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

From:

Dr.
Principal Investigator
Designation:
Department of NCN

Date:

To

The Member Secretary
IEC, NCN

Sir/ Madam,

IEC Certificate Reference No.:

I am herewith submitting Study Completion Report of my proposal entitled

"……
……
……
……".

I have enclosed the following documents, for your kindperusal.

1. Final / ClosureReport
2. Anyother:

Principal Investigator Details:

Email id:
Contact No.:

Thanking you,
Yourssincerely,

Signature ofPI

……

To be filled by IEC NCN Office

Received on:

Signature:
IEC NCN

Award: (Higher Education Review Top 10 Nursing College - 2020)
IAO (International Accreditation Organization (2020 - 2025))

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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:

Signature of the guide (if applicable):

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File No. EC/19/000532

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 20-Feb-2020

To

The Chairman
Institutional Ethics Committee
Narayana College of Nursing
Narayana College of Nursing Chinthareddy palem
NELLORE Nellore Andhra Pradesh - 523003 India

Subject: Ethics Committee Registration No. ECR/1348/Inst/AP/2020 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/IND/2019/6470 dated 12-Oct-2019 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/1348/Inst/AP/2020. The said registration is subject to the conditions as mentioned below:

Yours faithfully

V G SOMANI
(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;

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(v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,
(i) one lay person;
(ii) one woman member;
(iii) one legal expert;
(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

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19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee,bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

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Annexure

File No. EC/19/000532

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 20-Feb-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. V Mahidhar Reddy	MBBS (MS - General Surgery	Clinician
2	Dr. Nuvvula Siva Kumar	BDS (M.D.S)	Chair Person
3	Ms. Kantha Katari	BSc (MSc.-Nursing)	Member Secretary
4	Dr. Arumugam Indira	BSc (MSc.,PhD-Nursing)	Scientific Member
5	Dr. H Rajeswari	BSc (MSc.,PhD-Nursing)	Member
6	Mr. Kandati Jithendra	MBBS (MD-Microbiology)	Basic Medical Scientist
7	Mr. P Vijaya Kumara Reddy	B.A (LLB)	Legal Expert
8	Mr. Nath Krishna Kumar	BSc (MA)	Social Scientist
9	Ms. K Padma	10th (12th)	Lay Person

V G SOMANI
(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

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FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. ECR/1348/Inst/AP/2020

The Central Licencing Authority hereby registers and permits Institutional Ethics Committee , Narayana College of Nursing Narayana College of Nursing Chinthareddy palem NELLORE Nellore Andhra Pradesh - 523003 Contact No.: 0861-2317969 Fax No.: 0861-2317969 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

V G SOMANI
Central Licencing Authority

Stamp

Place : New Delhi

Date : 20-FEB-2020

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INSTITUTIONAL ETHICAL COMMITTEE MEMBERS-2018-19

s.no	Name	Designation in IEC
1	Dr .Sivakumar	Chairperson
2	Mrs.Kantha	Member Secretary
3	Dr. Vijaya Kumar	legal expert
4	Dr. Sambashiva Rao	Management Representative
5	Dr. Ram lingam	Basic medical Scientist
6	Mrs. Saritha	Member
7	Mr. Koteswar Rao	Common manor **General Manager:**
8	Mrs. .Rajeswari	Subject Experts(MHN)
9	Mrs. Jayanthi	Subject Experts(OBG)
10	Mrs.Vanajakumari	Subject Experts(COM)
11	Mrs.Latha.A	Subject Experts(MSN)
12	Mrs.Kalpana	Subject Experts(COM)
13	Mrs. .Latha .p	Subject Experts(OBG)
14	Ms.Ramya	Subject Experts(CHN)
15	Ms.Elizebath jasmine	Subject Experts(OBG)

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REVISED INSTITUTIONAL ETHICAL COMMITTEE MEMBERS-2020-21

s.no	Name	Designation in IEC
1	Dr .Sivakumar	Chairperson
2	Mrs.Kantha	Member Secretary
3	Dr. Vijaya Kumar	legal expert
4	Dr. Sambashiva Rao	Management Representative
5	Dr. Ram lingam	Basic medical Scientist
6	Mrs. Saritha	Member
7	Mr. Koteswar Rao	Common manor General Manager:
8	Mrs. .Rajeswari	Subject Experts(MHN)
9	Mrs. Jayanthi	Subject Experts(OBG)
10	Mrs.Vanajakumari	Subject Experts(COM)
11	Mrs.Latha.A	Subject Experts(MSN)
12	Mrs.Kalpana	Subject Experts(COM)
13	Mrs.Viji.A	Subject Experts(OBG)
14	Ms.Ramya	Subject Experts(CHN)
15	Ms.Elizebath jasmine	Subject Experts(OBG)

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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 undue 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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