ICD - 1B

PARENTAL OR LEGAL GUARDIAN INFORMATION & INFORMED CONSENT

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| --- |
| **Consent and assent:**  If there are children younger than 7 years in your study, the parents/ legal guardians need to give consent on their behalf and you will need to adapt the information document by substituting “you” with “your child”.  For children between 7 and 18 years, parents/ legal guardians give parental / legal guardian consent for their/the child to participate in the study and the child gives assent. The assent information consent form needs to be in very simplified language. Both the parental/legal guardian information consent document and the assent form have to be included with your application.  Please remove this instruction box from your final ICD. |

**STUDY TITLE**: **………………………………………………………………………………………**

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

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

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

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

**DAYTIME AND AFTERHOURS TELEPHONE NUMBER(S):**

**Daytime number/s…………………………………………………………………….**

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

**DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:**

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

**Dear Parent or Legal Guardian**

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

**1) INTRODUCTION**

We invite your child to participate in a research study. This information document will help you to decide if your child may want to participate. Before you agree that your child may take part, you should fully understand what is involved. If you have any questions that this document does not fully explain, please do not hesitate to ask the researcher.

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

The aim of this study is to **……………………………** [**Optional sentence, depending on the nature of the study – adapt according to your study:** You as a parent **…………………….** are a very important source of information on **…………………………………………………………………………………………………..**

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

We will ask you some questions about your child / will measure your child / will ask your child to do …………… and we will observe your child’s actions / ………... **GIVE CLEAR AND SUFFICIENT DETAIL, BUT DO NOT OVERWHELM THE POTENTIAL PARTICIPANT WITH TECHNICAL JARGON**…………………………………

**4)** **POSSIBLE RISK AND DISCOMFORT INVOLVE**

There are only minimal risks involved in participating in the study, namely……………Some of the processes may cause minimal / some discomfort or take some of your child’s time.

Your child needs to take off his/her shoes when we weigh your child and that may provide some discomfort. This will take about …………..…….. of your child’s time.

**5) POSSIBLE BENEFITS OF THIS STUDY**

Although your child will not benefit directly from the study, the results of the study will enable us to …………..………… in future.

Your child will benefit directly by the study because at the end of the study we will provide your child with ………………………………………………………………….

Apart from getting the results from your child’s tests, there will be no other direct benefit for you. However, the results of the study will ……… in future.

**6) YOUR CHILD’S RIGHTS AS A PARTICIPANT?**

Your child’s participation in this study is entirely voluntary. Your child can refuse to participate or stop at any time during the study without giving any reason. Your child’s withdrawal will not affect his/her treatment/access to……………….

**7) ETHICS 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.

**8) INFORMATION AND CONTACT PERSON**

The contact person / persons for the study is/ are ...............................If you or your child have any questions about the study please contact him / her / them at the following telephone numbers .............................................Alternatively you may contact my supervisor at telephone numbers ……………....................

##### 9) COMPENSATION

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

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

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

**10) CONFIDENTIALITY**

All information about your child will be kept strictly confidential. Once we have analysed the information no one will be able to identify your child. Research reports and articles in scientific journals will not include any information that may identify your child.

**11) CONSENT TO PARTICIPATE IN THIS STUDY**

* I confirm that the person requesting my consent for my child 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 for my child 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 my child will not be penalised in any way should my child wish to discontinue with the study and that withdrawal will not affect my child’s
* My child is participating willingly.
* I have received a signed copy of this informed consent agreement.

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Parent/Legal Guardian’s name (Please print) Date

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

Parent/Legal Guardian’s signature Date

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

Researcher’s name (Please print) Date

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

Researcher’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 participant informed consent document, which describes the nature and purpose of the study in which I have asked the child’s parent/legal guardian to participate. The explanation I have given has mentioned both the possible risks and benefits of the study and the alternative treatments available for the child’s illness. 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 the child’s standard care.

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

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

Parent/Legal Guardian’s name (Please print) Date

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

Parent/Legal Guardian’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