

IRB Approval
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UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

A5257, Version 1.0, 11/24/08; Letter of Amendment #1, 3/31/09

A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

If you are seen at the Hospital of the University of Pennsylvania [HUP], your contacts are:

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Coordinator:	Joseph Quinn, RN	(215) 349-8092
Study Nurse:	Kathryn Maffei, RN	(215) 349-8092
	Aleshia Thomas, RN	(215) 349-8092
	Wayne Wagner, RN	(215) 349-8092
	Larisa Zifchak, RN	(215) 349-8092

24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

Introduction:

You are being asked to take part in this research study because you are infected with HIV, the virus that causes AIDS, and have never received treatment or have received very minimal treatment for your HIV. You are treatment-naïve. This study is sponsored by the National Institutes of Health (NIH). The doctor in charge of this study at this site is Pablo Tebas, MD. 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. 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 will look at how well different combinations of anti-HIV drugs work to decrease the amount of HIV in the blood (viral load) of people who have never received anti-HIV therapy. The study will also see how well you tolerate the drug combinations and how safe they are.

The drugs being looked at in this study are atazanavir, ritonavir, darunavir, raltegravir, tenofovir disoproxil fumarate, and emtricitabine. All of the drugs used in this study are approved by the U.S. Food and Drug Administration (FDA) for treating HIV/AIDS; however, raltegravir is not currently approved by the FDA for treatment-naïve individuals.

How Many People Will Take Part in This Study?

About 1800 people will take part in this study. About 50 people are expected to participate at the University of Pennsylvania.

How Long Will I Be in This Study?

You will be in this study between 96 weeks and 192 weeks depending on when you join.

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

If you agree to join this study, you will be asked to sign this consent form. After you have signed the form, you will be asked some questions and will undergo some tests at the screening visit to see if it is safe for you to join the study.

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Screening

The screening visit will take about 1-2 hours. About 3 tablespoons of blood will be drawn.

- You will be asked about your health and any medicines you have taken in the last 30 days. You will also be asked about any anti-HIV medications that you may have ever taken.
- You will have a physical exam. The clinic staff will check your vital signs such as temperature, blood pressure, breathing, and pulse.
- You will have blood drawn for routine blood tests, HIV viral load, CD4+ and CD8+ cell count (the number of white blood cells that fight infection).
- You may have blood drawn to test for hepatitis B and C (viruses that can affect your liver) and for resistance testing (a test to see if the virus in your blood is likely to respond to study drugs).
- If you are a woman able to become pregnant, you will have a pregnancy test. Pregnant women cannot enter the study.
- An HIV test may be required to document your HIV status.

If you do not enroll into the study

If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of this screening visit, some demographic (e.g., age, gender, race), clinical (e.g., disease condition, diagnosis), and laboratory (e.g., CD4 cell count, viral load) information is being collected from you so that ACTG researchers may help determine whether there are patterns or common reasons why people do not join a study.

Pre-Entry

If you meet all the requirements to enter the study, you will come to the clinic at least 24 hours after the screening visit for pre-entry evaluations. You must come to the clinic fasting (no food or drink except water, decaffeinated black coffee without sugar, and your prescription drugs for the 8 hours just before the visit). This visit will last about 1-2 hours. You will have about 2 tablespoons of blood drawn.

- You will have a physical exam and your waist will be measured.
- You will have blood drawn for HIV viral load.
- You will have blood drawn to measure your cholesterol and triglycerides (amount of fat in your blood) and glucose (amount of sugar in your blood).
- You will have blood drawn and stored for future resistance testing.
- You will have a cardiovascular risk assessment performed.

Entry

At least 24 hours after, but within 14 days of your pre-entry visit, you will come to the clinic for entry evaluations. This visit will last about 2 hours. You will have about 4 tablespoons of blood drawn.

