

Annexure 1

AX 01/SOP 20/V6



Checklist - Requirement for Research Involving Children

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

Investigator: _____

IEC :

Study

Title: _____

For the principal investigator		IEC Office
RISK DETERMINATION	BENEFIT ASSESSMENT	IEC ACTION
<input type="checkbox"/> Minimal *	<input type="checkbox"/> Direct benefit	Approvable
	<input type="checkbox"/> No direct benefit	
<input type="checkbox"/> Greater than minimal risk	<input type="checkbox"/> Potential to child	Approvable
<input type="checkbox"/> Greater than minimal risk	<input type="checkbox"/> No direct benefit to individual offer general knowledge about the child's condition or disorder.	Approvable case –by-case **

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.

** Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.

	Yes	No	NA
Does the research pose greater than minimal risk to children?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are convincing scientific and ethical justifications given?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are adequate safeguards in place to minimize these risks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve normal volunteers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Is the inclusion of normal volunteers justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are the studies conducted on animals and adults, appropriate and justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If No: Is the lack of studies conducted on animals and adults justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will older children be enrolled before younger ones?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is permission of both parents necessary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes: Are the conditions acceptable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are provisions made to protect subjects' privacy and the confidentiality of information regarding procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the research involve implications for other family member ?(for example, genetic risk , HIV infection , Hepatitis C)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes: Are there adequate mechanisms in place to deal with other members of the family?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are parents required to be present during the conduct of the research? (Are proposed participants to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Approval to proceed with this category of research must be made by the Administrator of the IEC, with input from selected experts

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	