

HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title: **A5336, Version 2.0, 05/21/15:**
A Randomized, Pilot Study of Ruxolitinib in Antiretroviral-Treated HIV-
Infected Adults. A DIVISION OF AIDS/ AIDS CLINICAL TRIALS
GROUP (ACTG) Study

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Introduction:

When a person becomes infected with HIV (the virus that causes AIDS), his/her immune system (the system that helps fight infection) is weakened (partly because the number of CD4+ cells [the number of white blood cells that fight infection] goes down). Despite successful treatment with antiretroviral therapy (ART), latent reservoirs (infected cells that are not actively producing HIV) remain present in the blood and contribute to ongoing immune system activation (immune system becomes active in response to an infection) and inflammation (reaction to an infection or irritation) in the body.

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

- are infected with HIV-1
- have a very low viral load (amount of virus in the blood)
- have CD4+ T cell count of more than 350 cells
- are on stable ART for at least 3 months

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?

The purpose of this study is to find out more about the safety and tolerability (how well your body accepts the study drug) of the use of ruxolitinib in persons with HIV-1 infection who are also being treated with ART. We want to learn whether ruxolitinib will decrease inflammation and immune activation in the body; whether ruxolitinib will change the level of HIV-1 in your blood; and how ruxolitinib interacts with ART in the blood.

Ruxolitinib is approved by the U.S. Food and Drug Administration (FDA) to treat myelofibrosis, a disorder in which bone marrow is replaced by scar (fibrosis) tissue. Many of the cytokines (regulators of the body's reaction to infection, immune response, and inflammation) affected by myelofibrosis are also affected by HIV. Because ruxolitinib acts on these cytokines, it is proposed that it may also be a possible treatment for HIV by reducing inflammation. Inflammation has been associated with organ disease in people living with HIV.

How Many People Will Take Part in This Study?

About 60 people will take part in this study. About 3-5 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 12 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 can join the study. If so, you will be randomly assigned (by chance) to either one of the two groups, Group A or Group B (see below). The screening visit will take about 1.5 hours.

Screening visit

- Your HIV-1 infection will be confirmed. If there is no record available, you will have another HIV-1 test. You may have to sign a separate consent form before having this test.
- You will have a physical exam and will be asked about your health and medicines you have taken in the past or are taking now.
- You will have about 1 tablespoon of blood drawn for routine safety blood tests and to measure HIV-1 viral load. You will be given the test results when they are available.
- If you are a woman able to 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. You will be told the result of the test when it becomes available.

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.

Pre-Entry

If you qualify for the study, you will come to the clinic at least one day after the screening visit for the pre-entry visit. Please note it is possible that the pre-entry and screening visits may be combined. If not, at the pre-entry visit you will have a complete physical exam. You will also have blood drawn for CD4+

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T cell count and for samples to be stored for future HIV-related testing for this study. A total of 2 tablespoons of blood will be drawn at this visit. Saliva and cells from your cheeks will be collected with an oral swab and tested for the presence of human herpes viruses (HHV; viruses causing sores most often found around the mouth or the genitals). The visit will last about 30-60 minutes.

Entry visit

If you are eligible for the study, you will come in for an entry visit. You will need to fast before your entry visit. Fasting means nothing to eat or drink other than water and medication for 8 hours before your visit. The visit will last about 60-90 minutes.

During this visit:

- You will have a physical exam performed. You will be asked about medical history and any medicines you have taken since the last visit.
- If you are a woman able to get pregnant, you will be asked to provide blood or urine for a pregnancy test. You cannot start treatment if you are pregnant. You will be given the results of your pregnancy test as soon as it becomes available.
- You will have 7 tablespoons of blood drawn for routine safety blood tests including lipid testing, CD4+ T cell count, viral load, immune tests along with other tests. In addition, some of your blood will be stored for future testing required by the study.
- Saliva and cells from your cheeks will be collected with an oral swab and tested for the presence of HHV.
- You will be asked questions about adherence to antiretroviral (ARV) medicines.
- If you are in Group A, you will be given a medication diary to record the date and time of ruxolitinib, and ARV medicines for the 3 days preceding the week 1 study visit. The medication diary will be collected at the week 1 study visit.

Once all these tests are done, you will be randomly assigned to either one of the two groups (Group A or Group B). However, because of the way the study is designed, there will be a greater chance of your being in Group A.

- Group A: Takes ruxolitinib by mouth twice per day for the next 5 weeks.
- Group B: No study treatment.

If you are randomized to Group A, during this visit, study staff will give you enough study drug to last until the next study visit. You will be asked not to drink grapefruit juice or eat grapefruit while taking the study drug since it can affect your body's response to the drug. At the week 5 visit, you must return any remaining study drug.

