HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title:	**A5353, Version 1.0, 08/14/15**: A Study to Evaluate Dolutegravir plus Lamivudine Dual Therapy for the Treatment of Naïve HIV-1-infected Participants A DIVISION OF AIDS/ AIDS CLINICAL TRIALS GROUP (ACTG) Study
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Introduction:

You are being asked to take part in this research study because you:

- are infected with HIV (the virus that causes AIDS)
- have never taken any medicine for the treatment of HIV

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?

This study is being done to see if the combination of two anti-HIV medicines, dolutegravir (DTG, Tivicay) and lamivudine (3TC, Epivir) taken once a day, will provide a safe, effective, and well-tolerated treatment for HIV. DTG is a type of HIV medicine called an integrase inhibitor; 3TC is a type of HIV medicine called a reverse transcriptase inhibitor. DTG works by blocking integrase and 3TC works by blocking reverse transcriptase, two HIV proteins (enzymes). This prevents HIV from multiplying and lowers the viral load (amount of HIV in the blood). Both DTG and 3TC are currently part of Food and

Drug Administration (FDA) recommended regimens along with a third active drug. Since some HIV medicines have side effects and are costly, there is interest in whether HIV can be successfully controlled with fewer than three HIV drugs. The treatment used in this study is considered experimental because of the use of only 2 drugs instead of the traditional 3.

How Many People Will Take Part in This Study?
About 120 people will take part in this study. About 5 people 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 52 weeks

What Do I Have To Do If I Am In This Study?
If you decide to take part in this research study, you will be asked to sign this consent form and schedule a screening visit to determine if you are eligible to enter this study. If screening visits determine that you are eligible and you agree to be in this study, you will take DTG and 3TC once a day for 52 weeks. While you are in this study, you will be seen in the clinic about 13 times. The study staff will tell you about how long each visit will last. During the study, you will get the results from any routine tests that are done during the study when they are available.

Screening visit
- Your HIV infection will be confirmed if there is no record available. You have another HIV test and may have to sign a separate consent form before having this test
- You will be asked about your medical history and any medicines you have taken.
- You will have a brief physical exam and be asked about your health.
- You will have blood drawn for routine safety tests to check your blood count, kidney and liver function, to measure your HIV viral load (the amount of HIV in your blood).
- You will have blood drawn to test for hepatitis B (infection caused by a virus that attacks the liver).
- You will have blood drawn to determine your HIV integrase genotype (genetic makeup of the virus that will show if there is any evidence of HIV drug resistance). You will have blood drawn to determine your HIV protease and reverse transcriptase genotype as part of your routine medical care if this was not already done.
- If you are a woman who could become pregnant, you will be asked to give a urine or blood sample to see if you are pregnant. You will not be able to enroll in this study if you are pregnant or breastfeeding.

If you do not enroll into the study
If you do not qualify to take part in this study or you decide not to take part in this study, we will still use some of your information. As part of the screening visit, some demographic (for example, age, gender, race), clinical (for example, disease condition, diagnosis), and laboratory (for example, CD4+ cell count, HIV viral load) information is being collected from you so that ACTG researchers may see if there are patterns or common reasons why people do not join a study. If you do not want your information to be used, then you should not sign this consent form.

Entry visit
- If the screening evaluations show that you are eligible for the study, you will return to the clinic for the entry visit.
- You will have a physical exam. The study staff will check the different systems in your body and your vital signs such as temperature, pulse, blood pressure, and respiratory rate.
- You will be asked about medicines you have taken in the past or are taking now.

