INTRODUCTION:
You are being asked to take part in this research study because you are infected with human immunodeficiency virus (HIV), you are receiving anti-HIV medications as part of another AIDS Clinical Trials Group (ACTG) study with a history of non-adherence to these HIV medications. 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. 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 determine if regular telephone calls from a registered nurse specializing in HIV care will help participants stick to their HIV therapy and improve their body’s ability to fight their HIV infection.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?
You may or may not already be enrolled in another AIDS Clinical Trials Group (ACTG) study (referred to as the partner study). If you are not enrolled in a parent study, you will have most of the testing for this study performed as part of your routine HIV care. If you have already enrolled in a parent study, some of the information collected as part of that study will be used for this study. The staff at your clinic will work with you to schedule your appointments for this study at the same time as the appointments for the partner study, so that the information and lab results collected can be used for both studies. However, if you stop being in the partner study, you may continue to be in A5251 and have all of the evaluations described below done as part of A5251 and your routine HIV care.

SCREENING
If you would like to be in this study, after you have read and signed this informed consent form, you will have a screening visit to make sure you meet the requirements for joining the study. This visit...
should last about 30 minutes. You may be asked questions about the anti-HIV medications you have taken. The results of a HIV viral load test (a measure of how much HIV is in your blood) done as part of your partner study or your routine HIV care will be recorded for this study.

Pre-Entry
If you qualify for the study, you will be asked to return to the clinic. The pre-entry visit should last about 30 minutes and will include:

- About 2 tablespoons of your blood (30 mL) will be drawn for a CD4+ cell count (a measure of blood cells that fight infection) and an HIV viral load test, as part of your parent study or your routine HIV care.

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 the screening and pre-entry visits, demographic (e.g., age, gender, race), clinical (e.g., disease condition, diagnosis), and laboratory (e.g., CD4+ cell count, viral load, HIV resistance genotype test result) data are 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. This information will be stored with the usual protectors of identity.

Entry
If you are eligible for the study, you will be contacted to come in for an entry visit within 45 days after the screening visit. This visit will last about 1 hour and will include:

- Questions about any medical conditions that you have or medical events that you have had in the past. You will also be asked about the medications that you have taken in the past or are currently taking.
- Questions about how often you miss taking your HIV medications and how satisfied you are with your life.
- About 2 tablespoons (30 mL) of your blood will be drawn for a CD4+ cell count and HIV viral load test, as part of your parent study or your routine HIV care.
- Enrollment to one of the study groups: the telephone group or the usual care group. You will be randomly assigned to one of the two groups. Random assignment means that you will be assigned by chance (like flipping a coin). You will have an equal chance of being randomized to either the telephone group or the usual care group. If you are randomized to the usual care group, you will continue to receive your HIV care as usual. If you are randomized to the telephone group, you will continue to receive your HIV care as usual and you will receive regular calls from an HIV nurse specialist (NEW-START nurse) at scheduled times over 48 weeks. The staff at your ACTG study site will know that you will be randomly assigned to either the telephone group or the usual care group. However, to protect your confidentiality, the staff at your site will not know which group you are in.

Telephone Calls from NEW-START Nurse
Participants assigned to the telephone group will receive calls from a NEW-START nurse in addition to usual care. If you are assigned to the telephone group, you will receive the first call from the NEW-START nurse within 3 days after your entry visit at the time and number you asked to be called (at study entry). If you do not receive a call within 1 week, you are in the usual care group. If the NEW-START nurse calls you, he/she will say his/her first name from the NEW-START Center and ask to speak with you (e.g., “This is Sam from the NEW-START Center”). The NEW-START nurse will then ask if you know the reason for the call. You should say something like “the HIV or HIV telephone
study”, “ACTG study” or “adherence study”, so that the NEW-START nurse can be sure that he/she is talking to you, the study participant. If you are called when you are not in a place where you can have privacy, ask the NEW-START nurse to call you back later. For example, you might say, “Now is not a good time. Please call me again in 1 hour.”

The NEW-START nurse is a specialist who is very experienced with HIV and medications used to treat HIV. During the first call, the NEW-START nurse will ask you some questions to learn a little about your situation such as how you have been doing with your HIV and what sort of problems you may have had taking anti-HIV medications in the past. At the end of the first call, the NEW-START nurse will schedule a regular time with you for follow up calls. Generally, the NEW-START nurse will ask how you are doing and try to address concerns you may have about management of your HIV and anti-HIV medications as they are prescribed. Some of the follow-up calls may be a little longer while others may be very brief, if, for example, you are doing well, do not have any questions, or are not able to speak with the NEW-START nurse at that time.

The NEW-START nurse will always try to call you at the arranged time, day and number of your choice. You will be asked to give a time and number at which you would like to receive the first call from the NEW-START nurse when you enter the study. Following this first call, you will be called at least weekly for 8 weeks and then at least every other week for 40 more weeks. The nurse will also be available by pager 10 hours each day while you are in the study. If you are not able to receive a call at the arranged time, please notify the NEW-START nurse so that the call time can be rescheduled. You will be given the cell phone number of the NEW-START nurse so that you can contact him/her directly if you need to. If the NEW-START nurse is not able to reach you at the arranged time, a message will not be left on a phone message system or with someone else who answers the phone. Instead, the NEW-START nurse will try reaching you again during the week of the scheduled call. If the NEW-START nurse is still not able to reach you (up to six attempts during that week), he/she will call you at the next scheduled time.

