You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Why are you being asked to take part in this study?

You are being invited to take part in this research study because you are HIV-infected and are about to start medication to fight the virus.

What is the purpose of this research study?

The purpose of this research study is to look at the effects of the HIV virus (the virus which can lead to AIDS) on the immune system, and the ability of the immune system to fight the virus.

How many people will take part?

About 15 people will take part in the study.

What is involved in the study?

If you agree to take part, your participation will last for two or three (if necessary) visits. A third visit may be required to repeat some of the laboratory tests.
Study Procedures

If you take part in this study, 5 teaspoons (25 ml) of blood will be drawn for this study at each visit. Visit 1 will take place prior to the start of medication. Visit 2 and 3 (if necessary) will take place approximately 8 and 16 weeks after the start of medication. There are no other study procedures.

Visit Schedule

The table below provides a brief description of the purpose and duration of each study visit.

<table>
<thead>
<tr>
<th>Visit</th>
<th>Purpose</th>
<th>Procedures</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>Entry visit</td>
<td>Blood drawn</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Visit 2, Month 2</td>
<td>Follow up visit</td>
<td>Blood drawn</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Visit 3, Month 4 (if necessary)</td>
<td>Follow up visit</td>
<td>Blood drawn</td>
<td>10 minutes</td>
</tr>
</tbody>
</table>

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you are at risk for the following side effects:

**Risks associated with blood drawing procedures:**

There may be some discomfort from the blood drawing procedures, such as bruising or pain at the site of blood removal, but being in this study will not increase these risks.

Are there any benefits to taking part in this study?

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may benefit children/adults in the future through better understanding of the effects of HIV on the immune system.

Do you need to give your consent in order to participate?

Once you read this form and had your questions answered, you will be asked to decide if you wish to participate. If you wish to participate in this study, you will have the choice of signing or not signing this form. A copy will be given to you to keep as a record.
What happens if you decide not to take part in this study?

Participation in this study is voluntary; you do not have to take part in order to receive care at PENN. If you decide not to take part or if you change your mind there will be no penalties or loss of any benefits to which you are otherwise entitled. Your current and future medical care at PENN will not be affected by your decision.

Are there alternatives to participation in this study?

There are other options for you other than this study including:

Not participating in the study.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

All blood samples collected for this study will be coded and anonymously tested so the donor’s identity will be protected. We will do this by assigning a study number to your sample and your name will not appear on the sample. A master list of study participants will be kept in a locked filing cabinet in a locked office at 834 Penn Tower. Only the study doctors and those working with them on this study will be able to see this information.

Medical information about you, including HIV status, CD4 count and HIV viral load will be available to laboratory personnel only. We need to collect health information about you in order to conduct this study. This includes information about you from medical records and from the tests that are part of this research. Routine clinical laboratory tests performed as part of this study will appear in your medical record. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation about the study.

People and organizations that may inspect and/or copy your research records to conduct this research, assure the quality of the data and to analyze the data include:

• Members of the research team at CHOP and UPenn;
• Medical staff who are directly or indirectly involved in your care related to this research;
• People who oversee or evaluate research and care activities at CHOP;
• People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your
information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

**What are my rights and responsibilities as a research subject?**

This research study only involves two or three blood draws.

You may change your mind and take back your authorization to use and disclose your health information at any time. Even if you take back your authorization, we may still use and disclose the health information we have already obtained about you as necessary to maintain the integrity or reliability of the current research. To take back your authorization, you must send a letter to Dr. Steven D. Douglas. In the letter, you must say that you changed your mind and do not want us to collect any more health information about you. If you ask that we no longer collect your health information you will have to leave the study.

**Financial Information**

**Will there be any costs to you?**

The National Institutes of Health are providing financial support and material for this study and the procedures described above. There are no additional costs to you or your insurance.

**Will you be paid for taking part in this study?**

If you decide to take part in this study, you will be compensated $40.00 cash at the time of each blood donation.

**Who is funding this research study?**

The National Institutes of Health is providing funding for this study.

**What if you have questions about the study?**

If you have questions about the study, call the study doctor, Dr. Steven D. Douglas at 215-590-1978. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children’s Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure your rights and welfare are protected. You can talk to a person from this group if you have questions about your rights as someone taking part in a research study. You can call the IRB Office at 215-590-2830 if you have questions or complaints about the study.
Consent to Take Part in this Research Study and Authorization to Disclose Health Information

Do I have your permission to enroll you in this study?:

<table>
<thead>
<tr>
<th>Person Obtaining Verbal Consent</th>
<th>Signature of Person Obtaining Verbal Consent</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Date:</td>
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CHOP IRB#: IRB 09-007380
Approval Date: 12/28/2009
Expiration Date: 12/27/2010