- You will have blood drawn for routine safety tests to check your blood count, kidney and liver function, and to measure your CD4+ cell count and HIV viral load. Some of your blood will be stored for future testing.
- You will have blood drawn to test for hepatitis C (infection caused by a virus that attacks the liver).
- You will have a fasting lipid blood test to measure the level of cholesterol in your blood. Fasting means no food or drink, except for sips of water with medications for 8 hours before the test. If you are not fasting at the time of the blood draw, your blood will still be drawn.
- You will be asked to provide a urine sample.
- If you are a woman who could become pregnant, you will be asked to give a urine or blood sample to see if you are pregnant. You will not be able to enroll in this study if you are pregnant.
- Some of your blood will be stored to check your genetic makeup which may be useful in understanding your response to the study drugs. The way medication affects a person is often varied and depends to a certain degree on genes and variations in those genes. Blood will be stored with the usual protectors of identity.
- You will begin taking DTG and 3TC by mouth once a day for the next 52 weeks.
    - There are no food restrictions with this combination so you may take these drugs with or without food. If you are taking some antacids, laxatives, or iron or calcium supplements you will need to take the DTG 2 hours before or 6 hours after these medications. Alternatively, you may take iron or calcium supplements at the same time as DTG if taken with food.
    - You will be given DTG and 3TC at your study visits to take home, and you will need to store them in a safe place at room temperature
    - Both DTG and 3TC will be supplied by the study.

<u>During the study visits:</u>
After the entry visit, your study visits will be on weeks 2, 4, 8, 12, 16, 20, 24, 32, 40, 48 and 52.
All (or some) of the following tests will be done at each visit, depending on the week you come to the clinic:

- You will have a brief physical examination performed at each study visit.
- At each study visit, you will be asked questions about any medicines you are taking now and about any signs or symptoms that you are experiencing and any changes in other medications that you have had since your last visit.
- You will have blood drawn for routine safety tests to check your blood count, cholesterol level and kidney and liver function and to measure your CD4+ cell count.
- Blood will be drawn to check your HIV viral load at each study visit.
- You will have a fasting lipid blood test taken to measure the level of cholesterol in your blood.
- You will have a urine sample collected.
- If you are a woman who could become pregnant, you will have a pregnancy test whenever pregnancy is suspected.
- The study staff will contact you between some of your study visits to remind you of your appointment and to take your study medications.
- You will be asked about how well you take the study medicines at each study visit. The study staff will give you information and encouragement to help you take your medications as prescribed.
- Some of your blood will be stored to check the level of study drugs in your blood. Blood will be stored with the usual protectors of identity. You will not be told the results of these tests.

<u>Confirmation of Viral Load</u>
You will be asked to return to the clinic to have blood drawn if your HIV viral load gets too high and it is suspected that the study drugs might be failing to fight your HIV. You will have a brief physical exam and be asked about how well you have been taking your study medications. You will have blood drawn to measure your viral load and to do HIV-1 genotype resistance testing if virologic failure is confirmed.

Your study doctor will talk to you about the plan for future treatment. This visit may be combined with another study-scheduled visit.

Pregnancy

If you are a woman and you become pregnant, you will have to stop taking the study drug but we will ask you to stay in the study to be followed on study/off treatment until study completion. If you do not wish to continue to be followed on study/off treatment, the study staff will ask your permission to contact you regarding the outcome of your pregnancy. Your pregnancy will be reported to the Antiretroviral Pregnancy Registry, an international database that collects information about pregnancies in women taking anti-HIV drugs. These reports will not use your name or other information that could be used to identify you.

Premature Treatment/Study Discontinuation

If you stop taking the study drug before the study-defined treatment period, you will be asked to return to the clinic to complete some evaluations:

- You will have a brief physical exam and be asked about any medicines you have been taking.
- You will be asked about how well you took the study medicines.
- You will have blood drawn for routine safety tests to check your blood count, liver and kidney function, CD4+cell count, and viral load.
- You will be asked to provide a urine sample.
- Some of your blood will be stored for future testing.

Other Information

As stated above, some of your blood will be stored for study-required testing which is part of your participation in this study. If you agree to be in this study, you are also agreeing to have blood stored for study-required tests.

If you agree, some of your blood that is left over after all required study testing is done may be stored (with usual protectors of identity) and used for future ACTG-approved HIV-related research.

You will be asked to confirm whether or not you allow your left over samples can be used at the end of this consent form.

A5353 Study Visits

The study staff can answer any questions you have about individual study visits, the evaluations that will occur, or how long each visit will be. The table below can be used as a quick reference.