- You will have a physical exam.
- You will be asked about any medicine changes you have had since your screening visit.
- You will have blood drawn for routine blood tests, HIV viral load, and CD4+ and CD8+.
- You will have extra blood drawn and stored for future HIV-related ACTG approved research tests.
- You will be asked to give a urine specimen to monitor for possible drug effects on your kidney function.
- If you are a woman able to become pregnant, a pregnancy test will be done before you begin your study medications.
- You will be asked to complete some questionnaires and you will be asked about your smoking and alcohol habits.

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At entry you will be randomly assigned into one of three treatment groups. You will be assigned by chance (as if by the toss of a coin) to one of these groups. Your chance of being assigned to one of the groups is one in three. You will be told which group you are in. The groups are as follows:

Group A - emtricitabine/tenofovir disoproxil fumarate once a day + atazanavir and ritonavir once a day

Group B - emtricitabine/tenofovir disoproxil fumarate once a day + raltegravir twice a day

Group C - emtricitabine/tenofovir disoproxil fumarate once a day + darunavir and ritonavir once a day

Your study drugs will be given to you at this visit. Emtricitabine, tenofovir disoproxil fumarate, atazanavir, raltegravir, and darunavir are provided by the study. However, ritonavir is not provided by the study and will have to be obtained through your primary care physician (if you are assigned to Group A or C). If you become intolerant of any of the study medications during the study, your doctor can switch you to another regimen.

Post-Entry

During the study, you will be asked to return to the clinic at weeks 4, 8, 16, 24, 36, 48, and then every 16 weeks until the end of the study. You will also be contacted by telephone at week 2 to check on your status. Visits will last about 1 hour. At most visits you will have a physical exam and be asked about any medications that you may be taking. You will be given questionnaires to complete and asked about your smoking and alcohol habits. You will have blood drawn (2 to 4.5 tablespoons) for routine blood tests, viral load, CD4+ and CD8+. You will be asked to give urine specimens. Extra blood may be drawn and stored for future HIV-related ACTG approved research tests.

At some visits you will be asked to come to the clinic fasting (no food or drink except water, decaffeinated black coffee without sugar, and your prescription drugs for the 8 hours just before the visit) to measure cholesterol, triglycerides, and glucose. At some visits you will also have your waist size measured.

If you are in Group A or Group C, you may have approximately 4 tablespoons of blood drawn at your week 4 or 8 visit to measure the amount of study drug in your blood depending on when you join the study.

If you are a woman able to become pregnant, a pregnancy test will be done at any visit if pregnancy is suspected to make sure that you are not pregnant.

Virologic Failure Confirmation Visit

If your viral load has not decreased enough on the viral load test or your viral load increases at or after week 16, you will return for an additional visit and have a second viral load test within 30 days. You will also have blood drawn for resistance testing.

Evaluations After Virologic Failure Confirmed Visit

If your viral load has not decreased enough or has increased in the second viral load test, your doctor will ask you to come back to the clinic for another visit. This visit will last about 1 hour. You will have about 4 tablespoons of blood drawn.

- You will have a physical exam. The clinic staff will check your vital signs such as temperature, blood pressure, breathing, and pulse.

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- You will be asked about any medicine changes you have had since screening.
- You will have blood drawn for routine blood tests, HIV viral load, CD4+ and CD8+.
- You will have extra blood drawn and stored for future HIV-related ACTG approved research tests.

Your doctor may keep you on your current study drugs, or you may be switched to another study drug regimen selected by your doctor. You will continue to come in for your regular study visits as described above until the end of the study.

Premature Discontinuation of Study Therapy Visit

If you stop taking the study drugs before the end of the study, you will be asked to return to the clinic for additional evaluations. This visit will last about 1 hour. You will have about 2.5 tablespoons of blood drawn. You must come to this visit fasting (no food or drink except water, decaffeinated black coffee without sugar, and your prescription drugs for the 8 hours just before the visit). You also will be asked to continue to be part of the study and attend study visits even though you are no longer taking the study drugs.

- You will have a physical exam. The clinic staff will check your vital signs such as temperature, blood pressure, breathing, and pulse.
- You will be asked about any medicine changes you have had since screening.
- You will have blood drawn for routine blood tests, HIV viral load, CD4+ and CD8+, cholesterol, triglycerides, and glucose.

