INSTITUTIONAL ETHICAL COMMITTEE, NDCH (IEC, NDCH)

GENERAL INSTRIUCTIONS

1. All studies (Short Studies, DRNTRUHS Dissertation Studies, Survey studies, Clinical trials (Both Regulatory/Academic & Non-Regulatory) / In-Vitro Research, Research under other regulatory body, PhD studies) including presentation / publication of case reports have to be applied to IEC, NDCH for obtaining ethical clearance.
2. Only Regulatory Clinical Trials (Use of a New Drug / Instrument / Technique) will be forwarded to IEC, NMCH for the Ethical Review Process. All the remaining studies will be reviewed by IEC, NDCH
3. Obtaining Department Head, Academic Dean and Institutional Head's permission for any study is mandatory. (approval letter template given)
4. If any other department/s within the college is involved in participant recruitment / investigation etc, a consent letter from that department/s with HOD signature must be enclosed along with application form.
5. All linkages / collaboration of research work either with sister concern and or with other institutes need to be approved by the Head of the Institute following proper protocol. Permission letters must be enclosed along with application form.
6. Applications must be addressed through a covering letter to the Member Secretary, Institutional Ethics Committee, NDCH
7. Relevant proformas, application forms, participant information form, participant consent form along with covering letter, checklist & approval letter need to be used based on the research / study planned.
8. All the "academic clinical trials" / "regulatory clinical trials" and all PG clinical studies (Studies involving Human participants/Clinical studies, i.e. interventional, observational, bioavailability / bioequivalence & post-marketing studies and clinical studies from traditional medicinal systems as well as clinical studies conducted as part of post-graduate thesis) should apply for Clinical trial registration at www.ctri.nic.in
9. A declaration signed by all the investigators, that the clinical trial would be prospectively registered in the CTRI, must be submitted to the IEC, NDCH
10. All "regulatory clinical trials" should get DCGI approval letter (acknowledgment before EC approval and later the copy of DCGI approval) https://cdsco.gov.in/opencms/opencms/en/Home/
11. All investigators and other relevant authorities of the Institution as applicable must sign all applications.
12. Applications must be addressed in a covering letter to the Secretary, IEC, NDCH.

13. All applications must be submitted in duplicate (print copies) and one soft copy by email to iec@narayanadentalcollege.com
14. Applications that are eligible for expedited review will receive approval within 2-4 weeks of receipt of complete protocol package.
15. Applications that are for full review if received (complete in all documents) at least 4 weeks before the scheduled meeting will be eligible to be kept as agenda, and approval letter (if approved) will be issued within 2 weeks of the meeting.
16. It is the PI's responsibility to submit the corrections advised within the stipulated time.
17. Applications received only before the announced date (Check Circulars / Dept Mails) will be eligible to be heard.
18. Incomplete forms / submissions are liable to undue delays.
19. **All submissions must be made personally to the member secretary at IEC office only**. The details pertaining to the submission protocol are mentioned below. **The soft copy has to be mailed to iec@narayanadentalcollege.com.**
20. **The PI must ensure that the names and title of study are mentioned correctly and remain the same in all documents.**
21. All proposals will initially go through scientific review by the Institutional Scientific Review Board (ISRB), following which the remarks letter with suggested modifications / amendments if any OR acceptance, will be handed over to the PI. After the corrections the ISRB will issue approval letter.
22. The proposals must be then submitted again to IEC for ethical review, after ISRB clearance.
23. All the proposals finally will be assessed by the members in the IEC meeting for ethical shortcomings and also scientific errors if any.
24. Decision on ethical waiver (exempted), expedited review or full review rests solely with the IEC, NDCH.
25. If required, the Secretary, IEC, NDCH may invite the PI, to clarify ethical doubts, either orally, or in writing or in the form of a presentation (PPT). In such an event, the PI personally must make himself / herself available for the clarifications. In the unusual event that the PI is unable to be present he/she can send his/her representative along with a letter highlighting reasons for absence.
26. After the ethical review in the IEC meeting, the remarks letter suggesting modifications / amendments OR acceptance, will be handed over to the PI.
27. Those proposals for which corrections/ amendments have been suggested have to be re-submitted again to IEC. The time allotted for making amendments will range from 7-10 days maximum. Thus, it is the PI's responsibility to submit the corrections advised within the stipulated time.
28. For all studies including PhD, Institutional Ethical Clearance Certificate is issued for a period of one year.

29. **Ethical Clearance Certificate is provisional for all "academic clinical trials / regulatory clinical trials", till a valid CTRI registration number is provided to the ethics committee, along with a copy of the details of CTRI registration & DCGI approval letter (for only regulatory clinical trials) following which the final Ethical Clearance certificate will be issued.**

30. For studies extending beyond a year, the PI must apply for extension of the validity period of the Ethical clearance sanctioned along with continuing review form before the expiry of the IECC issued. *It is mandatory*. The Ethical Clearance will be then extended for 06 months / 01 year. Every time it is extended the Certificate for Extension of Validity of Ethical Approval is issued and not a fresh Institutional Ethical Clearance Certificate.

