PHARMACOGENETIC BLOOD DNA SAMPLE CONSENT

TITLE:	A Multi-arm, Phase 3, Randomized, Placebo Controlled, Double Blind Clinical Trial to Investigate the Efficacy and Safety of BMS-663068/GSK3684934 in Heavily Treatment Experienced Subjects Infected with Multi-drug Resistant HIV-1
PROTOCOL NO.:	AI438047/205888 WIRB® Protocol #20150142
SPONSOR:	ViiV Healthcare
INVESTIGATOR:	Pablo Tebas, MD 502 Johnson Pavilion Philadelphia, Pennsylvania 19104 United States
STUDY-RELATED PHONE NUMBER(S):	Pablo Tebas, MD 215-349-8092 215-662-6059 Ask for the Immunodeficiency Program Doctor on call (24 hours)
STUDY COORDINATOR(S):	Aleshia Thomas, RN, BSN Joseph Quinn, RN, BSN

Pharmacogenetic Research Amendment
This consent form may contain words that you do not understand. Please ask a Study Doctor or a member of the study staff to explain any words that you do not know, or any information that is unclear or confusing.

Researchers:
ViiV Healthcare, its research partners, collaborators, assignees, licensees or designees and its/their affiliates.

Purpose:
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 choose not to participate in this part of the study or choose to later withdraw, there will be no penalty or loss of benefits. If you decide that you do not want to participate in the pharmacogenetic research you may still participate in the main clinical trial, AI438047/205888. In connection with the pharmacogenetic research, you will also be asked to sign a separate form, known

as a HIPAA form, authorizing the use and disclosure of your protected personal health information for this additional study. There is no set number of patients 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 HIV-1 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, one blood sample (of approximately two teaspoons for an adult), will be drawn from your arm by study personnel. 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 blood sample will be stored by the centralized laboratory at the following location:

- LabCorp Clinical Trials Lab North America, 750 Walnut Ave, Cranford, NJ 07016 United States.

This sample may be sent by the centralized laboratory to:

BioProcessing Solutions Alliance, RUCDR-BioProcessing Solutions, 604 Allison Road, C120, Piscataway, NJ 08854 United States

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.

To withdraw your consent, you must contact the Study Doctor, Pablo Tebas, MD at 215-349-8092 or 215-662-6059 Ask for the Immunodeficiency Program Doctor on call (24 hours), 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.

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, subject to policies of **the University of Pennsylvania** to access information in your medical records, 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), the Western Institutional Review Board® (WIRB®) 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 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 Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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.

Records identifying you will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. All of your study data will be kept in a secure location. Your personal information may be given out if required by law. If you test positive for HIV, Hepatitis B or Hepatitis C, 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. Please note that it is likely that this information has been already reported to the PA Health Department as the HIV test being done for this study is not the first test for you. In the event of any publication regarding this study, your identity will remain confidential.

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 (if you receive more than $600 for participating in studies at PENN, we will need your SSN for the W-9)
- Personal and family medical history
- Current and past medications or therapies
- Results of physical exams, laboratory 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:
- Pharmaceutical sponsor (ViiV Healthcare): This is the company that supplies drugs for the study. Information regarding safety and adverse effects needs to be collected and monitored.
- Contract Research Organization: Monitors will visit the site on a regular basis to review data and assure accuracy and completeness of information before the data are analyzed.
- Regulatory and safety oversight organizations
- The Food and Drug Administration and regulatory agencies in other countries
- 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 or medical record number. Information regarding your health, such as side effects of the study medications 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?
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.

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 or tissue obtained for the study, the Sponsor may need to retain and use any samples that have already been collected to comply with its legal obligations and to maintain the scientific integrity of the 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.

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).

Questions/Information:
If you have any questions concerns or complaints regarding this sample collection or pharmacogenetic research or if you experience an injury caused by the sample collection procedure, you should contact Pablo Tebas, MD at 215-349-8092 or 215-662-6059 Ask for the Immunodeficiency Program Doctor on call (24 hours). If you have any questions about your rights as a study subject or if you have questions, concerns, or complaints about the research, you should contact Western Institutional Review Board® WIRB®, 1019 39th Avenue SE Suite 120, Puyallup Washington 98374-2115, by telephone at 1-800-562-4789 or 360-252-2500, or by e-mail at Help@wirb.com. An IRB or ethics committee is a group of medical and non-medical individuals who have reviewed the study information with the subject's protection in mind.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Consent:
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 have consented to participate in the main clinical trial.

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
Physician/Designee's Signature	Printed Name	Date

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

Witness Signature	Printed Name	Date