest of the time you are on the study.

Blood will also be taken to measure the amount of HIV in your blood (viral load) at the screening visit, on the visits when you receive the study agent, 1 month after each dose of the study agent, weekly while you remain off ART, and at weeks 36, 40, 48, 56 and 60.

If your viral load increases to more than 400 copies/ml after you stop your HIV medications, a blood sample will also be collected to test the sensitivity of the virus to your HIV medications (this test is called “HIV genotype”).

We will also measure the CD4 and CD8 cell counts at the screening visit, on day 0, weeks 4, 12, 16 and 24, every 2 weeks while you remain off ART, and at weeks 48 and 60. Up to 15 ml (1 tablespoon) of blood will be taken for these tests at these visits.

Blood samples will also be taken to measure the amount of study agent in your blood before and right after you receive each dose of the study agent, and 1 day, 1 week, and 4 weeks after you receive each dose of the study agent. Blood samples for these measurements will then be taken every 4 to 8 weeks for the rest of the time you are on the study.

At weeks 12 and 36, a large blood draw will occur (250 ml or approximately 17 tablespoons or half-pint of blood will be collected).

You will have a second leukapheresis procedure on week 23.

Given the close monitoring of safety and extensive research blood draws that will be performed during the study, a volume of 550 ml (approximately 34 tablespoons or 1 pint of blood) may be drawn over periods of 8 weeks.

Laboratory testing done on your blood during the research study will fall into two general categories, 1) New York State-approved tests, and 2) experimental tests that have not been certified by New York State.

We will tell you or your doctor about any tests related to the research protocol that are performed by a New York State-approved laboratory, if the results may affect your health or safety.

In this study, you will not receive routine care for any other medical conditions that you have.

Your medical information and test results will be written in your Hospital chart. The researchers of the study may also keep separate records with information about you and your study tests.

Dr. Caskey and her research team will also keep separate records with information about you, including research results. Your name will not appear in these records.

If we need to get medical information from other doctors or other health care providers who have seen you, we will ask you to sign a consent form to get this information. We will also ask you to sign a separate form if we need information from other hospitals where you have been treated.

III. What are the risks of taking part in this research study?

There may be some risks and discomforts in taking part in a research study. We know that

these risks and discomforts may happen during this research study:

Study Agent:

This study agent, 3BNC117, has been tested in a small group of research participants, including 12 HIV-infected participants who received one dose of 3BNC117 and were on HIV medications. These participants tolerated the dose well.

This is the first time that this study agent will be given more than two times, and the first time that two doses will be given three weeks apart. In addition, the study agent has not yet been tested during a pause of standard HIV treatment. In another study with this study agent, participants received only one or two doses of the study agent. When two doses were given, they were given 3 months apart. It is possible that side effects that we do not know about will occur when four doses are given. You will return to the study clinic many times during the study, so that you can let the study team know if you feel any discomfort and they can examine you.

It is possible that you may feel the side effects listed below after receiving the study agent:

- Infusion of medications like 3BNC117 may lead to pain or burning at the place where you have the IV (where the plastic tube enters the skin).

- People can be allergic to many things including substances like 3BNC117. An allergic reaction means that the body is very sensitive to something. If you are allergic to any part of the study agent or to the liquid used to mix the study agent, you may develop a rash on your skin, fever, chills or trouble breathing. Very rarely, severe allergic reactions may result in a severe reaction or even death. The severe reaction is called “anaphylaxis”.

- Medications like 3BNC117 may cause body aches, sore muscles, fever, chills, shakes, pain in the stomach, or pain in the back. Some participants in another study said they felt tired and experiences headache after receiving the study agent.

- There is small chance that the study agent could cause a release of chemicals from your cells during the infusion. This could cause nausea, headache, rapid heartbeat, shortness of breath and rash. If severe, your blood pressure could drop affecting how organs like heart, lungs and liver work. It is very unlikely that this reaction will happen. None of the participants that have received 3BNC117 experienced this.

- By joining with other substances in your body, medications like 3CBC117 can form something called immune complexes. This happens when the antibody and parts of the HIV or something like HIV become linked. These complexes can go through and stay in the kidneys. If this happens then you can get blood or protein in your urine. Sometimes this can also affect how well your kidneys work.