Final Visit

When you complete the study or if you leave the study early, you will be asked to come in to the clinic for final study evaluations. This visit will last about 1 hour. You will have about 4.5 tablespoons of blood drawn. You must come to this visit fasting (no food or drink except water, decaffeinated black coffee without sugar, and your prescription drugs for the 8 hours just before the visit).

- You will have a physical exam. The clinic staff will check your vital signs such as temperature, blood pressure, breathing, and pulse.
- You will be asked about any medicine changes you have had since your last visit.
- You will have blood drawn for routine blood tests, HIV viral load, CD4+ and CD8+, cholesterol, triglycerides, and glucose.
- You will have extra blood drawn and stored for future HIV-related ACTG approved research tests.
- You will be asked to give a urine specimen.
- You will be asked to complete some questionnaires and you will be asked about your smoking and alcohol habits.

You will be given the results of the pregnancy (if done), CD4+ and CD8+ cell counts, viral load, cholesterol, triglycerides, glucose, hepatitis B and C, and routine blood tests.

Other

Some of your blood will be stored (with usual protectors of identity) and used for immunology, virology, and metabolic testing that is required for this study.

Some of your blood that is leftover after all required study testing is done may be stored (with usual protectors of identity) and used for ACTG-approved HIV-related research. Storage of leftover blood is not a requirement to participate in the study and you may withdraw your approval for the storage of your leftover blood, at anytime. These samples may be held for an indefinite length of time. We

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cannot ensure that you will be told of the results of the research done on these samples. Please indicate and initial below whether you approve the use of your leftover blood.

_____ YES

_____ NO

Why Would The Doctor Take Me Off This Study Early?

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

- the study is cancelled by the ACTG, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), National Institutes of Health (NIH), other government agencies, the drug companies supporting this study, or the site's Institutional Review Board (IRB). (An IRB is a committee that watches over the safety and rights of research subjects.)
- a Data Safety Monitoring Board (DSMB) recommends that the study be stopped early. (A DSMB is an outside group of experts who monitor the study.)
- you are not able to attend the study visits as required by the study.
- You become imprisoned or involuntarily incarcerated in a medical facility and miss too many study visits and/or are unable to take your study drugs.

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

- continuing the study drugs 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 drugs as required by the study.
- you become pregnant or are breast-feeding (Group B only).

If you must stop taking the study drugs 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 I have to permanently stop taking study-provided drugs, or once I leave the study, how would drugs be provided?

During the study:

If you must permanently stop taking study-provided drugs before your study participation is over, the study staff will discuss other options that may be of benefit to you.

After the study:

After you have completed your study participation, the study will not be able to continue to provide you with the drugs you received on the study. If continuing to take these or similar drugs would be of benefit to you, the study staff will discuss how you may be able to obtain them.

What Are The Risks Of The Study?

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. If you have questions concerning the additional study drug side effects please ask the medical staff at your site.

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 also before starting any new medications while on the

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study. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.

Risks of the Questionnaire

You may feel embarrassed answering the questions in the questionnaire.

Risks of Drawing Blood

Taking blood may cause discomfort, bleeding, and bruising where the blood is drawn. Occasionally, there is swelling in the area where the needle enters the body and there is a small risk of infection. There is also a risk of lightheadedness, fainting, and blood clots.

Risks of Fasting

Some individuals find fasting to be bothersome. It may make some individuals feel anxious, irritable, or hungry. Patients who are required to take their morning medications with food should wait until after the visit has been completed to take their medications.

Risks of Combination Antiretroviral Therapy

Immune Reconstitution Inflammatory Syndrome (IRIS): In some people with advanced HIV infection, signs and symptoms of inflammation from other infections may occur soon after anti-HIV treatment is started.

The use of potent anti-HIV 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

Risks with the Use of Nucleoside Analogues (tenofovir disoproxil fumarate and emtricitabine are nucleoside analogues)

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.

Tenofovir Disoproxil Fumarate (Tenofovir DF, TDF, VIREAD®)

Gilead Sciences, Inc.

