**Form #2 02/99**

**Human Studies Committee**

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

Participant HSC Approval Number

Principal Investigator PI’s Phone Number:

Title of Project: Report India Project: **Blood Donation for the Immunology Quality Assessment Program**

 This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

You are being asked to participate in a blood donor program for the Immunology Quality Assessment Program (IQA) under the local direction of Dr William Powderly.

1. **You are invited to participate in a research study conducted by Dr. and/or colleagues. The overall purpose of this research is:** to measure the quality of blood tests being done by our laboratories by sending a blood specimen from two donors to a central testing lab which will compare its findings to our labs to make sure that our laboratory reports the correct results. This type of testing for quality will help assure that HIV infected patients throughout the United States have accurate immune blood tests that monitor their disease. We are one of many laboratories throughout the United States that perform immune blood tests to follow the course of HIV disease.

This study will enroll approximately 8-12 people. This study will last seven years. Your participation, however, will be limited to one blood donation per year.

# Your participation will involve: Screening

If you decide to participate as a blood donor in this study and sign this consent, you will have tests and examinations done before you donate any blood. This is being done to be make sure that you qualify for the study and that you will be able to donate blood without harm to you.

These tests and procedures include a history, general physical exam, including blood pressure, body temperature, heart, and breathing rate. Your hemoglobin level will (about 2 teaspoon of blood) be measured to make sure that you are not too anemic (having low numbers of red cells) to participate in this program without affecting your health.

# Blood Donation

Once it is determined that you are able to participate in this project, an appointment will be made for the days that your blood will be drawn. Blood will be obtained by inserting a needle in your arm vein; the amount of blood to be taken will vary, but will not exceed 100 ml (6 tablespoons). You will be allowed to donate no more than once a year and will receive payment for each pre-screen visit and blood donation. The Medical Director will be available to discuss any screening test results with you and will share these results with your physician, if you approve.

**Financial consideration:** Your ability to pay will not affect your participation in this study. You will receive payment for your participation in this blood donor program in the amount of $50.00 to

$100.00. The amount you receive is dependent on the amount of time required to complete the pre-screen visit and the blood donation.

Screening visit = $50.00/enrollment

Up to one hour of time (Blood Donation) = $50.00

1. **There are certain risks and discomforts that may be associated with this research. They include:** As a blood donor, you should understand that there may be some risks and side effects associated with donating blood. Drawing blood from a vein can cause local pain, bruising or bleeding from where the needle enters the skin. There is also a minimal risk of inflammation or infection of the vein, decreased blood pressure, dizziness or fainting that can occur during or after you donate blood.

# The possible benefits to you and society from this research are:

As a blood donor, you will receive no therapeutic benefit from this study. However, the improvement in the quality of the blood studies being performed in the laboratories throughout the United States, will benefit all HIV infected patients who need to have these blood studies done as part of their routine medical care and participation in clinical drug trials

1. Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time. Your choice will not at any time affect the commitment of your health care providers to administer care and there will be no penalty or loss of benefits to which you are otherwise entitled. Other than non-participation in the research, available alternatives include:

Since this is not a treatment study, there is no alternative, except not to participate and have blood tests done by your primary care doctor at a clinical laboratory.

1. All reasonable measures to protect the confidentiality of your records and your identity will be taken. Your identity will not be revealed in any publication that may result from this study. The confidentiality of all study related records will be maintained in accordance with State and Federal laws. There is a possibility that your medical research record, including identifying information, may be inspected and photocopied by officials of the Federal or State government agencies and the University Human Studies Committee and the National Institutes of Health.
2. If you have any questions or concerns regarding this study, or if any problems arise, you may call the Principal Investigator at . You may also ask questions or state concerns regarding your rights as a research subject to Dr. , Chairman of the University’s Institutional Review Board, at
3. University investigators and their colleagues who provide services at University Medical Center hospitals, and facilities recognize the importance of your contribution to research studies that are trying to improve medical care. University investigators and their staffs will make every effort to minimize, control, and treat any complications that may arise as a result of this research. If you believe that you are injured as the result of the research question being asked in the study, please contact the Principal Investigator and/or the Chairman of the Institutional

Review Board as stated in item 7. Washington University reserves the right to make decisions concerning payment for medical treatment for injuries solely and directly relating to your participation in biomedical or behavioral research.

1. You will be informed of any significant new findings developed during the course of participating in this research that may have a bearing on your willingness to continue in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

# I have read this consent form and have been given the opportunity to ask questions. I will also be given a signed copy of this consent form for my records. I hereby consent to my participation in the research described above, titled: ACTG 001: Blood Donation for the Immunology Quality Assessment Program

Parent or legal guardians’ signature on /Date Participant’s Signature Date Participants’ behalf if participant is less than 18

years of age or not legally competent.

(Blood drawing only: Less than 17 years of age.) Informed Consent provided by:

Relationship to Child Signature of Principal Investigator or Designee Date

 Signature of Principal Investigator or Collaborating Investigator when informed consent responsibility is entrusted to a designee. See HSC Guidelines on Who May Obtain Consent to Participate in Research Activities.

**This form is valid only if the Institutional Review Board’s current stamp of approval is shown below.**