



**INSTITUTIONAL ETHICS COMMITTEE, NDCH**

**Checklist for Protocol Submission**

**(Research under other Regulatory Body)**

Sl No.	Document	Yes	Not Applicable (NA)	If pending, mention the date of submission	Checked by IEC, NDCH (S/NS) *
1	Covering letter for Initial submission				
2	Approval letter from Head of Department, Principal & Dean (Academics)				
3	CV for investigators				
4	Declaration duly signed by all investigators that the clinical trial would be prospectively registered in the Clinical trial registration (CTRI) at <a href="http://www.ctri.nic.in">www.ctri.nic.in</a> & under DCGI ( <a href="https://cdsco.gov.in/opencms/opencms/en/Home/">https://cdsco.gov.in/opencms/opencms/en/Home/</a> ) (as applicable)				
5	Institutional Scientific Review Board (ISRB) clearance letter				
6	Application Form for Initial review (checklist is included)				
7	Application Form for Clinical trials or Socio-Behavioural & Public Health Research (Use appropriate one)				
8	PROFORMA II (Research Protocol Under Other Regulatory Body) With complete details				
9	Application form for Expedited review / Exemption from review (if required)				
10	Patient Consent Form in English				
11	Patient Consent Form in Regional / Vernacular language				
12	Participant Information Sheet in English				
13	Participant Information Sheet in Regional / Vernacular language				
14	Vulnerability Checklist for children (as applicable)				
15	Form for Waiver of consent (as applicable)				
16	Any other Documents submitted (please fill in the reverse)				
17	All documents pertaining to the Checklist mentioned in "Application Form for Initial Review"				

**Please tick mark (√) as applicable**

**\*S-Submitted, NS – Not submitted**