- The study agent attaches to HIV, but when it was tested on different human tissues

outside the body, it was found that 3BNC117 can also attach to cells in the conjunctival tissue (the lining that covers the inside of the eyelids and the white part of the eyes). This binding can lead to inflammation of the eyes. "Inflammation" can cause your eyes to be red, swollen, itchy, or you could feel pain. Some participants who received the study agent in another study said they felt itching in the eyes, watery eyes or eye redness. These complaints did not last long. It is possible that you will feel some of the same discomforts they did after you receive the study agent.

- To avoid these problems your study team will see you often during the study and talk to you about how you feel. If you your eyes start to bother you, the study doctor will send you to an eye doctor to have your eyes checked. You will not have to pay to see the eye doctor. The study team will also examine you and take blood and urine tests. You will be told the results of the tests to make sure that you are not having side effects from the study agent.

- HIV strains (viruses) in your body that are "resistant" to (not blocked by) the study agent could become detectable in your blood after you receive the study agent. However, the study does not interfere with approved HIV medicines. Standard HIV medications should be able to control the growth of these viruses. If you get resistance to the study agent, this may limit your future use of it, if the FDA approves its use.

- With any new medicine, there is a possibility of totally unexpected side effects. The Rockefeller University Hospital inpatient unit (where you will receive the study agent) has the medications needed to take care of you, if you have an allergic reaction to the study agent. In case of an emergency, you will receive immediate necessary treatment at the Rockefeller University Hospital and then you will be sent to New York Presbyterian Hospital (Cornell) for specialized medical care.

- Because we don't know how the study agent would affect your baby or your unborn child, if you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice an effective form of birth control before receiving the study agent and during the entire study. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control for a female include:

- Condoms (male or female) with or without a spermicidal agent
- Intrauterine device (IUD)
- Hormonal [birth control pills, injections, or implants]
- Diaphragm or cervical cap with spermicide

If you are a sexually active male participating in sexual activity that could lead to pregnancy and you have not had a vasectomy you must agree to use an effective method of birth control and condoms from screening until your 'End of Study' clinic visit.

For female participants: If you become pregnant you will not receive any more doses of the study agent. If you become pregnant after you have already received the study agent, the study doctor will request that you return to the clinic every 4 to 6 weeks for follow up until delivery. If you become pregnant you will not stop your HIV medications, or you will be asked to start taking them again. The study doctor will ask that a pediatrician examine your baby to check his/her health about 2-4 weeks after delivery. The health of the baby will be reported to the local IRBs, Clinical Research Office at the Rockefeller University Hospital, the Safety Monitoring Committee and the Antiretroviral Pregnancy Registry.

- Because there may be side effects associated with the study agent that we do not yet know, and since pausing HIV medications was associated in the past with side-effects related to the heart, participants with certain medical problems such as history of heart attack and other heart problems, diabetes, auto-immune diseases – for example, lupus, rheumatoid arthritis, Crohn's disease will not be able to participate in the study. This will be done to make sure a healthy population of participants is selected.

Pausing HIV medications:

- There is a chance that your HIV viral load will increase when you stop your HIV medications. If this happens, your CD4 cell counts might drop. However you will be followed very closely and your HIV medications will be restarted if your HIV viral load increases to more than 200 copies/ml or if your CD4 count cell drops to less than 350 cells/μl, two weeks in a row. If your viral load becomes detectable and your HIV meds are restarted within three weeks from when you stopped taking them, you will not receive the fourth dose of the study agent.

- If you become pregnant while not taking your HIV medications, the study doctors will ask you to restart your medications immediately because there is a chance that you could transmit HIV to your unborn child while you are off your medications.

- When your HIV medications are stopped, you might experience symptoms similar to when you first got HIV, such as fever, rash, swollen glands, headache, sore throat, nausea, vomiting. If you develop these symptoms, the study doctors will evaluate you and your HIV medications will be resumed if the symptoms are believed to be due to increased HIV levels.

- Resistance to your HIV meds might occur, since your HIV meds will be stopped for about 3 months. In order to decrease that risk, you will be asked to restart your HIV meds if your viral load increases to ≥ 200 copies/ml, two weeks in a row.

- While you are off your HIV medications, you are at increased risk of transmitting HIV to a sexual partner and at increased risk of HIV "superinfection" from an HIV-infected partner. Therefore you are asked to practice safer sex and use condoms at all times during the study. If you feel you have been exposed to HIV while off your HIV

medications you may restart your medication if your primary care physician recommends this.

Leukapheresis Procedure: Leukapheresis is a well-tolerated procedure which is commonly used for blood cell donations. The risks associated with a leukapheresis are mild pain or discomfort with catheter insertion (common) in both arms, temporary numbness of lips or extremities (occasionally), bleeding under the skin, nausea, chills, transient numbness and infection (rare). The best method to obtain the number of cells needed for this research is leukapheresis.

