# INFORMATION & INFORMED CONSENT DOCUMENT FOR RELATIVES OF CRITICALLY ILL PATIENTS ADMITTED IN AN

# INTENSIVE CARE UNIT

**Study title:**

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

**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 Relative of a potential 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)**

**1) INTRODUCTION**

We would like to enroll your relative in a research study. The information in this document is provided to help you decide if your relative may participate in the study. Before you agree that your relative may 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 for your relative to take part unless you are completely happy about all the procedures involved.

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

The aim of this study is to evaluate …………………………………………………………………..By doing so we wish to learn more about …………………………………………………………...

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

You relative will receive the standard management of their illness. The researchers would like ………………………………………………………………………………………………………………..(explain the aspect that will be specific to the research).

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

There are no medical risks associated with the study. The only possible risk and discomfort involved is the taking of blood from a vein which can result in bruising and bleeding from the puncture site.

**OR**

We foresee the following risks if your relative takes part in the study…………………………………….

**5) POSSIBLE BENEFITS OF THIS STUDY**

Although your relative may not benefit directly, the study results may help us to …………………

**6) COMPENSATION**

Your relative will not be paid to take part in the study. There are no costs involved for you or your relative to be part of the study.

**7)** **YOUR RELATIVE’S RIGHTS AS A PARTICIPANT**

Your relative’s participation in this study is entirely voluntary. You can decline that your relative participate or stop their participation at any time during the study without giving any reason. Should you wish that your relative should not to participate, your relative’s care will not be compromised and their management/treatment will not differ in any way to those participating. All services usually provided to patients in the hospital will be provided to your relative, even if you decide your relative may not participate in the research study. Once your relative is able to give consent themselves, they will be asked to confirm or withdraw consent to participation in this research.

**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 your relative as a 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 have questions about the study, you can contact:

………………………….…Cell…………………………or Telephone nr. ………………………

**PART II: Certificate of Consent**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the SPOUSE/PARTNER/PARENT/GRANDPARENT/ADULT CHILD/BROTHER/SISTER (circle applicable) of patient \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 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 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 for my relative to take part 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 my relative will not be penalised in any way should they wish to discontinue with the study and that their withdrawal will not affect their further treatment /management.
* I have received a signed copy of this informed consent agreement.
* I understand that when my relative can give their own consent at a later stage, they will be asked to confirm or withdraw the consent.

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

Relative’s name (Please print) Date

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

Relative’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’s relative. I confirm that I have to the best of my ability made sure that the participant’s relative understands all the procedures outlined therein to be undertaken on enrollment of the patient in the study.

I confirm that the participant’s relative was given an opportunity to ask questions about the study, and all the questions asked by them have been answered correctly and to the best of my ability. I confirm that the relative 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’s relative.

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

Investigator's Name (Please print) Date

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

Investigator's Signature Date

**AFFIRMATION OF INFORMED CONSENT BY AN ILLITERATE RELATIVE OF PARTICIPANT (if suitable)**

I, the undersigned, ………………………………………..…, have read and have explained fully to the relative…………………………………………………………….. of the patient: named ………………………… ……., the informed consent document, which describes the nature and purpose of the study. The explanation I have given has mentioned both the possible risks and benefits of the study. The relative of the patient has indicated that he/she understands and also that the patient will be free to withdraw from the study at any time for any reason and without jeopardizing his/hers treatment / management..

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

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

Relative’s name (Please print) Date

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

Relative’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