On Study Visits after Entry

Regardless of which group you are assigned to, you will come to the clinic one week after your initial entry visit (week 1) and then study weeks 2, 4, 5. For the week 5 visit, you will be asked to fast, which means that for eight hours before your visit, you cannot eat or drink anything except water and your medication. Your next visit will not be until week 10 on study and your final visit will be at week 12. Visits will take about 30-60 minutes except weeks 1 and 4 study visits if you are in Group A (see 5th bullet below). If you are in Group A, at the week 2 study visit you will be given a medication diary to record the date and time of ruxolitinib, and ARV medicines for the 3 days preceding the week 4 study visit. The medication diary will be collected at the week 4 study visit.

During these visits:

- You will have a brief physical exam performed.
- You will be asked about any new medications since your last visit including your HIV-1 medications.

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- You will have 1 tablespoon of blood drawn for routine safety blood tests, including lipid testing at week 5, and immune tests. At weeks 2, 5, and 12 study visits, blood will be drawn for CD4+ T cells count and viral load tests.
- You will have approximately from 2 to 6 tablespoons of blood drawn and stored for future protocol-related testing (except at the week 1 visit).
- Saliva and cells from your cheeks will be collected with an oral swab and tested for the presence of HHV.
- If you are in Group A, at weeks 1 and 4 study visits you will have about 2 tablespoons of blood drawn over 6-8 hours to measure ruxolitinib and ARV medicines levels in your blood. You will be contacted the night before each pharmacokinetic (PK) visit to remind you not to take your morning dose of ruxolitinib or ARV medicines (including efavirenz) until instructed during your clinic visit in the morning. You will be asked to bring your study drug and ARV medicines to the clinic. You will have blood drawn 4 times during this time period to determine the levels of ruxolitinib and ARV medicines in your blood. For the multiple blood samples required, an indwelling catheter (a small, thin tube) will be put into an arm vein and left in place during your stay in the clinic if preferred. An IV tube will be placed at the end of the catheter for the PK blood draws. This will allow the blood samples to be drawn without any additional needle sticks. You may eat or drink as you wish during this period.
- You will be asked questions about adherence to the study drug (Group A) and your ARV medicines.

Virologic Failure

If the study staff sees that your viral load has gone up, and there is no other known explanation such as the flu, you will be asked to have another test done within 7 days. If your viral load is still up and you are still taking study drug, you will be asked to stop the study drug and come to the clinic within 2 weeks. You will be followed on study/off study treatment until the final study visit, week 12.

Pregnancy

If you become pregnant, the study drug will be discontinued immediately, and you will be encouraged to remain in the study to be followed on study/off treatment until study completion. You will be followed by telephone contact thereafter to determine the pregnancy outcome.

Premature Treatment/Study Discontinuation

If you stop taking the study drug before the study-defined 5-week treatment period, you will be asked to return to the clinic to complete some evaluations.

- You will have a brief physical examination performed.
- You will be asked about any new medications since your last visit including your HIV-1 medications.
- You will have approximately 6 tablespoons of blood drawn for routine safety blood tests including lipid panel, CD4+ T cells count, viral load, immune tests along with other tests. Also, some of your blood will be stored for future protocol-related testing.
- Saliva and cells from your cheeks will be collected with an oral swab and tested for the presence of HHV.
- If you are in Group A, you will have 2 tablespoons of blood drawn for measuring ruxolitinib and ARV medicines in your blood if you are discontinuing study treatment prior to week 4.
- You will be asked questions about adherence to the study drug (Group A) and your ARV medicines.

Other

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 ACTG-approved HIV-1 related research. Please check the appropriate response if you agree to storing samples for future use.

What Are The Risks Of The Study?

The drug used in this study may have side effects, some of which are listed below. Please note that this list does not include all the side effects seen with this drug. This list includes the more serious, life-threatening or common side effects with a known or possible relationship. If you have questions concerning the additional study drug side effects please ask the medical staff at your site. The most common side effects observed in the past ruxolitinib clinical studies include:

- Thrombocytopenia (decreased cells in the blood that are needed to stop bleeding)
- Neutropenia (an abnormally low count of white blood cells that help fight off infections)
- Diarrhea
- Fever
- Urinary tract infections
- Anemia
- Bruising
- Dizziness
- Headache
- Transaminase elevations (increased liver enzymes that may indicate liver disease)
- Cholesterol elevation
- Infections

It is not known whether the study drug passes through breast milk and whether it can produce adverse effects in the infant. Additionally, it is not known whether taking the study drug will reduce the risk of passing HIV to the baby while breastfeeding. You must tell the study doctor or nurse whether you are breastfeeding before enrolling in the study. You cannot participate in the study if you are breastfeeding.

