HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title:	**A5341s, Version 2.0, 03/30/2018**: Size and Decay of HIV-1 Reservoirs in Tissues and Cerebrospinal Fluid in Participants on Long-Term Antiretroviral Therapy: A Substudy of A5321, the ACTG HIV Reservoirs Cohort (AHRC) Study A DIVISION OF AIDS/ AIDS CLINICAL TRIALS GROUP (ACTG) Study
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INTRODUCTION:

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.

A5341s is a substudy of A5321. This means that only people who are already in A5321 can be in A5341s.

You were asked to participate in A5321 because the level of HIV in your blood has remained very low while you have been taking anti-HIV drugs. In A5341s, we would like to learn more about the levels of HIV in different parts of the body.

Researchers now know that HIV can 'hide' in areas that we call reservoirs. HIV can be found in blood and can also be found another part of the body, like the central nervous system (CNS), which includes the brain and spinal cord, the gut or intestines, and the genital tract.

Researchers do NOT know how or whether these different reservoirs are related. By comparing samples from blood to samples from other reservoirs, we hope to learn more about the following:

- where HIV can be found
- whether the amount of HIV is different in different reservoirs
- what the best way is to measure the amount of HIV in different reservoirs
- whether the amount of HIV found in any one reservoir can tell us anything about the amount of HIV in any of the other reservoirs

Description of Sampling Groups

A5341s includes these 4 sampling groups:

- Group A: lumbar puncture – cerebrospinal fluid (CSF) collected 4 times during the 2-year study
- Group B: leukapheresis – blood collected using a special procedure, up to two times during the 2-year study
- Group C: rectal biopsy – tissue collected from your rectum, 2 times during the 2-year study
- Group D: genital secretions: semen from men and vaginal cells and fluid from women, collected 5 times during the 2-year study

What are the different sampling groups testing?

Group A, lumbar puncture – When HIV is found in the CSF, researchers can try to learn about how the virus survives in the central nervous system (CNS) and whether its level is the same or different from HIV levels (or viral load) in other parts of the body (including blood and other tissues). The levels of anti-HIV drugs in your CSF will also be tested.

Group B, leukapheresis – Researchers are able to get many more white blood cells from leukapheresis than from a regular blood draw; with these extra cells, they will be able to better describe the HIV that is in your blood, especially in your immune cells. The levels of anti-HIV drugs in your blood will also be tested.

Group C, rectal biopsy – Researchers will test the level of HIV and of anti-HIV drugs in rectal tissue.

Group D, genital secretions – Researchers will test the level of HIV in genital secretions. They will also test for herpes viruses. The levels of anti-HIV drugs will be tested in semen only; this is because the collection method for female genital secretions makes it difficult to test for anti-HIV drug levels.

In addition, everyone in the study will have some blood and hair collected approximately every 6 months and will also take some neuropsychological tests (called neuro tests, for short) approximately every 6 months.

Anti-HIV drug levels in hair may give us a better idea of a person's long-term exposure to these drugs than we can get from anti-HIV drug levels in blood.

Neuro tests can help researchers understand more about the effects of HIV and anti-HIV drugs on the brain. The tests are some exercises that test your memory, coordination, and response time. You will also be asked to answer some questions about daily activities. These are questions about what you are able to do for yourself.

Which sampling groups am I eligible for?

The site staff will talk with you about the study and will review some of the basic things that must be true for you to be eligible. After that, you will hear about some of the things that must be true for you to be eligible for each of the sampling groups.

Group A

If you do not have syphilis or you have finished treatment for syphilis, then you are eligible for Group A.

Group B

If you are able to have blood collected from a vein in your arm without difficulty, then you are eligible for Group B. The site will also need to make sure that you do not have a bleeding disorder.

Group C
If you do not have any abnormalities or infectious or other conditions of the rectum and you will be able to avoid inserting anything into your rectum shortly before and after the procedure, then you are eligible for Group C. The site will also need to make sure that you do not have a bleeding disorder.

Group D
Females or males: If you do not have chlamydia, gonorrhea, or trichomonas, or if you have finished treatment for these infections, then you are eligible for Group D.

Females: If you still have your cervix and you do not have any abnormality of your cervix or your vagina, then you are eligible for Group D.

Males: If you have not had a vasectomy, then you are eligible for Group D.