31. Submission of Continuing Review / Progress and Study Closure Reports are *mandatory*.

32. Changes / amendments in the title, objectives, methodology and/or analysis or co-investigator require reporting to the ethics committee, which will decide on whether fresh application for ethical clearance is required.

33. When it becomes available, the WHO ICTRP's Universal Trial Registration Number must be submitted to the IEC, NDCH

34. Please procure all the relevant application forms, proformas, checklists, guidelines etc. posted to your department e-mail id. No printouts will be provided from the NDCH Office or IEC Office.

DOCUMENTS NEEDED FOR THE INITIAL SUBMISSION PROCESS (Provisional IECC) (BOTH HARD & SOFT COPY)

1. **Dissertations to be submitted to Dr NTRUHS:**
    a. Covering letter for Initial submission
    b. Approval letter from Principal & Dean (Academics)
    c. CV for investigators
    d. Declaration for prospective CTRI registration
    e. Institutional Scientific Review Board (ISRB) clearance letter
    f. Application Form for Initial review (all regulatory & non-regulatory clinical studies) (checklist is included)
    g. Application Form for Clinical trials or Socio-Behavioral & Public Health Research (Use appropriate one)
    h. Dr NTRUHS Proforma (for DRNTRUHS Dissertation studies)
    i. Application form for Expedited review / Exemption from review (if required)
    j. Patient Consent Form (both in English and Vernacular Language)
    k. Participant Information Sheet (both in English and Vernacular Language)
    l. Vulnerability Checklist for children (as applicable)
    m. Form for Waiver of consent (as applicable)
    n. Any other relevant document

2. **Short studies / Research other than DRNTRUHS Dissertation studies (non-regulatory clinical trial / in-vitro / survey etc) proposals:**
   a. Covering letter for Initial submission
   b. Approval letter from Principal & Dean (Academics)
   c. CV for investigators
   d. Declaration for prospective CTRI registration
   e. Institutional Scientific Review Board (ISRB) clearance letter
   f. Initial review application form (all regulatory & non-regulatory clinical studies) (checklist is included)
   g. Application Form for Clinical trials or Socio-Behavioral & Public Health Research (Use appropriate one)
   h. Proforma I For Research (Other than DRNTRUHS Dissertation study) & Short Studies
   i. Application form for Expedited review / Exemption from review (if required)
   j. Patient Consent Form (both in English and Vernacular Language)
   k. Participant Information Sheet (both in English and Vernacular Language)
   l. Vulnerability Checklist for children (as applicable)
   m. Form for Waiver of consent (as applicable)
   n. Any other relevant document

3. **Research studies under other Regulatory Body (Regulatory clinical trial / in-vitro / survey etc.) proposals:**
   a. Covering letter for Initial submission
   b. Approval letter from Principal & Dean (Academics)
   c. CV for investigators
   d. Declaration for prospective CTRI registration
   e. Institutional Scientific Review Board (ISRB) clearance letter
   f. Initial review application form (all regulatory & non-regulatory clinical studies) (checklist is included)
   g. Application Form for Clinical trials or Socio-Behavioral & Public Health Research (Use appropriate one)
   h. Proforma II for Research Under Other Regulatory Body
   i. Application form for Expedited review / Exemption from review (if required)
   j. Patient Consent Form (both in English and Vernacular Language)
   k. Participant Information Sheet (both in English and Vernacular Language)
   l. Vulnerability Checklist for children (as applicable)
   m. Form for Waiver of consent (as applicable)
   n. Any other relevant document

DOCUMENTS NEEDED FOR ISSUE OF FINAL IEC CLEARANCE CERTIFICATE (HARD & SOFT COPY)

a. Covering letter for issue of IECC
b. CTRI registration letter

DOCUMENTS NEEDED FOR APPLYING FOR EXTENSION OF IECC VALIDITY (HARD & SOFT COPY)

All Dissertations / Short Studies / Research extending beyond one calendar year from the date of issue of IECC submitted for Continuing Review:

a. Covering Letter for IECC renewal
b. Application for extension of study
c. Continuing review / progress/ annual report Form
d. Application form for Protocol amendment (if applicable)
e. Any other relevant document pertaining to the changes made

DOCUMENTS NEEDED FOR SUBMISSION OF CLOSURE REPORT (HARD & SOFT COPY)

All Dissertations / Short Studies / Research to be submitted for Closure Report must include

a. Covering Letter for Closure Report
b. Final / Closure report form

OTHER RELEVANT FORMS

a. Application form for protocol amendment
b. Reporting form for protocol violation
c. SAE reporting form (Academic Clinical trials)
d. SAE reporting form for Regulatory Clinical trials
e. Premature termination form