

**IEC COMMITTEE
FORMULATED
FROM CDSCO**

FEB-2020



सत्यमेव जयते

File No. EC/19/000532

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;

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, 1940 and 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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Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

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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

Dr. B. Chamy
Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003



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.narayanannursingcollege.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 undue delays.



Dr. R. S. Srinivas
Principal
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S. S. Srinivas
Principal
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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.

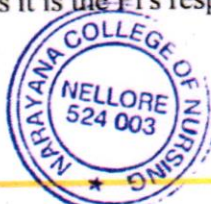
15. All the proposals finally will be assessed by the members in the IEC meeting for ethical shortcomings and also scientific errors if any.

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.



Dr. B. S. Prasad
Principal

A. S. Reddy
Principal

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Award: (Higher Education Review Top 10 Nursing College - 2020)

IAO (International Accreditation Organization (2020 - 2025))



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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.

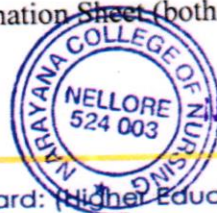
23. After the study completion, submission of Closure Report is mandatory.

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)



Dr. B. Anuraj
Principal

A. J. Reddy
Principal

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Award: Higher Education Review Top 10 Nursing College - 2020)

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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)



Dr. B. Srinivas
Principal

A. S. Sai
Principal

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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)



Dr. Bohanj
Principal

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A. S. Reddy
Principal

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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:



Dr. B. Ch...
Principal

NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
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Signature of the guide (if applicable):

A. Indira

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Award: (Higher Education Review Top 10 Nursing College - 2020)
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MAHARAJA
COLLEGE OF ENGINEERING



**NEWLY
FORMULATED IEC
AND SUBMITTED
TO DHIR - 2024**


Ethics Committee

2/2

Add Correspondence Address

(/DHR/AddressForm)

Edit User Profile



Department of Health Research
Ministry of Health & Family Welfare,
Government of India
National Ethics Committee Registry for
Biomedical and Health Research (NECRBHR)

(/DHR/Dashboard)

Your Application has been submitted successfully.

Kindly note your file no.

EC/NEW/IND/2024/4782 for future correspondence.

An Email has been sent to your registered mail id. For more information, kindly check your mail.

ed by:

<https://naitik.gov.in/DHR/FinalSubmission/OA==/NDc4Mg==>

Edit User Profile

(/DHR/AddressForm)

Add Correspondence Address

Committee

FORM CT-01

(See rules 8, 10 and 17)

APPLICATION FOR REGISTRATION/RENEWAL OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALENCE STUDY OR BIOMEDICAL HEALTH RESEARCH

I/We, Dr. VANAJA KUMARI B (Principal) , CHINTHAREDDYPALEM, NELLORE, ANDHRA PRADESH, INDIA NELLORE Nellore, Andhra Pradesh - 524003 (India) of IEC NARAYANA COLLEGE OF NURSING Room No. 2 Floor No. FIRST FLOOR Building No. NARAYANA COLLEGE OF NURSING , NARAYANA COLLEGE OF NURSING, CHINTHAREDDYPALEM, NELLORE, ANDHRA PRADESH - 524003, NARAYANA COLLEGE OF NURSING, , CHINTHAREDDYPALEM NELLORE ANDHRA PRADESH, Nellore, Andhra Pradesh - 524003 Telephone No.: 08612317969 FAX: 08612311968 hereby apply for grant of registration of ethics committee.

The details of the application are as under:

1. Name of Applicant: Dr. VANAJA KUMARI B
2. Nature and constitution of applicant: Private
3. (i) Applicant address : CHINTHAREDDYPALEM, NELLORE, ANDHRA PRADESH, INDIA NELLORE Nellore, Andhra Pradesh - 524003 (India)
- (ii) Address for correspondence : M/s NARAYANA COLLEGE OF NURSING , CHINTHAREDDYPALEM, NELLORE, ANDHRA PRADESH, Andhra Pradesh, (India) - 524003 Telephone No.: 08612317969 FAX: 08612311968
4. Details of accreditation, if any (self-attested copy of certificate to be attached): INTERNATIONAL ACCREDITATION ORGANISATION (IAO)
5. I have enclosed the documents as specified in the Table 1 of the Third Schedule of the New Drugs and Clinical Trials Rules, 2019.
6. I hereby state and undertake that:
- (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.

