INSTITUTIONAL ETHICS COMMITTEE
BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY

*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 must be explained in writing to the subject 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, nontechnical & 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 any time.

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

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 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 throughout the study.

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

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*Child Assent Form

Study Title_____
Study Number_____
Subject's Full Name (with father's name)_____
Date of Birth/Age_____
Address of subject
_____
_____

I_____, exercising my free power of choice, hereby give my consent for participation in the study entitled:
"……"
I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug. I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

Signature of the study participant
_____Date:_____
Name of the study participant_____

Signature of Parents/ Legal guardian: _____

Signature of the Witness
_____Date_____
Name of the Witness _____

Signature of the attending physician_____Date:_____
Name of the attending Physician

BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY
LUCKNOW
प्रज्ञा शील करुणा
ESTABLISHED 1996

इंस्टीट्यूशनल एथिक्स कमेटी

बाबा साहेब भीमराव अम्बेडकर विश्वविद्यालय, **लखनऊ**

शिशु सहमति पत्र

अध्ययन
शीर्षक_____

अध्ययन
संख्या_____

प्रतिभागी के पूर्ण नाम (पिता के नाम के
साथ)_____

जन्म तिथि / आयु

_____

पता

_____

मैं ----------में भाग लेने के लिए अपनी सहमति प्रदान करता हूँ | मुझे इस अध्ययन के उद्देश्य एंव किये जाने वाली प्रक्रिया के बारे में चिकिस्तक द्वारा बता दिया गया है। मुझे पता है की परीक्षण सम्बन्धी किसी छति जिसका की परीक्षण की दवाई से हेतुक सम्बन्ध है उसका खर्च मेरे माता पिता/ अभिभावकों को वहन नहीं करना है। मुझे यह भी पता है की मैं इस परीक्षण से किसी समय बिना कोई कारण बताये बाहर हो सकता हूँ ।

प्रतिभागी का हस्ताक्षर _____

प्रतिभागी का नाम_____ दिनांक _____

अभिभावक/ लीगल अभिभावक के हस्ताक्षर _____

गवाह के हस्ताक्षर_____दिनांक_____

गवाह का नाम_____

अन्वेषक के हस्ताक्षर _____दिनांक _____

अध्ययन अन्वेषक का नाम

_____