Blood draw: the risks associated with a blood draw are generally minor. They are mild pain at the needle site (common), local bruising at needle site (rare), infection and fainting (extremely rare).

Privacy and Confidentiality Risks: There is the risk that there could be computer security breaches which could reveal your identity. There may be the risk that data about you may become public, and could be used by employers or law enforcement agencies. These privacy risks are described in greater detail below.

There may be other risks and discomforts that we do not know about now, but we will tell you any new information discovered which might affect your decision to participate or remain in the study.

IV. What are the alternatives to participating in this research study?

You do not have to participate in this study. You can still receive your usual HIV treatment from your primary care doctor.

V. What are the benefits of taking part in this research study?

You are unlikely to have any direct benefits from participating in this study. It is possible that this study agent, 3BNC117, may help future patients have better control of their infection and improve their treatment.

VI. Who will be able to see the information learned about you in this research study?

We will protect your personal information and will do our best to keep this information confidential. We will listen to what you say we may do with this information, and we will follow the law. For example, by New York State law hospitals must inform the New York State Department of Health if we find that you have a reportable communicable disease(s), such as sexually transmittable diseases like chlamydia, hepatitis, gonorrhea, syphilis. Also, the researchers must report to the authorities if they believe that child abuse or neglect has happened, or to prevent serious harm to you or others.

Whenever possible, data about you will be unlinked from your name and identified by a code. Sponsors and members from the Safety Monitoring Committee receive your data linked only to a code. However, auditors and regulators from government agencies that oversee research, study monitors from the International AIDS Vaccine Initiative (IAVI), and people at the Rockefeller University Hospital and at Rockefeller University may see your information in the course of their duties.

We will share information about you only with the government agency that oversees this research, and the people at the Hospital and the Rockefeller University in connection with their duties.

During the research study, only the researchers will know that your samples came from you, because your stored samples will be identified only by a special code instead of your name. As a result, the others who study your samples will not know that they came from you and will not be able to figure out that they came from you.

If the researchers publish the results of this study, they will not mention your name or other information that could identify you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Genetic Information Nondiscrimination Act

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information is available in the outpatient or inpatient information handbook.

VII. What are the payment arrangements?

There is no cost to you for being in this research study.

Payment will be made to participants who fill out a form from The Rockefeller University Finance Office and are eligible for and want to receive payment.

There will be no compensation for the initial screening visit.

Each study volunteer will be compensated $200 for each 3BNC117 infusion visit, $ 200 for each leukapheresis and $50 for each eye exam. You will be compensated $60 dollars for each post infusion follow up visit and for weekly visits during the pause of your HIV medications (from weeks 25 to 36). For late follow up visits, you will be compensated $100. If you complete all study visits, you will be receive a total of $ 2,660.

If your HIV viral load remains suppressed by week 36 and you choose to remain off your HIV medications, you will return to the clinic every week for follow up. You will be compensated $50 for each of these additional visits. In total, you may receive up to $3,860 if you remain off your HIV medications until the final study visit at week 60.

If the study doctors ask that you return for an unscheduled visit, you will be compensated $25 each time.

Compensation is provided to help cover your travel expenses, as well as child care and time lost from gainful employment. If you stop participating in the study before the last study visit, you will be paid for the portion of the study you completed.

Dr. Nussenzweig and Dr. Scheid, co-investigators on this study, are inventors of the study agent and are named on a patent application for their invention. Dr. Nussenzweig has financial interests in Celldex, the company that made the study agent. Dr. Nussenzweig, the Rockefeller University, and Celldex may benefit financially if the study agent is sold to a pharmaceutical company.

If research using your samples helps develop a drug or another product that is sold to the public, the drug company, the University and the researcher may share in some of the profits. For example, a cell line from your samples could be used to make a product for sale. There are no plans to pay you any money resulting from such discoveries. However, by signing this form, you do not give up any rights you may have.

VIII. What happens if you don't want to stay in this study or your participation is ended?

You can choose if you want or do not want to be part of this study. If you do not join, there is no penalty and no one will hold this against you. If you decide to join this study, you may change your mind and stop taking part in this study at any time, and this will not be held against you. Information about you up to that time may stay a part of the study.

During this study, the researchers may learn new information that might make you change your mind about whether you want to stay in the study. You will be given that information promptly.

If you decide to join this study but later want to stop, you should let the researchers know. The study team would still like to follow all volunteers who received the study agent for safety reasons.