Date: 12-Sep-24
Place: Nellore

Dr. B. Vanaja Kumari
Digital/Physical Signature
(Name and Designation)



Dr. B. Vanaja Kumari
Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
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Date: 27/8/2024

To,
The Secretary,
(NECRBHR) National Ethics Committee Registry for Biomedical and Health Research,
Department of Health Research
2nd Floor, IRCS Building.
Red Cross Road,
Ministry of Health & Family Welfare,
Government of India,
New Delhi - 110001.

Subject: Application for Registration of Institutional Ethics Committee

Dear Sir/Madam,

Subject: Application for Registration of the Institutional Ethics Committee (IEC) of
Narayana College of Nursing

Dear Sir/Madam,

I, Dr. B. Vanaja Kumari, serving as the Principal of Narayana College of Nursing, located at Chinthareddypalem, Nellore, hereby submit this formal application for the registration of our Institutional Ethics Committee (IEC) with the Department of Health Research (DHR), Government of India.

Currently registered with the Central Drugs Standard Control Organization (CDSCO) under Reference No: ECR/1348/Inst/AP/2020. In line with our ongoing commitment to upholding the highest standards of ethical review and oversight in research involving human participants, we are seeking registration with the DHR to further strengthen the ethical governance of our research practices. Additionally, Narayana Medical College and hospital a 1450-bed super-specialty hospital, offers undergraduate, postgraduate, and super-specialty courses.

The requested documents are enclosed herewith for your kind perusal. We kindly request you to process our application and register our IEC with the DHR at the earliest.

Thank you for your attention to this matter. We look forward to your favorable response.

Details of the Institutional Ethics Committee:

- Name of the IEC:** Institutional Ethics Committee, Narayana College of Nursing
Chairperson of the IEC: Dr. Siva Kumar Nuvvula, MDS, FICD
Contact Details of the Chairperson: 9441624429, sivakumarn@narayanagroup.com

Dr. B. Vanaja Kumari
Principal

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Members of the IEC:

2. **Member Secretary:** Mrs Thejovathi, HOD of Nursing Research Associate. Professor, M.Sc. (Nursing), Research IIP(International Innovation Program)
3. **Basic Medical Scientist:** Dr Sreenivasulu Munna, Professor cum Principal, M. Pharm, PhD, FAGE
4. **Scientific Member:** Dr. V. Kumari, HOD of Obstetrics and gynecology Nursing/Professor
5. **Member:** Dr. Anjani Devi.N, Associate Professor, HOD of Mental Health Nursing, M.Sc.(N), Ph.D Nursing
6. **Clinician:** Dr Mahidhar Reddy, Professor, MS in General Surgery.
7. **Social Scientist:** Mr Natha Krishna Kumar, B.Sc., M.A
8. **Legal Expert:** Mr. P. Vijaya kumara Reddy, Private Practitioner, B.A, B.L
9. **Lay Person:** Mr. Sudhakar. Bandhila, Telugu Lecturer, M.A Telugu, M.Sc. Zoology

Attached herewith the following documents as required for the registration process:

1. Authority letter
2. Memberships Standard Operating Procedures (SOPs) of the IEC.
3. Constitution and Terms of Reference (TOR) of the IEC.
4. Appointment of Quorum (SOP)
5. Procedure for resignation, replacement or removal of members
6. List of IEC members with their qualifications and CVs.
7. SOPs to be followed by the committee in general
8. SOPs to be followed by the committee in Vulnerable population
9. Policy regarding training for new and existing committee members along with SOPs.
10. Policy to monitor or Prevent conflict of interest along with SOPs
11. Audited Details
12. Undertaking by the Chairperson and members of the IEC.
13. Duly filled IEC registration form (Upload Form CT-01)

Thank you for your consideration

Yours sincerely,

Dr. B. Vanaja Kumar

Dr. B. Vanaja Kumar
Principal

Principal
NARAYANA COLLEGE OF NURSING
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Thejovathi
Member Secretary
Institutional Ethics Committee
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Dr. B. Vanaja Kumar
Principal
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3. Memberships requirements of the ethics committee (upload relevant SOP/Document)

Institutional Ethical Committee

| | | |
|-------------------------|---|--------------------------------------|
| Chairperson | : | Dr. N. Siva Kumar |
| Member Secretary | : | Mrs. G. Thejovathi, |
| Scientific Member | : | Dr V. Kumari |
| Clinician | : | Dr Mahidhar Reddy |
| Member | : | Dr. Anjani Devi.N |
| Basic Medical Scientist | : | Dr Sreenivasulu Munna |
| Legal Expert | : | Mr. P. Vijaya Kumara Reddy |
| Social Scientist | : | Mr Natha Krishna Kumar |
| Lay Person | : | Mr. Sudhakar. Bandhila |
| Frequency of Meeting: | : | Yearly Thrice & as and when required |

Selection of Members:

4.5.1 Members were selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.

4.5.2 Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.





