# ICD 9a

# PARTICIPANT’S INFORMATION & INFORMED CONSENT

# DOCUMENT FOR CRITICALLY ILL PATIENTS ADMITTED IN AN

# INTENSIVE CARE UNIT [ONCE A PATIENT HAS BECOME CAPABLE OF CONSENTING TO THE RESEARCH]

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

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

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

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

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

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

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

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

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

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

**Dear Prospective Research Participant**

**Dear Mr. / Mrs. ......................................................................**

**This Informed Consent Document has two parts: (You will be given a copy of the full Informed Consent Document)**

* **PART I: Information Document (to share and explain information about the research with you)**
* **PART II: Certificate of Consent (for your signature if you agree to take part in the research)**

**PART I: Information Document**

**1) INTRODUCTION**

You are invited to volunteer for a research study. I am doing this research for …………degree purposes at the University of Pretoria. The information in this document is provided to help you decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this document, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about all the procedures involved.

**2) THE NATURE AND PURPOSE OF THIS STUDY**

The aim of the study is to evaluate the…………(type of disease etc) …....................................................................................................................

By doing so we wish to learn more about ……………………………………………

…………………………………………………………………………………………….

**3) EXPLANATION OF THE PROCEDURES TO BE FOLLOWED**

This study involves answering some questions with regarding your illness, examination of yourself, ECG, weight and height, measurements, blood and urine tests. We will also measure the blood pressure. The following tests will be done for the research specifically: ………………………………………. ……………………………………………………………..

…………………………………………………………………………………………………………….

**4) POSSIBLE RISKS AND DISCOMFORTS OF THE STUDY**

There will be no foreseeable physical or emotional discomfort or risk involved. The only possible risk and discomfort involved is taking blood from a vein with possible bruising and bleeding at the site etc.………………………………………………………….

……………………………………………………………………………………………………………

**5) POSSIBLE BENEFITS OF THIS STUDY**

There are no anticipated direct benefits to you for participating in this study. Your participation is important for gathering more information on…………………. ..……………………………………………………………………………………………………

The information you provide may help researcher improve………………………………………

…..……………………………………….…………………………. ………………….

**6) COMPENSATION**

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

**7)** **YOUR RIGHTS AS A PARTICIPANT**

Your participation in this study is entirely voluntary. You can refuse to participate or stop at any time during the study without giving any reason. Should you wish not to participate your care will not be compromised and your management / treatment will not differ in any way to those participating. All services usually provided to patients in the critical care unit will be provided to you no matter if you decide to participate or not.

**8) HAS THE STUDY RECEIVED ETHICAL APPROVAL?**

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, Medical Campus, Tswelopele Building, Level 4-59, 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 humans. A copy of the Declaration may be obtained from the investigator should you wish to review it.

**9) CONFIDENTIALITY**

All information obtained during the course of this study will be regarded as confidential. Each participant that is taking part will be provided with an alphanumeric coded number e.g. A001. This will ensure confidentiality of information so collected. Only the researcher will be able to identify you as participant. Results will be published or presented in such a fashion that participants remain unidentifiable. The hard copies of all your records will be kept in a locked facility at ………………………, University of Pretoria.

**10) INFORMATION ON WHOM TO CONTACT**

Should you wish to discuss withdrawing from the study or still have questions about the study, you can contact: Dr ……………………………………………………… Cell nr ……………………………………………or Telephone nr. ………………………………………

**PART II: Certificate of Consent**

**CRITICALLY ILL PATIENTS THAT ARE ABLE TO CONSENT IN WRITING:**

I declare that I have read the Information Document contained in PART I above, or it has been read to me.

* I confirm that the person requesting my consent to take part in this study has told me about the nature and process, any risks or discomforts, and the benefits of the study.
* I have also received, read and understood the above written information about the study.
* I have had adequate time to ask questions and I have no objections to participate in this study.
* I am aware that the information obtained in the study, including personal details, will be anonymously processed and presented in the reporting of results.
* I understand that I will not be penalised in any way should I wish to discontinue with the study and my withdrawal will not affect my current treatment or the services I will receive.
* I am participating willingly.
* I have received a signed copy of this informed consent agreement.

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

Participant’s name (Please print) Date

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

Participant’s signature Date

**STATEMENT BY RESEARCHER OBTAINING INFORMED CONSENT:**

I declare that the Information Document (PART I above) has been read by or accurately read out to the potential participant. I confirm that I have to the best of my ability made sure that the participant understands all the procedures outlined therein to be undertaken on enrollment of the patient in the study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the participant has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

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

Investigator's Name (Please print) Date

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

Investigator's Signature Date

**AFFIRMATION OF INFORMED CONSENT BY AN ILLITERATE PARTICIPANT**

**(if suitable)**

I, the undersigned, ………………………………………..…, have read and have explained fully to the participant, named ………………………… , the informed consent document, which describes the nature and purpose of the study in which I have asked the him/her to participate. The explanation I have given has mentioned both the possible risks and benefits of the study. The participant indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason and without jeopardizing his/hers standard care.

I hereby certify that the patient has agreed to participate in this study.

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

Participant’s name (Please print) Date

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

Participant’s signature Date

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

Investigator's Name (Please print) Date

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

Investigator's Signature Date

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

Name of the person who witnessed

the informed consent (Please print) Date

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

Signature of the Witness Date