UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Bristol Myers-Squibb AI467003: A Phase IIb Randomized, Controlled, partially Blinded Clinical Trial to Investigate Safety, Efficacy and Dose-response of BMS-986001 in Treatment-naive HIV-1-infected Subjects, Followed by an Open-label Period on the Recommended Dose

CONSENT FOR PHARMACOGENETIC BLOOD DNA SAMPLE AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Your contacts for this study at the Hospital of the University of Pennsylvania [HUP] are:

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Coordinator:	Joseph Quinn, RN, BSN	
Study Nurse:	Jenna Lewis, RN, BSN	

Site address: 502 Johnson Pavilion Philadelphia PA 19104
24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

Participation

You are being invited to participate in a research study. 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. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form

Purpose of the Study

The purpose of this consent form is to give you information so that you can decide whether you want to provide health information and an additional blood sample for pharmacogenetic research. The Study Doctor will collect the sample and health information and provide these to the Researchers. The Researchers (and not the Study Doctor) will conduct the pharmacogenetic research described in this form.

Your participation in this pharmacogenetic research is voluntary. If you decide that you do not want to participate in the pharmacogenetic research you may still participate in the main clinical trial **AI467003**.

There is no set number of subjects expected to participate in this research.

Introduction

Cells in the human body contain genes composed of deoxyribonucleic acid (DNA). The genes contain key instructions for cell function and help determine the characteristics of each individual. Pharmacogenetic research uses DNA samples from healthy and ill individuals to do the following:

- study the causes of human diseases
- help understand how different individuals respond to drugs
- obtain information to help develop new methods to diagnose and treat diseases

About This Research

The Study Doctor will replace your name with a code number and provide both the blood sample and your health information to the Researchers. The Researchers will place your coded information in a database and will store ("bank") your blood sample for up to 15 years, for use in pharmacogenetic research during this 15 year timeframe. When (or before) the 15 year period ends, your blood sample will be destroyed. Your health information collected from the main clinical trial will be kept on file in accordance with the Researchers' retention policies.

The Researchers will use DNA information obtained from your blood sample, along with your health information collected from the main clinical trial, to study the causes and progression of acquired immune deficiency syndrome (AIDS) and drug related response. The health information will be limited to information collected by your study doctor and data generated from any blood samples collected in the main clinical trial. You will not be contacted in the future by the Researchers to provide any further information.

This research may help us understand how individuals with specific medical conditions respond to drug treatments. The Researchers may also try to identify additional genes associated with these medical conditions, which may eventually lead to new treatments.

By signing this consent form, you give the Researchers permission to use your health information, your blood sample, and the DNA obtained from your sample for all the research described in this form

Procedure

If you agree to participate, and sign this informed consent, one blood sample (of approximately two teaspoons for an adult), will be drawn from your arm by study personnel during stage 1 of the Main trial, week 8 or later. This sample is in addition to any blood samples that will be drawn for the purpose of your medical care or the main clinical trial.

The Study Doctor and/or staff personnel are the only ones who will know your specific personally identifiable information that would allow someone to identify you and contact you. The Study Doctor will replace your personal information with a coded identification number when your samples and health information are given to the Researchers. The Researchers do not intend to use any information to identify or contact you.

Your Primary Physician may be informed about your participation in this clinical trial.

Risks

Risks associated with drawing blood from your arm include pain, bruising, lightheadedness and, on rare occasion, infection or numbness. Precautions will be taken to avoid these difficulties. Whenever possible, blood for the pharmacogenetic research discussed above will be drawn at the same time as samples for other required laboratory tests. If not, an additional needle stick may be required.

There are also non-physical risks associated with taking part in this study, such as the risks associated with a loss of privacy or confidentiality. For example, if your identity as a participant in pharmacogenetic research or your identifiable genetic or health information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers or insurance providers. The Researchers believe that the risks of such improper disclosure are very small because

strict privacy and confidentiality procedures for this research have been adopted. (See the "Privacy and Confidentiality" section of this Informed Consent).

Benefits

Although it is not anticipated that there will be any direct benefit to you as a result of your participation in the pharmacogenetic research, your participation may contribute to an increase in the knowledge and understanding of medical conditions and how different individuals respond to drugs, or help in the development of new methods to diagnose and treat diseases. **Neither you nor your doctors will be contacted by the Researchers in connection with the research or any information about the results of genetic tests performed on the sample that you donate for this research.**

Withdrawal of Consent and Destruction of Samples:

You may withdraw this consent and discontinue your participation in the pharmacogenetic research described above at any time without affecting your participation in the main clinical trial and without penalty or loss of benefits you are entitled to. There is the possibility for you to withdraw consent for the main clinical trial and discontinue your participation in the main clinical trial and still participate in the pharmacogenetic research.

To withdraw your consent, you must contact the study team at Penn listed on page one of this form, because only he/she has access to all of your identifying information. The Study Doctor will retain records that link information that identifies you (for example, your name and contact information) with your coded blood sample and health information, for the period of time required by applicable law. **If** you withdraw your consent for the pharmacogenetic research during this time, you may request that your blood sample and DNA obtained from your blood sample be destroyed and no longer used in research. However, after these records linking your identity to your sample are destroyed, it will no longer be possible for the Researchers to discard your sample if you withdraw your consent. The Researchers shall be entitled to retain and use any research results that were obtained prior to your withdrawal of consent. However, if you withdraw your consent but sample is partially analyzed, the part of the sample that is not analyzed will be destroyed but the results obtained from the part of the sample already analyzed before you withdrew consent will be retained.