How many sampling groups will I be in?
You must be in at least one sampling group in order to join A5341s, but we hope that you will agree to be in more than one. This is because we believe that having different types of samples from the same person gives researchers a much better understanding of the size and scope of the reservoir. This is more helpful than having different types of samples from many different people.

You will identify the sampling group or groups that you are willing to participate in. You will be asked about this again several times during the study.

You are free to change your mind during the study about how many groups you are in. If you agree to participate in a group that has multiple collection time points, you may have fewer collections if you join that group after you have been in the study for more than 6 months.

More information about each of the study procedures is below.

WHY ARE THESE PROCEDURES BEING DONE?

These procedures are being done to:

- measure HIV viral load in blood and other body fluids and tissues
- compare HIV viral load in blood and other body fluids and tissues
- help researchers understand the best way to measure how much HIV is left in blood and other body fluids and tissues of people who have a low blood HIV viral load
- help researchers measure the amount of anti-HIV drugs that are in blood and other body fluids and tissues of people who have a low HIV viral load
- help researchers understand how HIV affects the central nervous system, which includes the brain

How Many People Will Take Part in This Study?

About 85 people will take part in this study. About 5 people are expected to enroll at the University of Pennsylvania. Each of the four sampling groups will include 55 people but we hope that many people will participate in more than one sampling group. This is why the total enrollment expected for the study is much less than 220 (or, 55 x 4).

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

If you agree to be in this substudy, you will have visit 'sets' about every 6 months in a 2-year period. Because of the possible number of procedures in this study, there will be multiple visits within each visit set. Each visit set will last between 1 and 12 weeks.

During the screening visit, you will decide which of the procedures you are willing to participate in. It is possible to agree to additional procedures after you enter the study.

The study staff will give you more information about some instructions you will need to follow before the procedures (for example, fasting, avoiding certain medicines or activities, drinking extra fluids, cleaning out your bowel).

Visits

At the screening visit, you will have a physical exam, some blood will be collected for safety tests and for women who can become pregnant, a pregnancy test. You will not be able to enter the study if are pregnant; the site staff will talk with you about whether you would be interested in entering the study later, when you are no longer pregnant.

Depending on which groups you will be in, some urine and blood will be collected and you may have a rectal swab performed. Samples will be tested for sexually transmitted infections. If any infections are found, you will see your own doctor to get the right treatment before you can enter the study.

You will be asked to answer questions about your health and any medications you are or have been taking. This visit might be part of an already scheduled A5321 study visit.

Once you have entered the study, you will have visits approximately every 6 months. Most of the evaluations listed above will be repeated at these visits unless they have been done recently as part of A5321. As at screening, if a sexually transmitted infection is found, you will see your own doctor to get treatment before a procedure is performed.

If your HIV viral load increases beyond 200 copies/ml, you will be asked to return within 4 weeks for another blood test. If the second test confirms that the level is above 200 copies/ml or if the first viral load was over 1000 copies/ml, you will be taken off the substudy. You may still remain in A5321 if you are discontinued from this substudy.

You will be given the results of routine blood and urine tests as soon as they are available.

Lumbar puncture, Group A

If you are in Group A, the first sampling visit you will have will be for the lumbar puncture. This will be conducted just as it was in A5321.

You should drink plenty of fluids the day before the lumbar puncture procedure. The procedure will be performed at CHPS in the Perelman Center for Advanced Medicine. On the day of the lumbar puncture, you will have a brief physical exam. Then you will be asked to lie down on your side or to sit ‘backwards’ in a chair (so that you are facing the back of the chair). An area of skin on your lower back will be sterilized with fluid. You will get an injection to numb the skin in the sterilized area. You may feel a burning sensation from the fluid that is injected. When the area is numb, the doctor will insert a thin needle between two of the bones in your spine. A small amount of fluid will be collected through the needle. The entire lumbar puncture procedure to this point will take about 30 minutes.

After the CSF collection, you may be asked to lie flat for up to 30 minutes to reduce the chance that you will get a headache. You should limit your physical activity for the remainder of the day.

It is possible that after your CSF is evaluated, a re-test for syphilis will be done. You will be told the results of the syphilis test when they are available. You and your doctor will receive results from these

CSF tests: cell counts, glucose level, protein. Neither you nor your doctor will receive other results from CSF tests because these are for research only.

If you are in one or more of the other groups, the other procedures (leukapheresis, rectal biopsy, and genital secretion collections) will be performed at two or three other visits within an 8-week period. The study staff will tell you where the procedures will be performed and will take care of all the scheduling for you.

