**ICD 1C**

# INFORMATION AND ASSENT DOCUMENT FOR 7-18 YEARS

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

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

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

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

**Daytime telephone number/s: …………………………………………………………………….**

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

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

1. **INTRODUCTION**

My name [is researcher name] and my job is to do research on children with………. We want to know how children with ………………………………….is the same as healthy children. What your circumstances at home are how many people are living with you and if you ……………………………………………………...

I am going to explain this research to you and invite you to be part of this research study. You can choose whether or not you want to participate in this study. We have discussed this research study with your mom /dad/legal guardian and they know that we are also asking for your permission. If you are going to be part in this research, your mom/dad/legal guardian also has to agree.But if you do not wish to participate, you do not have to.

You may discuss anything on this form with your mom/dad/legal guardian or friends. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain to you. Please ask me to stop at any time and I will explain.

1. **WHAT IS RESEARCH?**

Research is what we do to find new knowledge about subjects (and people). We use research studies to help us find more information about disease or illness. Research also helps us to find better ways of treating children who are sick.

1. **WHAT IS THIS RESEARCH PROJECT ALL ABOUT AND WHAT IS EXPECTED OF ME?**

Children with ……………………………. and we want to find out more about …………………………..

We need information about what you eat, what type of house you live in…………………………………

1. **WHY HAVE I BEEN INVITED TO TAKE PART IN THIS RESEARCH PROJECT?**

You were diagnosed with ....……………………………………………………………………………………

1. **WHO IS DOING THE RESEARCH?**

We the researchers e.g. paediatricians/dieticians etc………………………………………………………..

1. **WHAT WILL HAPPEN TO ME IN THIS STUDY?**

We are going to ask your mom/dad/legal guardian questions about your home circumstances. You are going to be weighed on a scale and your height measured ………………………………………….. you come to the clinic or are admitted to the ward. You are going to be examined for clinical signs of …………, but it will not hurt. Your blood will be drawn by the sisters from a blood vein in your arm and it may hurt, but only for a short time, but it is necessary for the doctors to treat you for your …………………………….

1. **CAN ANYTHING BAD HAPPEN TO ME?**

It might be painful when the sisters draw your blood, but the doctors need the tests to make sure you are doing well during your treatment. Nothing bad can happen to you because of this research study.

1. **CAN ANYTHING GOOD HAPPEN TO ME?**

The researcher or ward personnel will measure and examine you while you are in hospital and/or the clinic ……………………………………………………………………………………………………………....

1. **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.

1. **WILL ANYONE KNOW I AM IN THE STUDY?**

Only the study personnel and some of the sisters that have to draw blood for the study etc…… will know that you are participating in the study.

1. **Who can I talk to about the study?**

[Researcher’s name and telephone number]

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

1. **WHAT IF I DO NOT WANT TO DO THIS?**

You do not have to participate in the study, even if your mom/ dad/ legal guardians have signed consent that you can participate.

You can also withdraw from the study at any time without getting in trouble.

You must just remember that you’ll still be weighed and the sisters need to draw blood, because it’s part of the treatment at the ward or clinic.

1. **CONSENT TO PARTICIPATE IN THIS STUDY**

Do you understand this research study and are you willing to participate in it?

|  |  |  |
| --- | --- | --- |
| YES |  | NO |

Do you understand that ………………………………………(What is expected of you as participant)

|  |  |  |
| --- | --- | --- |
| YES |  | NO |

Has the researcher answered all your questions?

|  |  |  |
| --- | --- | --- |
| YES |  | NO |

Do you understand that you can pull out of the study at any time without any one consequences?

|  |  |  |
| --- | --- | --- |
| YES |  | NO |

You don’t have to give us your answer now, take your time and read the rest of this form before you decide.

If you sign at the bottom it will mean that you have read this paper, and that you would like to be in this study.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Your Name** | **Person Obtaining** **Consent** | **Parent / Guardian / Nurse** **As Witness** |
| **Name**Please Print |  |  |  |
| **Signature** |  |  |  |
| **Date** |  |  |  |