INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital





IEC-I Re-registration No. ECR/229/Inst./MH/2013/RR-16,IEC-II registration No. ECR/417/Inst./MH/2013 Issued under rule 122DD of Drugs & Cosmetic rule 1945.

Recognized by:

The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER),
Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP)
for its compliance with international and local standards in ethical review.

Annexure 7

AX 07/SOP 05/V5

Sample Format of an Assent to be a Participant in a Research Study (For Children between 7-18 years old) in English

(This template should be customized according to the requirement of individual research project)

(TIIIS CEITIF	state should be easternized according to the requirement of marviadal research projectly
1. What do w	ve wish to tell you?
research s something	We want to tell you about something we are doing called a study. A research study is when doctors collect a lot of information to learn more about g related to health and disease. Tell / explain you about it, we will ask if you'd like to be in this study or not.
•	ve doing this study?
	to find out
So we are	getting information from boys and girls of your age.
3. What will	happen to you if you are in this study?
	u agree, two things will happen:
(as applica	able to research study)
This v	all amount of your blood will be drawn. That means it will be taken by a needle in your arm will happentimes. [If some or all of blood draws would be done anyway as part of child's cal care, emphasize here what will be done extra for the study.]
	doctors will do some tests on
	will need to answer some questions about
4. You\	will be given a medicine(explain as applicable)
	I or dangerous for you to get involved in this research? Will this study hurt? (explain risks as applicable)
The stick f	from the needle to draw your blood will hurt, but it will soon disappear.
5 How will t	his research study be useful to you?
No, this st	tudy won't make you feel better or get well. But the doctors might find out something that other children like you later.
6.Will everyb	oody come to know about your condition? (Confidentiality)
We will no	ot tell other people that you are in this research and we won't share information about you

8. Will you tell me the results?

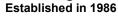
to anyone who does not work in the research study.

[Mention any reimbursements or small gifts/incentives]

7.Do you get anything for being in the research?

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[Include details if relevant. Also inform about possibility of publication and keeping confidentiality in publication]

9. Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

10. Do you have to be in this study?

No, you don't. No one will be force you if you don't want to do this. If you don't want to be in this study, just tell us. And remember, you can say yes now and change your mind later. It's up to you. This will not affect in any way your future treatment in this hospital.

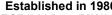
11. Who can you talk to or ask questions to?

[Contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).]

12. Signature of Person Conducting Assent Discussion (print name of shild here) in language he/she
I have explained the study to(print name of child here) in language he/she can understand, and the child has agreed to be in the study.
can understand, and the child has agreed to be in the study.
Signature of Person Conducting Assent Discussion Date
Name of Person Conducting Assent Discussion (print)
Assent Statement
I have read this information (or had the information read to me) I have had my questions answered and
know that I can ask questions later if I have them.
I agree to take part in the research.
Name of child Signature of child:
Date:
OR
I do not wish to take part in the research and I have not signed the assent below
(initialed by child/minor)
I have witnessed the accurate reading of the assent form to the child, and the individual has had the
opportunity to ask questions. I confirm that the individual has given consent freely. [in case of illiterate
child]
Name of witness (not a parent) and
Thumb print of participant
Signature of Witness
Date

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Seth GS Medical College and KEM Hospital Established in 1986





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Name of Investigator Date : Date :
(Copies of the Child information sheet and duly filled and signed ICFs of child and parent shall be
nanded over to the participant or his/her attendant)