Privacy and Confidentiality

The Researchers are sensitive to the privacy risks associated with genetic research, and will apply internal procedures to safeguard your privacy and confidentiality. For example, when your sample is sent to laboratories for DNA analysis, the sample may be identified by a randomly-generated bar code number. The link between your coded identification number and the bar code number on your sample is kept in a secure database and is not shared with the laboratories that analyze your sample.

Pharmacogenetic research is not intended to provide you with clinical information. Although you have the right to access information in your medical records at the University of Pennsylvania, including information related to the main clinical trial (once that study is complete), the information that is maintained in databases and created during pharmacogenetic studies is for research purposes only. The Researchers will not initiate the return of any of the genetic information to you or your health care provider. **Information resulting from the research will not be entered into your medical records.** At some point, information about the results of the research may be published; however, you will not be identified in any such publication.

It is possible, however, that members of regulatory authorities, such as the United States Food and Drug Administration, or the European Medicines Agency (EMEA) and other persons required by law may have access to the research results.

The Researchers may use other laboratories, investigators, commercial or academic third parties as their "agents" to assist in this research. If these agents assist in the research, your sample and some of your health information will be shared with them. The Researchers will require that these agents protect your privacy.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
• Health insurance companies and group health plans may not request your genetic information that we get from this research.
• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

HIPAA Authorization

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What information about me may be collected, used or shared with others?
The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- 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
- Social Security Number

Information that is created during your participation in the **AI467003** study will be used in this pharmacogenetic research. The information used and disclosed for this research will include the results of all tests and procedures performed during the AI467003 study.

If your medical or study records contain information concerning HIV/AIDS, substance abuse, mental health treatment, or genetic testing, by signing this form you also authorize the release of such information for purposes of the research.

Why is my 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.

Who may use and share information about me?
The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of 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 the School of Medicine, might receive my information?
As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- The Study Sponsor : The sponsor of the study will be able to view all study data along with its collaborators, research partners, assignees, licensees or designees and its/their affiliates and agents, and other individuals and organizations that analyze or use the data in connection with these studies, including laboratories and other study sites.
- Contract Research Organization : Monitors that are hired by the sponsor through CRO will visit the site to review data and correct mistakes before the data are sent for analysis.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration 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

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at 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, you will not be able to stay in this study.

Remember that this authorization applies to the use and disclosure of your information. If you no longer wish to have your samples used in the pharmacogenetic studies, you must also tell the Investigator that you withdraw your consent for use of the samples in the research.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

Will I have access to my protected health information that is obtained or created during the pharmacogenetic studies?

Although you have the right, subject to policies of University of Pennsylvania to access information in your medical records, including information related to the core clinical study (once that study is complete), the information that is maintained in study databases and created during future pharmacogenetic studies is for research purposes only. Any recipients of your protected health information, e.g., the research sponsor, will not initiate the return of any of the genetic information to you or your health care provider. At some point in the future information about the results of the studies may be published; however, you will not be identified in any such publication.

Development for Commercial Gain
The Study Doctor will be paid to obtain your blood sample for pharmacogenetic research and to transfer your health information to the Researcher. The DNA obtained from your blood sample may be used for the development of new therapies, diagnostic methods, medicines, treatments for disease, information, and other developments which may be patented or otherwise have commercial value to the Researcher, the Study Doctor, or other third parties. By consenting to participate in this research, you authorize the use of your sample for the research described above, and you acknowledge that there are no plans to provide financial benefits or compensation to you should this occur.

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.

Consent:
Protocol AI467003: **A Phase IIb Randomized, Controlled, partially Blinded Clinical Trial to Investigate Safety, Efficacy and Dose-response of BMS-986001 in Treatment-naive HIV-1-infected Subjects, Followed by an Open-label Period on the Recommended Dose**

By signing this Authorization form, you authorize (give permission for**)** the University of Pennsylvania and Dr. Pablo Tebas and the research staff to use and disclose your protected (identifiable) health information as described in this form. Your health information will be placed in one or more databases and this information will be used, in combination with the information learned about the DNA in your blood sample, to conduct current and future research involving genetic factors that influence the course of certain diseases such as cancer and patients' responses to medications. This research is referred to as pharmacogenetic research/studies.

I have read the preceding information describing this sample collection and all my questions regarding collection of my blood sample and health information for pharmacogenetic and related research have been answered to my satisfaction. I understand that after agreeing to participate in this research, I may later decide to withdraw this consent.

I agree to provide a blood sample and to permit my health information to be used and disclosed for pharmacogenetic research as described above. I understand that I will receive a signed copy of this consent form.

_____	_____	_____
Subject Signature	Printed Name	Date
_____	_____	_____
Signature of Person Obtaining Informed Consent	Printed Name	Date

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Investigator's Signature	Printed Name	Date

If the subject cannot read, the signature of an impartial witness is required:

Name of Impartial Witness	Date (to be entered by witness)	Signature

For situations in which consent of an adult subject cannot be obtained (e.g., emergency situations, dementia), the signature of a legally acceptable representative is required:

Name of subject's legally acceptable representative	Date (to be entered by subject's legally acceptable representative)	Signature
State relationship to the subject		

At any given time an incapacitated individual may explicitly refuse to participate in or request to be withdrawn from the clinical trial. The study doctor must respect the request.