The researchers also may stop you from taking part in this study, even if you do not choose to stop being in it. You may be asked to leave the study if:

- You fail to keep appointments

- The research study is terminated or canceled by the investigator, the FDA or the Rockefeller University Institutional Review Board, NIAID or other government entities.
- There is a significant adverse event to you or to other participants in the study
- If your primary care doctor requests that you no longer participate in the study because he/she believes it isn't in your best interest to stay in the study.

If the study doctor ends your participation in the study before the study is over, you will be asked to return to the study clinic for a last study visit. During this visit, the study doctor will re view your medical history and talk to you about any discomfort you may have, will examine you and will collect urine and blood samples. These samples will be used for a pregnancy test, measure your blood counts and liver and kidney functions, viral load, CD4 and CD8 counts and levels of the study agent in your blood. Additional samples will be collected for experimental tests to check how your body responded to the study agent. The study doctor will make sure you have appropriate follow up with your primary care physician.

IX. Consent to the use, storage and sharing of your samples or data for separate research studies

The scientific value of your samples and the information obtained from them is greatly increased if we can share them with other scientists at universities, pharmaceutical and technology companies worldwide. May we store, use and share your blood/or tissue samples and data with other investigators at the Rockefeller and elsewhere for separate studies for many years? Your samples will either be stripped of information identifying them as yours or coded (we will hold the key to the code) so that they cannot be identified as having come from you. Other data related to your sample, but that does not identify you may accompany your samples.

Any time in the future, you may withdraw your consent to use any samples that have not already been used in research or shared. If you withdraw your consent, the remaining unused samples will be destroyed, unless the samples cannot be identified as having come from you.

Would you like us to store, use and share your blood/or tissue samples/associated data as described above?

Yes_____ No_____

If you say "no" to this question, this will not affect your participation in this study.

X. Who do you call if a medical problem results from this research study?

If you believe that this study has led to a medical problem, you should call the researcher

listed below right away. The investigator will help you to get the appropriate, available medical care.

Name: Marina Caskey, MD
Phone: 212-327-7396
Fax: 212-327-7234
E-mail: mcaskey@rockefeller.edu

The Rockefeller University does not plan to pay for medical care that you may have as a result of taking part in a research study at The Rockefeller University Hospital. If you are injured, the Rockefeller University Hospital will give you immediate necessary treatment for your injuries. You will not have to pay for this treatment. You will be referred and/or transferred to where you can receive additional treatment for your injuries. The U.S. National Institutes of Health (NIH) does not have a mechanism to pay money or give other forms of compensation for research related injuries. However, you do not give up any rights you may have to seek compensation by signing this form.

XI. Who do you contact if you have questions about the research study?

Please ask as many questions as you want about this research study and this consent form. If you agree to take part in this study and have questions later on, you may contact the following researcher:

Name: Allison Settler, FNP
Phone: 212-327-7394
Fax: 212-327-7234
E-mail: asettler@rockefeller.edu

If you have any concerns about your experience while taking part in this research study, you may contact The Rockefeller University Institutional Review Board (IRB) Office at (212) 327-8410, or the Office of Clinical Research at (212) 327-8408.

XII. May we have permission to contact you about future studies?

May we contact you by phone to find out if you are interested in hearing about new research studies? Contact would be made by the Rockefeller staff of the Clinical Research Support Office for Recruitment. If you decide at any time that you no longer want to be contacted, please tell us, and we will stop calling you.

Would you like us to contact you about future research studies?

Yes _____ No _____

If you say "no" to this question, this will not affect your participation in this study.

AGREEMENT TO PARTICIPATE -- SIGNATURES REQUIRED

I have read this consent form, and my questions have been answered.

A copy of this consent form will be given to you. Please keep a copy of the form as it contains important information that you may wish to refer to during the research study and thereafter.

I hereby voluntarily consent to take part in this research study.

Name of the Study Participant (Print) _____

_____ _____

Signature of Study Participant **Date (To Be Filled in by Study Participant)**

Signature of the Person Conducting the Informed Consent Discussion

I have explained the research protocol and this consent form to the participant and have answered the participant's questions about this research study and/or the consent process.

Name of Person (Print) _____

_____ _____

Signature of Person Discussing Consent **Date (To Be Filled in by Person Discussing Consent)**

Signature of the Witness to the Informed Consent Discussion

Name of Person (Print) _____

_____ _____

Signature of Witness **Date (To Be Filled in by Witness)**