# ICD 3C

# INFORMATION AND ASSENT DOCUMENT FOR CHILDREN 7-18 YEARS

# FOR A MEDICATION TRIAL

**Dear ………………………..**

**Protocol Title: …………………………………………………………………………………………………**

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

We wish to know if you would like to volunteer to be part of a research study in which you will be given medicine called □□□ (let’s call it □□□ for short), together with the other medicine which you are already taking. We are asking you, because the doctor thinks that you are still having too many sick days on the medicine you are taking now. The study will help us to gather information on the safety of this medicine in children. It will also tell us if it reduces the number of sick days in children like you.

Your parents (or legal guardian) and Dr...................................... think that adding □□□ to your other medicines may help to control your illness even better.

About □□□ children are going to take part in this study, and it will last □□□ months. During that time you will have to visit your doctor between □□□ and □□□ times.

We will give you a little diary in which you or your parents must record every time you are ill. Every time you visit your doctor you must take this diary with you. Every time you visit the doctor, he or she will ask you how you’ve been feeling. It is very important that you tell your study doctor, nurse or your parents if you don’t feel well at anytime during the study.

During the study they will do different kinds of tests on you. Physical tests (blood pressure, your heart beat, how fast you are breathing and how much you weigh) and neurological tests (these are tests to see how your nerves are working) during each visit will be done. Your heart’s activity (this is called an electrocardiogram or ECG) will also be tested twice.

During □□□ number of the visits, they will take a tiny amount of blood from you form a vein in your arm. This may hurt a little, but it will only take a minute. Afterwards you might have a little bruise where the blood was taken.

These tests will last for about □□□ hours but will only take place □□□ times during the whole study.

The following side effects have been reported in children: sleepiness, restlessness, feeling uncertainty, lack of interest, not acting like your normal self, feeling down or unhappy and being moody.

Some more side effects are: ……………………………………………………………………….......

If you do not want to take part any more you may decide at any time during the study, not to carry on. No-one will force you to carry on. No-one will be cross or upset with you if you don’t want to, and your doctor will still look after you.

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.

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.

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