The NEW-START nurse calls will not change or interfere with the HIV care you normally receive from your ACTG site providers. The NEW-START nurse is an HIV specialist who is familiar with the ACTG, but the NEW-START nurse is not one of your regular ACTG site nurses. The calls made by the NEW-START nurse will be made from a cell phone at the NEW-START Center (located at a central ACTG site) which is not linked with your ACTG site telephones or health care providers. When the NEW-START nurse calls you, the calls will only be identifiable by a unique number. If you are in the telephone group and receive calls from the NEW-START nurse, the staff at your site will not know when you receive the calls or what you discuss on the calls unless you share this information with them. The NEW-START nurse will not have any contact with your ACTG site providers (e.g., by calls or e-mail) unless, in the rare event, the NEW-START nurse learns that you have a major health problem while you are in this study and have not yet let your ACTG site providers know about this health problem. If this happens, the NEW-START nurse will contact your site’s providers so they know about this problem. The NEW-START nurse will let you know if he/she is going to report any health problem to your site.

Study Visits After Entry
After you have enrolled into the study, you will come to the clinic for visits in 12, 24, 48, and 72 weeks. Staff at your clinic will try to schedule your visits so they occur at the same time as the visits for the other ACTG study that you are in. These visits will include:
• Questions about your health and any changes in your medications. You will also be asked about how often you miss taking your anti-HIV medications and how satisfied you are with your life.
• About 2 tablespoons (30 mL) of your blood will be drawn for a CD4+ cell count and HIV viral load test, as part of your ACTG parent study or routine HIV patient care. At the week 48 visit, the blood collected may be used as part of this study so that it may be analyzed for HIV viral load at a central laboratory, if not done so by your ACTG parent study or your routine HIV patient care.

Confirmation of Virologic Failure
If you have a blood test that shows that you might have virologic failure (the level of HIV in your blood is too high), you will be asked to return to the clinic within 4 weeks. This visit will include:
• Questions about your health and any changes in your medications. You will also be asked about how often you miss taking your HIV medications and how satisfied you are with your life.
• About 2 tablespoons (30 mL) of your blood will be drawn for a CD4+ cell count and HIV viral load test, unless this blood is collected and analyzed at the A5251 central laboratory as part of your parent study or your routine HIV care.

If You Have to Stop the Study Early
If you stop the study early, you will be asked to come to the clinic for a final visit This visit will last about 1 hour and will include:
• Questions about your health and any changes in your medications. You will also be asked about how often you miss taking your HIV medications and how satisfied you are with your life.
• About 2 tablespoons (30 mL) of your blood will be drawn for a CD4+ cell count and HIV viral load test, as part of your ACTG parent study or your routine HIV care.

How Many People Will Take Part in This Study?
About 296 people will take part in this study. About 10-20 people are expected to participate at the University of Pennsylvania.

How Long Will I Be In This Study?
You will be in this study for about 72 weeks (1.5 years).

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, NIH, Office for Human Research Protection (OHRP), or the site’s Institutional Review Board (IRB). (An IRB is a committee that watches over the safety and rights of research participants.)
• Your doctor no longer thinks it is in your best interest to continue the study.

What Are The Risks Of The Study?
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 Social Harm
Although the study site will make every effort to protect participant privacy and confidentiality, it is possible that participants’ involvement in the study could become known to others, and that social harms may result (i.e., because participants could become labeled as HIV-infected or at “high risk” for HIV infection). For example, participants could be treated unfairly or discriminated against, or could have problems being accepted by their families and/or communities.

Risks of Embarrassment
When you are interviewed about how satisfied you are with your life, you may feel embarrassment or discomfort.

What If I Become Pregnant While Taking Part In This Study?
If you become pregnant while participating in this study, your pregnancy will be reported to The Antiretroviral Pregnancy Registry, which collects information on the outcomes of pregnancies to women who took anti-HIV medications during pregnancy. Study staff may also contact you to ask about the outcome of your pregnancy.

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 support from the UPENN Clinical Trial Staff.

Please talk to your doctor about this and other choices available to you. The 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), University of Pennsylvania IRB, OHRP, National Institutes of Health (NIH), study staff, and study monitors. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study. Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

If you have a positive HIV test result in labs done for this study, by law we have to report the infection 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, date of birth
- Social security number (for W-9 so you can receive payments)
- 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 study

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:
A5251, Vsn 2.0, 9/23/11: An Adherence Study of Enhanced Nursing Telephone Support versus Usual ACTG Site Care

- AACTG Data Coordinating Center (FSTRF): Data will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. 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.
- 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 Food and Drug Administration and 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 Food and Drug Administration
- The Office of Human Research Protections
- The Study Monitoring Committee

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 vaccine 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 repository (database). However, UPHS and 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 to do so
- The University of Pennsylvania’s Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Will you be able to access your records?
During your participation in this study, you might not be able to access some or all of your medical records. For example, access to portions of your medical records may be denied in studies where your knowledge of study results included in such records could affect the reliability of the study.
You will have access to your medical record information when the study is over or earlier, if possible. The Principal Investigator is not required to release research information to you that is not part of your medical record.

Can you change your mind?
Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. 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 to use your personal health information, you will also be withdrawn from the research study.

If you withdraw your permission to use any blood obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that any information that could identify you is removed from these specimens.

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.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, 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.

Will I Receive Any Payment?
You will be compensated $25 for every visit (screen, pre-entry, entry, weeks 12, 24, 48 and 72) you attend as part of this study; this is in addition to the compensation given as part of the other ACTG study. The maximum compensation you can receive for participating in this study is $175. There is no other form of compensation available such as reimbursements for parking, tokens or child care available.

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, you must provide a Individual Tax Identification number or Social Security Number for tax purposes.

What Happens If I Am Injured?
If you have a medical emergency during the study 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 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 the University of Pennsylvania or the National Institutes of Health. If you have an illness or injury during this research trial that is 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:
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

________________________  _____________________________________
Name of Person Obtaining Consent (Please Print)  Signature                                  Date