

## **INSTITUTIONAL ETHICS COMMITTEE, NDCH**

## **Checklist for Protocol Submission** (DRNTRUHS Dissertation Studies)

| Sl<br>No. | Document  | Yes | Not<br>Applicable<br>(NA) | If pending,<br>mention<br>the date of<br>submission | Checked<br>by IEC,<br>NDCH<br>(S/NS)* |
|-----------|---|-----|---------------------------|---|---------------------------------------|
| 1         | Covering letter for Initial submission  |     |                           |   |                                       |
| 2         | Approval letter from Head of Department,<br>Principal & Dean (Academics)  |     |                           |   |                                       |
| 3         | CV for investigators  |     |                           |   |                                       |
| 4         | Declaration duly signed by all investigators that<br>the clinical trial would be prospectively<br>registered in the Clinical trial registration (CTRI)<br>at <u>www.ctri.nic.in</u> |     |                           |   |                                       |
| 5         | Institutional Scientific Review Board (ISRB)<br>clearance letter  | C   | 2                         |   |                                       |
| 6         | Application Form for Initial review (all<br>regulatory & non-regulatory clinical studies)<br>(checklist is included)  |     |                           |   |                                       |
| 7         | Application Form for Clinical trials or Socio-<br>Behavioural & Public Health Research (Use<br>appropriate one)   |     |                           |   |                                       |
| 8         | Dr NTRUHS SYNOPSIS PROFORMA (required<br>only for Dissertation/s to be submitted to<br>DRNTRUHS) With complete details  |     |                           |   |                                       |
| 9         | Application form for Expedited review /<br>Exemption from review (if required)  |     |                           |   |                                       |
| 10        | Patient Consent Form in English   | H   | ¥?                        |   |                                       |
| 11        | Patient Consent Form in Regional / Vernacular language  |     |                           |   |                                       |
| 12        | Participant Information Sheet in English  |     |                           |   |                                       |
| 13        | Participant Information Sheet in Regional /<br>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<br>mentioned in "Application Form for Initial<br>Review"  |     |                           |   |                                       |