Study Schedule

Evaluation or test	Screen	Entry	Post-Entry Visits		Confirm virologic failure	Early discontinuation
			On treatment (Weeks 2, 4, 8, 12, 16, 20, 24, 32, 40, 48	End of treatment (Week 52)		
Consent	✓					
Complete physical examination		✓				
Brief physical examination	✓		✓	✓	✓	
Medical/medication history	✓	✓	✓	✓	✓	✓
Blood sample collection and laboratory testing	✓	✓	✓	✓	✓	✓
Urinalysis		✓		✓		✓
Stored blood samples		✓	✓	✓	✓	✓
Phone call reminder			Between study visits			
Adherence questionnaire			✓	✓	✓	
Approximate amount of blood*	30 mL	30 mL	15 to 25 mL/visit	30 mL	22 mL	25 mL

* 30 mL of blood is equivalent to about 2 tablespoons

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:

- The study is stopped or cancelled.
- A Study Monitoring Committee (SMC) recommends that the study be stopped early (An SMC is an outside group of experts who monitor the study).
- Your doctor thinks the study is no longer in your best interest.
- The site investigator thinks that you are at significant risk of failing to comply with the requirements of the protocol.
- Your primary care physician requests you be taken off the study.

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

- Continuing the study medicine may be harmful to you.
- You need a treatment that you may not take while on the study.
- You become pregnant or are breastfeeding.
- Your viral load worsens.
- You are not able to take the study medicine as required by the study.
- You miss three consecutive clinic visits.

If you must stop taking the study drug before the study is over, the study doctor will ask you to continue to be part of the study and return for some study visits and procedures.

If I have to permanently stop taking study drugs through the study, or once I leave the study, how can I get study drugs?
If you must permanently stop taking DTG and 3TC before the study is over, the study staff will talk with you about other treatment options. After you have finished the study, you will not be able to get DTG or 3TC through the study.

What Are The Risks Of The Study?

Risks of Social Harm
Although the study site will make every effort to protect your privacy and confidentiality, it is possible that others could find out that you are participating in this study and that social harm 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. Poor adherence (failing to take HIV medications as prescribed) can increase the risk of drug resistance, HIV treatment failure, and a risk of HIV transmission to others.

Risks of Drawing Blood
Drawing blood may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection.

Risks of Study Drugs
The drugs used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects with a known or possible relationship. It is very important that you tell your study doctor of any changes in your medical condition while taking part in the study. At any time during the study, if you believe you are experiencing any of these side effects, you have the right to ask questions on possible and /or known risks.

There is a risk of serious and/or life threatening side effects when non-study medications are taken with the study drugs. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study and you must ask approval for taking any new medication while you are on the study.

Use of Combination Antiretroviral Drugs
Immune Reconstitution Syndrome:
In some people with advanced HIV infection, symptoms from other infections or certain diseases may occur soon after starting combination anti-HIV treatment but can also occur later. Some of these symptoms may be life threatening. If you start having new symptoms, or notice that existing symptoms are getting worse after starting your antiretroviral therapy, tell your healthcare provider right away.

The use of potent antiretroviral drug combinations may be associated with an abnormal placement of body fat and wasting. Some of the body changes include:

- Increase in fat around the waist and stomach area
- Increase in fat on the back of the neck
- Thinning of the face, legs, and arms
- Breast enlargement

It is also possible that the two drug combination may not control your HIV infection effectively.

Integrase Inhibitor
Dolutegravir, (DTG, Tivicay®)

The following serious and potentially life-threatening side effects have been associated with the use of dolutegravir. These include allergic reactions and liver problems.

Contact your health care provider right away if you develop a rash while taking dolutegravir, especially if it's associated with any of the following symptoms:

- Fever
- General ill feeling
- Extreme tiredness
- Muscle or joint aches
- Blisters or sores in your mouth
- Blisters or peeling skin
- Redness or swelling of your eyes
- Swelling of your mouth, face, lips, or tongue
- Trouble breathing

Contact your health care provider right away if you have any of the following symptoms that could be signs of liver problems:

- Yellowing of your skin or whites of your eyes (jaundice)
- Dark or tea-colored urine
- Pale-colored bowel movements
- Nausea or vomiting
- Loss of appetite
- Pain, aching, or tenderness on your right side below your ribs

People with pre-existing history of depression or other psychiatric illness may be at greater risk for suicidal thoughts, or attempts, which may lead to death. If your psychiatric condition worsens, or if you develop suicidal thoughts, call your healthcare provider right away.

