AN11-V1/KSSSCISOP 03/V1

*Child Information Document

Study title: " ..... "

Introduction

You have come to meet the doctor as you are suffering from ……...

You may be having symptoms…….

Describe briefly the purpose of this study

If this is a randomized trial, details of both arms of the trial/study must be explained in writing to the Participant being enrolled.

Disclose appropriate alternative treatments available, if any.
We invite you to participate in this study.

What will you have to do?

To participate in this research study, you will be examined by your doctor and if found to fulfill pre-specified criteria, you will be eligible to be enrolled in this research study.

Since you are in the age group of 7-18 years we ask your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, non-technical & direct language.

In addition, to record the same parameters daily your parent/guardian will also be provided with a diary where they will enter the same findings accordingly. You will have to tell them about your symptom and they will mark accordingly in the diary

Risks and discomforts

There is no foreseen significant risk/hazard to your health, if you wish to participate in the study. If you follow the directions of the doctors in charge of this study and you are injured due to any substance or procedure given under the study plan, the Sponsor will pay for the medical expenses for the treatment of that injury.

Benefits

If you participate in the study you will receive .....If you appear to have any acute

illness..... you will be offered free treatment for those visits in accordance with local standard medical care. You will not be offered free treatment for chronic diseases or conditions not related to study procedures.

Your participation in the study may help others, because this participation will help us determine if the study drug/procedure is safe.

Confidentiality

Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study.

Information about you will be collected and stored in files with an assigned number, and not directly with your name. All documents related to the study will only be accessed by the study investigator, sponsor, the Ethics Committee and the Regulatory authority.

Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent / guardian can take away your authorization to collect process and disclose data about you at anytime.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your treatment. You will still have all the benefits that you would otherwise have got at this clinic/hospital. You may stop participating in the research at any time you wish without losing any of your rights. Your treatment will not be affected in any form. The study doctor may decide to withdraw you from the study if he/she considers it is in your best interest

You will be informed of important new findings developed during the course of the study so you will be able to consider your participation in the study in light of new information **Parents responsibilities**

It is the responsibility of your parent / guardian to come along with you to the hospital during the study period for all the visits unless you withdraw or are prematurely discontinued from the study. It is also your responsibility and your parent / guardian to report to PI for any expected or unexpected reactions (side effects) that you notice during the study period.

It is also the responsibility of your parent / guardian to inform the doctor if you consume any other medication apart from the study treatment.

We expect your co-operation through out the study.

Contact for further information

You should give the participants a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **Name of the PI, Address, Telephone/Mobile Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers**

***(please translate in Hindi also)**