Leukapheresis

When you have a leukapheresis, the procedure will be performed at the Apheresis and Infusion Clinic on 3 Ravdin at the Hospital of the University of Pennsylvania. The procedure will take about 2 hours and the full visit will last about 3 hours. You will have to remain in a semi-reclining or reclining position for the most of this time.

Leukapheresis involves taking some of your blood, processing it, and giving most of it back to you. This will be done by inserting a needle attached to sterile tubing in one arm, and first sending your blood through a machine. This machine spins your blood to separate the red blood cells (cells that carry oxygen), the white blood cells (cells that fight infection) and the platelets (cells that help form clots). The white blood cells will be kept for testing. All the rest of your blood will be returned to your body through another needle and tube in your other arm. Not all of your white blood cells are removed and your body will make more white cells within a few days. Losing the number of white blood cells that are collected does not pose a danger to you or to your health. Neither you nor your doctor will receive any results from the leukapheresis because these tests are for research only.

Rectal Biopsy

The rectal biopsy procedure will be performed in the Gastroenterology outpatient clinic. The procedure will take about 30 minutes, and the full visit should last about 1.5 to2 hours.

A rectal biopsy is a procedure to remove small pieces of rectal tissue for examination. Just before to the rectal biopsy, you will have an enema (a salt water rinse that will flush out your lower bowel). A rectal exam will be done. Next, a lubricated instrument will be placed into your rectum. Using this instrument, the doctor will examine the inside of your lower large intestine and will collect approximately 16 individual samples of tissue for testing.

You should not have anal sexual intercourse or insert anything into your rectum (including medications of any kind) for 3 days before and for 7 days after the procedure. The study or clinic staff will call you within 1 week after the procedure to check on how you are feeling. Neither you nor your doctor will receive any results from the rectal biopsy procedure because these tests are for research only.

Genital secretions

Genital secretions will be collected at the CHPS; men will also have the option to collect the sample at home. For women, the procedure will take about 30 minutes. For men, you will be given a private space to collect the specimen.

Because of the testing that will be done on your samples, it is important that there is no contamination of the area being sampled. Women should avoid inserting anything in the vagina for at least 48 hours (2 days) before the procedure. Men should avoid sexual activity, including masturbation, for at least 48 hours (2 days) before the procedure.

Women will have a pelvic exam. During this exam, some tissue will be collected from the vagina with a small soft brush, just as is done for a Pap smear. Also during this exam, some fluid will be collected from the vagina by washing the vagina with a small amount of sterile fluid.

Men will be asked to masturbate into a container. The clinic staff will give you a sterile container and will give you more information about this collection. Samples collected at home need to be received at room temperature within 2 hours of collection.

The study staff can answer any questions you have about the procedures or about the how long each visit will be.

Neuropsychological tests

For everyone enrolled in A5341s, neuro tests will be conducted at entry and then again about every 6 months. You will be asked to do some simple tests to measure your memory and coordination. These tests will include being asked to remember a list of words, trace a pattern on a piece of paper, and put metal pegs into a series of holes. These tests will take about 1 hour. You will not receive any results from the neuro tests because they are used for research only.

During the neuropsychological tests you will answer questions, list items using pencil and paper (such as naming foods, or animals, or some other groups you know), do simple tasks using a special pegboard, and see how long it takes you to walk a short distance. You will be asked questions to see if you forget things, have difficulty understanding facts, or difficulty with your behavior and interacting with others.

Hair collection

At entry and then again about every 6 months, we will collect a small sample of hair (about 100 strands) by cutting some hair from your head, close to your scalp. Humans naturally lose about 100 hairs from their head every day so this amount of hair removal should not be noticeable. If you have no hair on your head or the hair on your head is too short to cut, the collection will not be made.

Blood collection

The amount of blood collected from you at any single visit will depend on which groups you are in and which procedures are being performed. You will be asked to fast (not have anything except medications and water to eat or drink for 8 hours) before most blood collections. The study staff will tell you how much blood will be collected at each of your visits. No more than 30 tablespoons (or about 1 pint) will be collected over any 12-week period.

How Will My Samples Be Used?

Use of Your Samples for this Study

Some of your blood and tissues that are collected during these procedures will be stored and used for testing that is required for this study. No one will know just from looking at the labels of your stored samples that they came from you.