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

Risk of Blood Draw

Taking blood may cause some discomfort, bleeding, bruising, and/or swelling where the needle enters the body and in rare cases it may result in fainting. There is a small risk of infection.

Risk 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 harms may result (because you could become labeled as being infected with HIV). For example, you could be treated unfairly or discriminated against by family members, friends, and/or the community.

Are There Risks Related To Pregnancy?

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

Because of the risk involved, you and your partner must use one form of birth control that you discuss with the study staff. You must start one method of birth control when you are taking your study drug. You must continue to use this method until 7 weeks after you stop the study drug.

- 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-1 transmission.
- Diaphragm or cervical cap with spermicide

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- Intrauterine device (IUD)
- Hormone-based contraceptive

If you can become pregnant, you must have a pregnancy test before you enter this study. The test must show that you are not pregnant. If you think you may be pregnant at any time during the study, tell your study staff right away. The study staff will talk to you about your choices.

Pregnancy will result in immediate discontinuation of the study drug for the pregnant participant. You will be followed on study until study completion and will be followed by telephone contact thereafter to determine the pregnancy outcome. Pregnancies that occur on study will be reported prospectively to The Antiretroviral Pregnancy Registry.

Why Would The Doctor Take Me Off This Study Early?

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

- You miss 2 visits in a row.
- The study is canceled.
- The study doctor or your regular doctor thinks the study is no longer in your best interest.

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

- You have confirmed virologic failure if you are in Arm A.
- You miss more than 3 doses of study drug a week for at least two weeks.
- You change or stop your anti-HIV-1 medicines if you are in Arm A.
- Continuing the study drug may be harmful to you.
- You need a treatment that you may not take while on the study.
- You are not able to take the study medicine as required by the study.
- You become pregnant.

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

If you must permanently stop taking ruxolitinib before your study participation is over, the study staff will discuss other options that may be of benefit to you. After you have completed your study participation, the study will not be able to continue to provide you with ruxolitinib that you received on the study. If continuing to take this or a similar drug/agent would be of benefit to you, the study staff will discuss how you may be able to obtain ruxolitinib.

Are There Benefits to Taking Part in This Study?

This study is intended to gather information about how ruxolitinib acts on your immune system, not to treat your HIV-1 infection. There is no anticipated benefit for taking part in this study. Information learned from this study may help others who have HIV.

What Other Choices Do I Have Besides This Study?

Instead of being in this study you have the choice of:

- treatment with prescription drugs available to you
- treatment with experimental drugs, if you qualify
- no treatment

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

What About Confidentiality?

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally.

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 <http://www.clinicaltrials.gov> as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your personal information may be given out if required by law. If you test positive for HIV or Hepatitis B or C 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 information about me may be collected, used or shared with others?

- Name, address, telephone number, email address, dates directly related to you such as date of birth and clinic visits.
- Personal and family medical history
- Current and past medications or therapies
- Information from questionnaires administered in the study
- 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 information and results of tests and procedures are used to:

- do the research

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

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator and the Investigator's study team
- Other authorized personnel at Penn, including offices that support research operations.

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 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.
- 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.
- Regulatory and safety oversight organizations: Data from this study will be made available to the The Office of Human Research Protections, the National Institutes of Health/Division of AIDS (DAIDS)/National Institute for Allergy and Infectious Disease (NIAID) and the Food and Drug Administration (FDA), for them to evaluate the safety and efficacy of the treatments being used in this study.

Once your personal health information is disclosed to others outside of 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.

Will I be able to access my records?

Since this is a double blinded study (treatment or placebo is not known to participant or study team), you will be able to access some or all of your medical records after the study is over. The Principal Investigator is not required to release research information to you that is not part of your medical record.

What if I decide not to give permission to use and give out my health information?

If you decide not to give permission to use and give out your health information, then you will not be able to be in this research study.

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

What is an Electronic Medical Record?

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

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

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

What Are the Costs To Me?

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. There will be no cost to you for study drug, study-related visits, physical examinations, laboratory tests, or other study procedures. Note that ARV medicines will not be provided by the study.

Will I Receive Any Payment?

You will be compensated \$50 for each required study visit (9 total) you attend. At the two visit when the 8 hour PK study will be done an additional compensation of \$100 (total compensation for each PK visit is \$150) will be provided. Compensation will be provided as cash for the screening visit and for the other visits on a ClinCard (debit card). The total compensation for the study is \$650 if all required visits

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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

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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