Annexure 1

AX 01/SOP 20/V 7

Checklist-Requirements for Research Involving Children

Principal Investigator (Name, Designation & Affiliation): ……..

IEC No. of the Project: ……..

Study Title: ……

……

For the Principal Investigator		IEC Office
RISK DETERMINATION	BENEFIT ASSESSMENT	IEC ACTION
☐ Minimal *	☐ Direct benefit	Approvable
	☐ No direct benefit	
☐ Greater than minimal risk	☐ Potential to child	Approvable
☐ Greater than minimal risk	☐ 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?	☐	☐	☐
If yes: Are convincing scientific and ethical justifications given?	☐	☐	☐
If yes: Are adequate safeguards in place to minimize these risks?	☐	☐	☐
Does the study involve normal volunteers?	☐	☐	☐
If yes: Is the inclusion of normal volunteers justified?	☐	☐	☐
Are the studies conducted on animals and adults appropriate and justified?	☐	☐	☐
If No: Is the lack of studies conducted on animals and adults justified?	☐	☐	☐
Will older children be enrolled before younger ones?	☐	☐	☐
Is permission of both parents necessary?	☐	☐	☐
If Yes: Are conditions under which one of the parents may be considered: “not reasonably available” described?	☐	☐	☐
If Yes: Are the conditions acceptable?	☐	☐	☐
Will efforts be made ensure that parents’ permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?	☐	☐	☐
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?	☐	☐	☐
Are provisions made to protect subjects’ privacy and the confidentiality of information regarding procedures?	☐	☐	☐
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	☐	☐	☐
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?	☐	☐	☐
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	☐	☐	☐
Does the research involve implications for other family members? (for example, genetic risk, HIV infection, Hepatitis C)	☐	☐	☐
If Yes: Are there adequate mechanisms in place to deal with other members of the family?	☐	☐	☐
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?)			
Recruitment strategies for paediatric studies: a. OPD or IPD b. By a qualified pediatrician or neonatologist c. From the departmental database d. From the well baby clinic e. Any other	☐	☐	☐

Signature of Principal Investigator: …… **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	