NARAYANA
COLLEGE OF NURSING
Chinthareddypalem, Nellore - 524003. A.P.
Ph No: 0861-2317969 | Fax: 0861-2311968.
Recognized by Indian Nursing Council and A.P. Nurses & Midwives Council
Affiliated to NTR University of Health Sciences, A.P. Vijayawada.
Accredited by "International Accreditation Organization (IAO)"
website: www.narayananursingcollege.com | | e-mail: narayana_nursing@yahoo.co.in

INSTITUTIONAL ETHICAL COMMITTEE, NCN (IEC, NCN)
GUIDELINES FOR SUBMITTING A PROPOSAL FOR ETHICAL CLEARANCE

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, NCN 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, NCN

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, NCN.

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 investigators and other relevant authorities of the Institution as applicable must sign all applications.

9. Applications received only before the announced date (Check Circulars / Dept Mails) will be eligible to be heard.

10. Incomplete forms / submissions are liable to undu+e delays.

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11. All submissions must be made personally to the member secretary at IEC office only. The details pertaining to the submission protocol are mentioned below. All submissions must be made in hard copy format except the final submission before IEC meet wherein both hard and soft copy (pdf) format is mandatory. The soft copy has to be mailed to iec@narayanacollege.com.

12. The PI must ensure that the names and title of study are mentioned correctly and remain the same in all documents.

13. All proposals will initially go through scientific review, following which the remarks letter with suggested modifications / amendments if any OR acceptance, will be handed over to the PI.

14. The proposals have to be re-submitted again to IEC for ethical review, after making the necessary modifications / amendments. 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.

15. All the proposals finally will be assessed by the members in the IEC meeting for ethical shortcomings and also scientific errors if any.

16. Decision on ethical waiver (exempted), expedited review or full review rests solely with the IEC, NCN.

17. If required, the Secretary, IEC, NCN 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 has to 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.

18. After the ethical review in the IEC meeting, the remarks letter suggesting modifications / amendments OR acceptance, will be handed over to the PI.

19. 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.

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20. Only the final submission of the proposal must in both hard & soft copy (pdf) format. The soft copy (single pdf file) has to be mailed to----------.

21. For all studies including PhD, Institutional Ethical Clearance Certificate is issued for a period of one year.

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

23. After the study completion, submission of Closure Report is mandatory.

24. Changes 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.

25. 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 NCN Office or IEC Office.

SUBMISSION PROTOCOL DOCUMENTS NEEDED FOR THE INITIAL SUBMISSION PROCESS (HARD COPY ONLY)

1. Dissertations to be submitted to Dr NTRUHS:

a. Check List

b. Covering Letter for initial submission

c. Approval Letter

d. Application Form for Clinical Trials / In-Vitro or Survey Studies (Use appropriate one)

e. Dr NTRUHS Proforma

f. Patient Consent Form (both in English and Vernacular Language)

g. Participant Information Sheet (both in English and Vernacular Language)

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h. Any other relevant document

2. Short studies / Research (clinical trial / in-vitro / survey) proposals:

a. Check List

b. Covering Letter for initial submission

c. Approval Letter

d. Application Form for Clinical Trials / In-Vitro or Survey Studies (Use appropriate one)

e. Proforma – I (Short Studies And Research Protocol)

f. Patient Consent Form (both in English and Vernacular Language)

g. Participant Information Sheet (both in English and Vernacular Language) h. Any other relevant document

3. Research Protocols to be submitted to other Regulatory Bodies:

a. Check List

b. Covering Letter for initial submission

c. Approval Letter

d. Application Form for Clinical Trials / In-Vitro or Survey Studies (Use appropriate one)

e. Proforma – II (Research Protocol Under Other Regulatory Body)

f. Proforma Specific to other Regulatory Body (if any)

g. Patient Consent Form (both in English and Vernacular Language)

h. Participant Information Sheet (both in English and Vernacular Language)

i. Any other relevant document

DOCUMENTS TO BE SUBMITTED BEFORE IEC MEETING (after doing the corrections / amendments as suggested in the scientific review) (HARD & SOFT COPY (single pdf file only)) a. Corrected / Modified Proforma – I / II / DRNTRUHS PROFORMA (as applicable)

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b. Patient Consent Form (both in English and Vernacular Language)

c. Participant Information Sheet (both in English and Vernacular Language)

d. Any other relevant document

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

1. 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 Continuing Review

b. Proforma – III (Continuing review Form)

c. Any other relevant document pertaining to the changes made.

DOCUMENTS NEEDED FOR SUBMISSION OF CLOSURE REPORT (HARD COPY ONLY)

1. All Dissertations / Short Studies / Research to be submitted for Closure Report must include a. Covering Letter for Closure Report addressed to Member Secretary, IEC, and NCN

b. Proforma – IV (Closure Report Form)

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INSTITUTIONAL ETHICS COMMITTEE,

Application for Extension of the Research study

1.	Date:	
2.	Name of the Principal Investigator:	
3.	Department:	
4.	Institution	
5.	Protocol Number:	
6.	Protocol title:	
7.	Date of IEC, NCN initial approval	From To
8.	Dates of Approval of amendments if any:	From To
9.	Dates of previous extension of EC clearance if any	From To
10.	Date of submission of the last continuing review application form:	
11.	Any lapse in IEC, NCN clearance validity:	
12.	Sample size approved at this site	
13.	Number of participants screened so far	
14.	Number of participants recruited so far	
15.	Number of participants who are ongoing	
16.	Number of participants who have completed the study	
17.	Projected duration of study at the time of first IEC, NCN approval	
18.	Duration of study completed so far	
19.	Expected duration in months to complete the study	

I declare that the above information is accurate and true. I request IEC, NCN to grant me extension of approval to conduct the study, with all the other terms of reference and conditions remaining unchanged.

Signature of the PI

Date:

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Signature of the guide (if applicable):

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