Approval Date: September 2, 2003
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University of Pittsburgh
Institutional Review Board
IRB #990609
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CONSENT FORM FOR HIV TESTING AND COUNSELING

CONSENT TO ACT AS A SUBJECT IN A CLINICAL STUDY

TITLE: HIV Testing and Counseling

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SOURCE (S) OF SUPPORT: **National Institutes of Health: National Heart, Lung & Blood Institute**

DESCRIPTION: You have been asked to participate in a research study which will involve testing your blood for HIV antibodies**.**

PURPOSE, MEANING, AND LIMITATIONS:
You agree to have about 2 tablespoons of blood drawn from a vein in your arm. This sample will be tested for the antibody to HIV. An antibody is a substance that blood cells make to fight infection. A positive HIV test means that your blood sample tested positive for HIV and that repeat testing will be performed to confirm (prove) this finding. If your sample is proved to be positive for HIV, it means that you are a carrier of HIV. It also means that you can pass the virus to others by intimate sexual contact, by sharing needles, and through donating blood and organs. A negative HIV test means that at this time, no antibody to HIV was found in your blood sample based on the result of the initial screening test, repeat screening tests, or a confirmatory test.

There can be individuals who have HIV test results that are called "false positive," i.e., for some reason, the test indicates that HIV antibodies are present in the blood when they are not. There can also be false negative results which can have two possible meanings; the person has been infected with HIV, but that person's body has not yet made antibodies to the virus, or HIV antibody is present in the person's blood, but for some reason the test failed to detect it. You will be contacted when your test results are complete and you will schedule an appointment to learn your HIV results.

If you test positive for HIV antibody, you will be asked to give 2 tablespoons of blood for a repeat HIV antibody test. You will also be counseled as to the risks for transmitting HIV to others, risks for developing AIDS, and the available treatments for HIV infection. You will return to the clinic to receive results from this repeat test, but will no longer be tested in the clinic for HIV antibody. You will be referred, if desired, for proper medical care. **Subject's Initials: _____**

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RISKS AND BENEFITS: The benefits of participating in this study is that you will be tested for HIV infection and counseled regarding HIV infection at no cost to you. You will be given the results of these tests and referred for proper medical care, if needed and desired. The risks of participating are minimal. They include the discomfort of drawing a sample of blood, rare bruising and infection at the site of needle stick, and very rarely, fainting. There may be emotional discomfort or stress associated with knowledge of the results of this test.

COSTS AND PAYMENTS: There will be no costs for participating in this testing and the associated counseling. The blood tests will be free of charge. Also, you understand that you will receive no payment.

CONFIDENTIALITY: You understand that your name is not recorded anywhere in the files for this study. Consequently, you understand that any information obtained from this testing will be anonymous and be stored in locked files. You will not be identified in any publication. You understand that all information will be handled in compliance with the Pennsylvania law on HIV-related confidential information. You understand that in the case of a positive test result, in accordance with Pennsylvania law, the study physician is required to report your name and other identifying information to Allegheny County Health Department officials. In unusual circumstances, you understand that your research records may be inspected by appropriate government agencies or be released in response to an order from a court of competent jurisdiction, but the records do not contain your name or identification.

RIGHT TO REFUSE: You understand that you do not have to take part in this testing. However, once you have the test performed you understand that it is a requirement that you be informed of the results. You understand that counseling is available to you before you make the decision to participate in this testing.

COMPENSATION FOR ILLNESS OR INJURY: In the event that you are injured as a result of this study, the University of Pittsburgh will provide you with necessary care. The University of Pittsburgh reserves the right to bill your third-party insurance provider for the cost of such treatment, and you may be billed for any costs your insurance does not cover. The University of Pittsburgh will not provide you with any additional compensation as the result of such injury.

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VOLUNTARY CONSENT: All of the above has been explained to me and all of my questions have been answered. I also understand that any future questions I have about this research will be answered by the investigator(s) listed on the first page of this consent document at the telephone numbers given. Any questions I have about my rights as a research subject will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (412-578-8570). By signing this form, I agree to participate in this research study.

_____ _____
Patient/Subject Signature **Date**

_____ _____
Witness Signature **Date**

CERTIFICATION OF INFORMED CONSENT: I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____
Printed Name of Person Obtaining Consent **Role in Research Study**

_____ _____
Signature of Person Obtaining Consent **Date**