# ICD 6

# PARTICIPANT INFORMED CONSENT FOR HUMAN IMMUNODEFICIENCY VIRUS

# (HIV) TESTING

**Study title: …………………………………………………………………………………………….**

**……………………………………………………………………………………………………………..**

**Principal Investigator: …………………………………………………………………………….**

**Supervisor: …………………………………………………………………………………………..**

**Institution: ……………………………………………………………………………………………**

**DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):**

**Daytime number/s: …………………………………………………………………………**

**Afterhours number: …………………………………………………………………………**

**Date and time of first informed consent discussion:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  | **:** |
| **date** | **month** | **year** |  | **Time** |

**Dear Prospective Participant**

**Dear Mr. / Mrs. ……………………………..**

1. **INTRODUCTION**

You are being invited to undergo a human immunodeficiency virus (HIV) test to test if you are positive for HIV. Before agreeing to participate in this research study, it is important that you read and understand the following information on HIV testing. There will be no costs involved for you to be part of the study.

1. **EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS**

Your will receive counseling both before and after you have taken the test. The HIV test will be carried out on a sample of your blood. The test can detect antibodies made by your immune system when HIV is present. The HIV/AIDS antibody test is used to determine if you have been infected with HIV. A HIV test is extremely accurate if performed three months after exposure to HIV.

A negative test means that it is unlikely that you are infected with HIV. If you had a recent exposure (less than three months ago), a HIV test will need to be repeated to confirm that you are not in the “window” period of HIV infection, before the antibodies are present.

A confirmed HIV-positive test means that it is very likely that you have been infected with HIV. This test does not determine how advanced the illness is and is it not a test for AIDS. Medical care and additional testing will be needed to help plan treatment.

You will be referred to a specialist clinic for further testing and counseling. The clinic is required to provide counseling and treatment that conforms to the national standard of care for HIV prevention and treatment.

1. **ADVANTAGES AND DISADVANTAGES OF HUMAN IMMUNODEFICIENCY VIRUS TESTING:**

Advantages of HIV testing include:

* Making yourself available to health care and counselling for HIV which has many benefits.
* Preventing the spread of HIV to your sexual partners.
* Informing your partner so that he or she can also prevent the spread of HIV.
* Avoiding blood donations.
* Preventing the spread of HIV from mother-to-child.

Disadvantages of HIV testing may include:

* Feeling emotional stress, depression and despair.
* Feeling shamed.
* Feeling judged.
* Feeling rejected by family, friends, sexual partners and/or spouse.

The advantages and disadvantages should be carefully considered before signing the consent form.

1. **POTENSIAL RISKS AND DISCOMFORTS**

Possible side-effects from drawing blood include feeling faint, inflammation of the vein, pain, bruising or bleeding at the site of puncture.

1. **COMPENSATION**

You will not be paid to take part in the study. However, any cost you have because of taking part in the study, for example ………………….. , and transport costs will be paid back to you (reimbursed).

**OR [delete the option that is not applicable]**

You will not be paid to take part in the study. There are no costs involved for you to be part of the study.

1. **YOUR RIGHTS AS A RESEARCH PARTICIPANT**

Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to other medical care.

1. **ETHICS APPROVAL**

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

1. **CONFIDENTIALITY**

Your HIV testing information and test results cannot be released to anyone without your written consent. General consent to health care and information release does not cover HIV-related information. If you are found to be HIV infected, you are personally not required to tell anyone about this diagnosis. However, it is very important to notify your sexual partners and those who might have been exposed to your blood.

1. **INFORMED CONSENT STATEMENT**

|  |  |
| --- | --- |
| 1. I confirm that I have read and understood the above information document, and that I have been informed about the nature, conduct, and potential benefits and risks of HIV testing, and have had the opportunity to ask questions. |  |
| 1. I understand that I will be informed of the results of the test in confidence, and that should the result be positive, I will be advised about further counselling and care. |  |
| 1. I will receive a signed copy of the *Patient information Document and Consent Document for HIV testing.* |  |

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Printed name of participant

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Participant signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of Investigator

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Signature of Investigator Date