The following side effects have been associated with the use of tenofovir:

- Upset stomach, vomiting, gas, loose or watery stools
- Dizziness
- Abdominal pain
- Lack of energy
- Kidney damage or failure

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- Inflammation or swelling and possible damage to the pancreas
- Shortness of breath
- Rash
- Low phosphate, a chemical in the blood
- Increase of liver functions tests in children
- Allergic reaction, which may include fever, rash, upset stomach, vomiting, loose or watery stools, abdominal pain, achiness, shortness of breath or a general feeling of illness
- Changes in bone growth and strength were seen in study animals given tenofovir. Bone thinning has been seen in adults and children taking tenofovir.

NOTE: 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 tenofovir is stopped.

NOTE: Because there is only a small amount of information on tenofovir in pregnant women, tenofovir should be used during pregnancy only if clearly needed.

Emtricitabine (FTC, Emtriva™)

Gilead Sciences, Inc.

The following side effects have been associated with the use of emtricitabine:

- Headache
- Dizziness
- Tiredness
- Inability to sleep, unusual dreams
- Loose or watery stools
- Upset stomach (nausea) or vomiting
- Abdominal pain
- Rash, itching, which sometimes can be a sign of an allergic reaction
- Skin darkening of the palms and/or soles
- Increased cough
- Runny nose
- Abnormal liver function tests, which could mean liver damage
- Increases in pancreatic enzyme (substances in the blood), which could mean a problem with the pancreas
- Increased triglycerides
- Increased creatine phosphokinase (CPK), which could mean muscle damage

NOTE: 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 emtricitabine is stopped.

Emtricitabine, FTC/Tenofovir Disoproxil Fumarate, TDF (TRUVADA™)

Gilead Sciences, Inc.

No new or unexpected side effects are observed with the FTC 200 mg/TDF 300 mg combination tablet than those observed when each drug is given separately.

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Risks with the Use of Protease Inhibitors (atazanavir, ritonavir, and darunavir are protease inhibitors)

The use of protease inhibitors may be associated with the following:

- Increases in the amount of triglycerides and/or cholesterol in the blood (this has not been observed with atazanavir)
- Development of diabetes or the worsening of high blood sugar

There have been reports of increased bleeding in HIV-infected persons with hemophilia who were treated with protease inhibitors. It is not known if protease inhibitors were the cause of these bleeding episodes.

Risks with the Use of Atazanavir (ATV, Reyataz®)

Bristol-Myers Squibb Company

The following side effects have been associated with the use of atazanavir given together with ritonavir:

- Increased bilirubin, which may be associated with yellowing of the skin or eyes
- Rash which, may be severe and rarely may cause death
- A change in the way your heart beats (heart rhythm change). Symptoms you may experience if this occurs include dizziness or lightheadedness.
- Upset stomach, vomiting, and diarrhea
- Abdominal pain
- Increases in liver function tests
- Headache
- Trouble sleeping
- Dizziness
- Depression
- Muscle pain
- Cough
- Fever
- Kidney stones
- Gallbladder disorders such as gallstones and gallbladder inflammation

NOTE: Your healthcare provider can provide more complete information about the side effects of ritonavir (the medicine you need to take together with atazanavir).

Darunavir (DRV, Prezista™)

Tibotec, Inc.

The following side effects are also associated with the use of darunavir given together with ritonavir (RTV):

- People taking darunavir together with ritonavir may develop severe liver problems, which may be life-threatening. People who have increased liver function tests before starting darunavir and people with liver diseases such as hepatitis B or C have an increased risk for worsening of their liver disease.
- Rash which, in some people, may be severe or life-threatening. Contact your health care provider if you develop a rash.
- Diarrhea
- Nausea

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- Stomach discomfort
- Vomiting
- Headache
- Abnormal increases in cholesterol
- Abnormal liver function blood tests
- Abnormal pancreatic blood tests

NOTE: Before starting darunavir, you should inform your healthcare provider if you are allergic to sulfa medicines.

NOTE: Your healthcare provider can provide more complete information about the side effects of ritonavir (the medicine you need to take together with darunavir).

