

YENEPOYA ETHICS COMMITTEE 2
Yenepoya (Deemed to be University)
Floor -2(Basement), Yenepoya Dental College, Mangalore-575018
yec2@yenepoya.edu.in,(0824)2206000- Extension Number - 2063
DCGI Registration No.: ECR/1337/Inst/KA/2020
DHR registration No.: EC/NEW/INST/2023/KA/0276

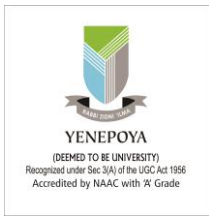
Annexure 1: YEC2/Ann01/SOP19/v1

**Checklist: Requirements for Research Involving Children
(Minors below the age of 18 years)**

Study Title:

Name of the Principal Investigator:

No.	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the protocol)	Y	N	NA
1	Does the research pose greater than minimal risk to children?			
2	If yes: Are convincing scientific and ethical justifications given?			
3	If yes: Are adequate safeguards in place to minimize these risks?			
4	Does the study involve healthy children?			
4A. If yes:				
4Ai	Is the inclusion of healthy children justified?			
4Aii	Are studies conducted on animals and/or adults appropriate and justified?			
4B. If no:				
4Bi	Is the lack of studies conducted on animals and/or adults justified?			
5	Will older children be enrolled before younger ones?			
6	Is permission of both parents necessary?			
If yes:				
6A	Are conditions under which one of the parents may be considered: "not reasonably available" described?			
6B	Are the conditions acceptable?			
7	Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			
8	Are provisions made to obtain the assent of children over 12 years, and where appropriate, honoring their dissent?			
9	Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			
10	Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
11	Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
12	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
13	Does the research involve possibility of findings which may have implications for other family members?(for eg. genetic risk, HIV infection, Hepatitis C)			
If yes:				
13A	Are there adequate mechanisms in place to deal with other members			



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	of the family?			
14	Are parents required to be present during the conduct of the research?			

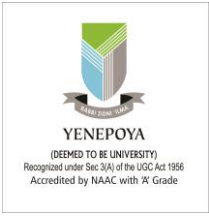
For the Principal Investigator (<i>tick whichever is applicable in the risk-benefit columns</i>)		For the YEC 2 Secretariat (<i>this column for YEC 2; circle whatever is applicable</i>)
Risk determination	Benefit assessment	YEC 2 Action
Minimal risk*	Direct benefit	Approvable
	No direct benefit	Approvable
Greater than minimal risk	Potential benefit to participant	Approvable
	No direct benefit; or offers new knowledge about the condition being investigated	Case-based approval on merits

* *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*
 ** *Consent of both parents (and assent) may be needed as applicable*

Signature of the Principal Investigator:

Date:

YEC 2 Office use only	
Comments of Primary Reviewer:	
Primary Reviewer Signature and Date:	



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