Other side effects include:

- Changes in liver test results, more common in people with hepatitis B or C
- Trouble sleeping
- Tiredness
- Headache

Nucleoside Analogue
Lactic acidosis (elevated lactic acid levels in the blood) and severe hepatomegaly (enlarged liver) with steatosis (fatty liver) that may result in liver failure, other complications or death have been reported with the use of antiretroviral nucleoside analogues alone or in combination. The liver complications and death have been seen more often in women on these drug regimens. Some nonspecific symptoms that might indicate lactic acidosis include: unexplained weight loss, stomach discomfort, nausea, vomiting, fatigue, cramps, muscle pain, weakness, dizziness and shortness of breath.

Lamivudine (3TC, Epivir®)

The following side effects have also been associated with use of lamivudine:

- Headache
- Feeling tired

- Dizziness
- Numbness, tingling, and pain in the hands or feet
- Depression
- Trouble sleeping
- Rash
- Upset stomach, vomiting, nausea, loose or watery stools
- Pancreatitis (inflammation of the pancreas), which may cause death. If you develop
- pancreatitis, you may have one or more of the following: stomach pain, nausea, and vomiting.
- Abnormal pancreatic and liver function blood tests

If you are infected with both Hepatitis B and HIV, you should be aware that your liver function tests may increase, and symptoms associated with hepatitis (an acute inflammation of the liver) may worsen if lamivudine is stopped. Although most of these cases have resolved without treatment, some deaths have been reported.

Are there Risks Related to Pregnancy?

It is not known if drug combinations in this study harm unborn babies. If you are a woman and having sex that could lead to pregnancy, you must agree not to become pregnant.

If you are a woman participating in sexual activity that could lead to pregnancy, you and/or your male partner must use one form of birth control that you discuss with the study staff. You must start one method of birth control before you start taking the study drugs, while you are taking the study drugs, and for 30 days after stopping study drugs.

- Condoms (male or female) with or without a spermicidal agent. Condoms are recommended because their appropriate use is the only contraceptive method effective for preventing HIV transmission.
- Diaphragm or cervical cap with spermicide
- Intrauterine device (IUD)
- Hormone-based contraceptive

If you can become pregnant, you must have a pregnancy test before you enter this study and before you start taking DTG and 3TC. The test must show that you are not pregnant. Pregnancy tests will also be performed whenever pregnancy is suspected. If you think you may be pregnant at any time during the study, tell your study staff right away. Pregnancy will result in immediate discontinuation of the study drugs.

BREASTFEEDING
It is unknown whether the study drugs pass through breast milk and may cause harm to your infant. You must not breastfeed while you are in this study.

Are There Benefits to Taking Part in This Study?

If you take part in this study, there may be a direct benefit to you but no guarantee can be made. Your health may be watched more closely than usual while you are on the study, which may help you to feel better. It is also possible however that you may receive no 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 FDA-approved HIV prescription drugs available to you.
- Treatment with HIV experimental drugs, if you qualify.
- No HIV treatment.

Please talk to your doctor about this 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.

People who may review your records include the ACTG, Office for Human Research Protections (OHRP) or other government agencies as part of their duties, the University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), study staff, study monitors, drug companies supporting this study, other government agencies and their designees. 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.

A description of this clinical trial will be available on www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your personal information may be given out if required by law. If you test positive for HIV or if a CD4 or HIV 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.

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
- Questionnaires
- 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.
- Pharmaceutical sponsor (ViiV Healthcare Ltd) The company that is supplying the study drugs.
- 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 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.

<u>What is an Electronic Medical Record?</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.

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 any of the laboratory tests that you have as part of this study, study visits or dolutegravir and lamivudine (drugs supplied by the study). You are still responsible for any deductibles or applicable co-pays for routine office visits, procedures and blood work. Taking part in this study may lead to added costs to you and your insurance company. In some cases it is possible that your insurance company will not pay for these costs because you are taking part in a research study. If you have any concerns about this, please discuss your concerns with the research staff.

Will I Receive Any Payment?

You will be compensated $50 for each required study visit (13) you attend. Compensation will be provided as cash. The total compensation for the study is $650 if all required visits are attended. If you are requested by the study team to come in for an unscheduled visit, you will be compensated $25 for that visit.

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 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

On page 4 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. 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.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date