INSTITUTIONAL ETHICS COMMITTEE, NDCH

Checklist: Research Involving Children <18 years

A. Need for the checklist:

Children (minors) have reduced capacity to understand and give informed consent. Such participants have decreased autonomy and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees in reviewing this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

Instructions for the PI:

1. *Please download the checklist, type the details, and email the signed copy to* iec@narayanadentalcollege.com *).*
2. *Please do not delete any of the questions/ sections/options provided by IEC,NDCH in the checklist.*
3. *Please note that all the details provided here are also reflected in the protocol and informed consent document.*
4. *Do not leave any question without a response. If not applicable, write not applicable*

B. Details of the protocol:

Protocol Number:	
Title of the protocol	
Principal investigator	
Department	
List of Co-investigators/ Guides/ Co-guides	

C. Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form):

No.	Checklist item	Yes, No or Not applicable (NA)
1	Does the research pose greater than minimal risk to children?	
2	If yes: Are there convincing scientific and ethical justifications to carry out the research as designed?	
	Please mention the page numbers of the protocol in which these justifications are described.	
3	If yes: Are adequate safeguards in place (and described in the protocol) to minimize these risks?	
	Please mention the page numbers of the protocol in which these justifications are described.	

4	Is there an alternate study design that can achieve the same objectives without involving such vulnerable participants?	
5	Does the study involve healthy children? If yes. Go to section 5A; If no, go to section 5B	
5A. If yes:		
5Ai	Is the inclusion of healthy children justified?	
5Aii	In case of clinical trial (regulatory or academic) have scientifically appropriate preclinical studies, including studies on animals, and clinical studies, including studies on children and/or adults, been conducted and do these provide data for assessing potential risks to children/minors?	
	Please mention the page numbers of the protocol in which these studies and results are described.	
5Aiii	Do the results of those studies justify this study?	
5B. If no:		
5Bi	Is the lack of studies conducted on animals and/or adults justified?	
5Bii	Would this study still be justified despite the lack of animal studies?	
6	Will older children be enrolled before younger ones?	
7	Is permission of both parents necessary?	
If yes:		
7A	Are conditions under which one of the parents may be considered: "one parent not reasonably available" described?	
	Please mention the page numbers of the protocol in which these details are described.	
7B	Are the conditions acceptable?	
8	Is informed consent document attached along with the protocol?	
8 1	Are provisions made to obtain? a. **Written assent** of children over 12 years b. **Oral assent** of children between 7 and 12 years, c. **Dissent where** appropriate (Please attach a copy of the written assent along with the protocol.)	
8.2	Will efforts be made to ensure that the parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?	

10	Are provisions made to protect participants' privacy and the confidentiality of information gathered in the course of the research?	
	Please mention the page numbers of the protocol in which these details are described.	
11	Are there special problems that call for the presence of an external monitor during consent procedures?	
12	Are special needs of adolescents such as counselling and confidentiality accounted for in the research design?	
13	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	
14	Does the research involve possibility of findings which may have implications for other family members? (for e.g. genetic risk, HIV infection, Hepatitis C)	
If yes:		
14Ai	Are there adequate mechanisms in place to deal with other members of the family, should there be a risk to such bystanders?	
14Aii	Are parents required to be present during the conduct of the research?	

For the Principal Investigator *(tick whichever is applicable in the risk-benefit columns)*		**For the IEC, NDCH Secretariat** *(this column for IEC, NDCH; circle whatever is applicable)*
Risk determination	**Benefit assessment**	**IECNDCH 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:

IEC NDCH Office use only	
Comments of Primary Reviewer:	
Primary Reviewer Signature and Date:	