Use of Your Stored Samples

Some of your blood and tissue that are left over after all required study testing is done may be stored and used for ACTG-approved HIV-related research. No one will know just from looking at the labels of your stored samples that they came from you. Although researchers will not be given your name or any other personally identifying information about you, some information about your medical condition, your race, ethnicity, gender, and age may be shared.

These samples may be held for an indefinite length of time. We cannot ensure that you will be told of the results of the research done on these samples.

Allowing your samples to be stored for this use is optional.

What Are The Risks Of The Study?

Most blood collections and physical examinations are the same as you would have when seeing any health care provider. 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.

You might get a slight cut when the hair sample is being collected.

Lumbar puncture
Headache, sometimes severe
Back pain, slight
Bruising, soreness at collection site
Dizziness, nausea
Fever
Numbness
Paralysis (extremely rare)

Leukapheresis

The potential risks include nausea, vomiting, fainting or dizziness, bruising or swelling where the needles are put in, low blood pressure, increased pulse rate, seizures, blood loss and infection. About one half of the people who have leukapheresis feel weak or tired for the rest of the day.

Rarely, people may have an allergic reaction to some of the material used during the leukapheresis. The procedure might have to be stopped early, before it is finished, and could, very rarely, result in the loss of as much as 1/2 pint of blood if it is not possible to complete the return of blood to you.

During the procedure you will receive a compound called ACD-A (citrate), which prevents blood from clotting. Citrate is approved by the Food and Drug Administration for use in this procedure. Citrate leaves the body within 15-30 minutes after the procedure is complete. Citrate may cause seizures (although this is rare) and commonly may cause muscle cramping, numbness or tingling of the lips and/or fingers, chills, a feeling that the body is vibrating, and/or feelings of anxiety. If you notice any symptoms while undergoing leukapheresis please let the nurse know immediately since the symptoms can usually be treated.

Insertion of the needles at the beginning of leukapheresis may cause temporary pain and a bruise may form at the site.

You will be monitored during and after this procedure and instructed to inform the medical staff immediately of any possible discomfort.

Rectal biopsy

There may be some discomfort during the collection of tissue samples. You may feel an urge to have a bowel movement. Cramping sometimes occurs as the instrument is placed into the rectal area. You may have the feeling of a “bloated stomach”. On extremely rare occasions, you may have pain, infection, bleeding or perforation (a cut or a hole) of the gastrointestinal tract (this occurs about once out of every 1000 procedures and may require hospitalization and surgical management).

Genital secretions collections
Females: the pelvic exam and collection of vaginal and cervical samples may cause minor temporary discomfort during collection, but no other risks are expected.

Males: there are no known physical risks associated with semen collection by masturbation.

Are There Risks Related To Pregnancy?
You may not undergo study collection procedures while you are pregnant. If you become pregnant on study, information about the pregnancy will be collected and shared for research purposes.

Why Would The Doctor Tell Me Not To Have The Procedures?
The study doctor may need to stop you from having one of more procedures without asking for your permission if:
- you develop a condition that makes a procedure unsafe for you
- your site becomes unable to perform a procedure
- at the request of the site investigator
- you are pregnant; you may be able to resume collections when you are not pregnant
- you were not treated for your sexually transmitted infection after it was found

Why Would The Doctor Tell Me Not To Continue In The Study?
The study doctor may need to take you off the study without asking for your permission if:
- your viral load increases
- you are not able to have the large blood collection as required by the study
- you are not able to follow study instructions
- you fail to attend three visits in a row
- you test positive for hepatitis C
- you have to take a drug that is not allowed on this study
- the study is stopped or cancelled

NOTE: If you choose not to continue in the study or are asked to stop being in the study, you may still remain in A5321. If you discontinue A5321, you will also have to discontinue this study (A5341s).

Are There Benefits to Taking Part in This Study?
If you take part in these procedures, there will be no direct benefit to you. Information learned from these procedures may help others who have HIV.

What Other Choices Do I Have Besides This Study?
Taking part in this study is optional. You may choose not to participate.

What Are the Costs To Me?
There will be no cost to you for study-related visits, physical examinations, laboratory tests or other procedures. 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?
For A5341s routine study visits (blood draw, neuropsychological tests, hair sampling), you will receive $50. In addition, you need to come to the clinic for a pre-procedure visit (when visits for the main study are more than 4 weeks prior to a A5341s procedure), you will receive $50.