Risks with Use of Raltegravir (RAL, Isentress™)

Merck & Co., Inc.

The following side effects have been associated with the use of raltegravir:

- Diarrhea
- Nausea
- Headache
- Fever
- Vomiting
- Dizziness
- Abdominal pain
- Feeling weak
- Tiredness

In addition to the side effects listed above, additional serious reactions include:

- Allergic reaction
- Low amounts of red blood cells (anemia)
- Low amounts of white blood cells (neutropenia)
- Heart attack
- Irritation of the stomach lining (gastritis)
- Liver problems (hepatitis)
- Herpes
- Kidney problems, including kidney failure

Abnormal blood tests which have been seen in studies of raltegravir in combination with other HIV drugs include:

- Elevated liver related function tests, which may be a sign of liver problems
- Increase in an enzyme that may be a sign of pancreas problems (pancreatic amylase)
- Increase in an enzyme released by muscle cells, with or without symptoms such as muscle aches or pain, tenderness or weakness

Cancers have been seen in people who took raltegravir with other HIV drugs. The types of cancers seen are typical for people with very sick immune systems. It is unknown if the cancers were related to raltegravir use.

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Are There Risks Related To Pregnancy?

The drugs used in this study may be unsafe for unborn babies. If you are having sex that could lead to pregnancy, you must agree not to become pregnant or make someone else pregnant. Because of the risk involved, you and your partner must use at least one method of birth control. You must continue to use birth control until 6 weeks after stopping your medicines. You must choose one of the birth control methods listed below:

- Condoms (male or female) with or without a spermicidal agent
- Diaphragm or cervical cap with spermicide
- IUD
- Hormone-based contraceptive (must contain at least 35 mcg of ethinyl estradiol)

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. If you become pregnant while on study, the study staff will talk to you about your choices.

If you become pregnant at any time during the study, tell your study staff right away. The study staff will ask you to continue your study visits and you will be asked to sign another consent form.

Breastfeeding

It is unknown whether the study drug passes through the breast-milk and may cause harm to your infant. You must not breast-feed if 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. It is also possible 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 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.

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People who may review your records include the FDA, University of Pennsylvania IRB, OHRP, National Institutes of Health (NIH), study staff, study monitors, drug companies supporting this study, 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.

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.

The darunavir, atazanavir, raltegravir, emtricitabine/tenofovir disoproxil fumarate components of any chosen regimen will be provided by the study. The other drugs will not be provided by the study and will have to be obtained through your primary care physician by a prescription. The study does not have a mechanism for providing ritonavir for subjects without insurance.

Will I Receive Any Payment?

You will be compensated \$5 for the screening and pre-entry visits to cover the cost of transportation to the clinic. At enrollment and for every study visit thereafter, you will be compensated \$25 (cash) to cover transportation costs, parking, child care, etc and for your time and inconvenience. Thus, for the first year (screen to week 48) of the study, if you attend all 9 scheduled visits, the maximum compensation you will receive from the study is \$185. For year 2 (3 visits), you can receive \$75. If you are able to participate in years 3 and 4 of the study (depending on when you started the study), you can receive \$75 for each of these years (3 visits per year).

Additionally, if you are randomized to a study arm receiving ritonavir, the cost of your co-payments will be reimbursed if allowed by federal regulations. Some participants receiving Medicare or Medicaid may not be eligible to have their copayments be reimbursed.

Dr. Tebas receives compensation from some of the sponsors supplying drug for this study.

What Happens If I Am Injured?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you. There is no program for compensation either through this institution or the National Institutes of Health. If you have an illness or injury during this research trial that is

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not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

You do not give up your legal rights by signing this 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?

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-349-8092)
- Clinical Trials Unit (215 349-8092)

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

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

CONSENT

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

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

Name of Subject (Please Print)	Signature of Subject	Date
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Name of Person Obtaining Consent (Please Print)	Signature	Date
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For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

_____	_____	_____
Authorized subject representative [print]	Authorized subject representative Signature	Date

Provide a brief description of above person authority to serve as the subject's authorized representative.