You will receive $150 for each lumbar puncture procedure, regardless of whether you are able to complete the procedure.

You will receive $150 for each leukapheresis procedure, regardless of whether you are able to complete the procedure.

You will receive $125 for each rectal biopsy procedure, regardless of whether you are able to complete the procedure.

If you are a women, you will receive $100 for each vaginal samples collection procedure (two are performed at once; the payment is for the set, not for the individual components), regardless of whether you are able to complete the procedure.

If you are a man, you will receive $100 for each seminal fluid collection procedure, regardless of whether you are able to complete the procedure.

Compensation will be given on a Clincard (similar to a debit card).

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?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania or the National Institutes of Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

What About Confidentiality?

We will do everything we can to protect your privacy but cannot guarantee absolute protection. 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.

People who may review your records include the ACTG, Office for Human Research Protections (OHRP) or other government agencies as part of their responsibility to protect the rights of research participants, the University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), study staff, study monitors and local, US and non-US regulatory entities. 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.

If you become pregnant while on this study, your pregnancy will be reported to the Antiretroviral Pregnancy Registry, which maintains records on women who become pregnant while taking anti-HIV medications.

Your personal information may be given out if required by law. If you test positive for HCV (Hepatitis C), by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health.. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements of reporting infectious diseases to the PA Health Department, please visit www.health.pa.gov and type 'Reportable Diseases' into the site search bar.

Will information about this study be available to the public?
A description of this clinical trial will be available on 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.

What May Happen To My Information And Samples Collected On This Study?
Biospecimens collected for this study will be used for safety and STD tests while others will be analyzed for protocol specific tests. With your permission, samples that are leftover may be used for future research. Your information and samples will be de-identified. De-identified means that all identifiers have been removed. The information and samples could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected on this study.

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. Most uses of biospecimens or information do not lead to commercial products or to profit for anyone. Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

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 information about me may be collected, used or shared with others?
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
- Questionnaires
- Results of tests and procedures you will undergo during this research
- Social Security Number, Medical record number

Why is my information being used?
Your information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- evaluate and manage research functions.

Who may use and share information about me?
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 UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need access to 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.)
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside the School of Medicine, might receive my 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 keyed into a password protected central database. 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.
- 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 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

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 the School of Medicine use or disclose my 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.

Electronic Medical Records and Research Results

<u>What is an Electronic Medical Record and/or a Clinical Trial Management System?</u>
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.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

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 information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining

any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be 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 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

This consent is the initial consent for this participant. The study staff will provide an overview of the study, required visits, treatment regimen, risk and all elements of consent. The physician investigator(s) or licensed Nurse Practitioner will conduct a focused discussion about risks, benefits and alternatives.

In the How will my samples be used section of this consent form you were informed about optional tests to be done on your leftover blood.

Please indicate below "yes" or "no" and initial and date whether you approve the use of these extra stored samples for future testing. Note that you can withdraw your consent for research on stored specimens at any time you want and the specimens will be discarded. If you change your mind, you must contact your study doctor or nurse and let them know that you do not want your samples used for research to be done at a later date. Every effort will then be made to destroy your left-over samples.

Your refusal or withdrawal of consent for the storage of these samples will not affect your study participation since storage of leftover samples is not a requirement for the study.

☐ I agree to allow additional testing performed my extra samples for future ACTG-approved research

☐ I do not allow my extra samples to be used in future research

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.

Please place your initials beside each sampling group that you are willing to participate in as of the day you are signing this consent form. You will be asked about your choices again later in the study; you may change your choices at any time.

_____ Group A: lumbar puncture – 4 times during the 2-year study
_____ Group B: leukapheresis – 2 times during the 2-year study
_____ Group C: rectal biopsy – 2 times during the 2-year study
_____ Group D: genital secretion collection: 5 times during the 2-year study

RESEARCH STAFF CONSENT

Name of Subject (Please Print)	Signature of Subject	Date/Time

Name of Person Obtaining Consent (Please Print)	Signature	Date/Time

INVESTIGATOR CONSENT

The risks, alternatives, and benefits have been reviewed with me by the Investigator, and I understand what we have discussed.

Name of Subject (Please Print)	Signature of Subject	Date/Time

I verify I have reviewed risks, alternatives, benefits with this subject, who demonstrates good understanding.

Investigator Name (PRINTED)	Signature	Date/Time

IRB APPROVAL FROM:
03/15/2019 TO: 01/08/2020