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Functions for Chairperson

- Conduct EC meetings and be accountable for independent and efficient functioning of the committee.
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations.
- Ratify minutes of the previous meetings.
- In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

Functions of the Member secretary

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review.
- Schedule EC meetings, prepare the agenda and minutes.
- Organize EC documentation, communication and archiving.
- Ensure training of EC secretariat and EC members.
- Ensure SOPs are updated as and when required.
- Ensure adherence of EC functioning to the SOPs.
- Prepare for and respond to audits and inspections.
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Assess the need for expedited review/ exemption from review or full review.
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

D.V.B. Prasad
Principal



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Basic Medical Scientist:

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

Clinician:

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report).
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

Legal expert:

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any

Social scientist

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

Lay person

- Ethical review of the proposal, ICD along with translation(s).

Dr. G. Srinivas
Principal



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- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any

Roles and responsibilities of the EC

- The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
- The EC must ensure ethical conduct of research by the investigator team.
- The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
- The EC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
- The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
- The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements. Responsibilities of members should be clearly defined, The SOPs should be given to EC members at the time of their appointment.
- The Secretariat should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.
- The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
- The EC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
- The EC should recommend appropriate compensation for research related injury, wherever required.

Dr. B. Anurag
Principal



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- The EC should carry out monitoring visits at study sites as and when needed.
- The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
- The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.

Chairperson IEC
Chairperson

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

Principal

Principal

NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003

Member secretary IEC

Member Secretary

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003



Principal

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Institutional Ethics Committee (IEC)

Nellore- 524003, Andhra Pradesh, India
Standard Operating Procedure (SOP); Version -2; 2024

The Genesis

The research at Nursing Colleges should be on par with international standards and ethics; however, it is often found lacking. In some institutions, researchers engage in unethical activities that could potentially harm study participants. Therefore, it is essential to have an Ethics Committee (EC) to safeguard the health of the study participants and to ensure that the study is conducted according to both national and international ethical guidelines. All clinical research should adhere to Good Clinical Practices (GCP) guidelines and must be conducted within the basic tenets of Autonomy (respect for participant's wishes), Beneficence (benefit to participant, family, society), and Justice (fair distribution of benefits, risks, and costs). It is the responsibility of a properly constituted IEC to ensure these principles are incorporated into the protocol and observed throughout the study. It is equally important for a researcher to provide the necessary information pertaining to the proposed study, including the detailed protocol, prior to the EC meeting; this facilitates the decision-making process.

The IEC at Narayana College of Nursing, Nellore, was established out of necessity to safeguard the rights of participants and to heighten the responsibilities of researchers involved in health research. This committee is committed to gradually developing sound conventions in the basic tenets mentioned above.

The present Standard Operating Procedures (SOPs) detailed in this booklet are developed with the goal of facilitating the ethical review and monitoring of research projects involving human subjects and eventually improving the quality of clinical research conducted at this institute. SOPs should be revised periodically (once every three years).



Dr. B. B. B. B.

Principal
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I extend my gratitude to the EC members and other faculty members of this institute for preparing these SOPs. I believe this SOP is easy to understand and follow for clinical researchers. Any suggestions for improvement are welcome.

Dr. B. Vanaja Kumari

Dr. B. Vanaja Kumari

Principal

Narayana College of Nursing

Principal

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Approval by EC - Chairperson

This EC - SOP booklet prepared by Dr B. Vanaja Kumari, Principal, & Mrs. G. Thejovathi, Member secretary, Narayana College of Nursing, reviewed by Member - Dr N. Anjani Devi and approved by all the IEC- members of Narayana College of Nursing is hereby released with effect from 9th Sep 2024 for the purpose of all IEC activities to be conducted henceforth.

I do hereby approve the SOP for the aforesaid purpose.

Dated: 9th Sep, 2024

Dr Siva Kumar Nuvvula. M.D.S, F.I.C.D

IEC - Chairperson,

Narayana College of Nursing

Chairperson

Institutional Ethics Committee

NARAYANA COLLEGE OF NURSING

Chinthareddypalem, Nellore-524003.

Dr. B. Vanaja
Principal

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Preparation of SOP for IEC, NCON

Effective Date: 9th May 2024

| SOP | Name | Designation of IEC | Signature |
|-------------|---------------------------------|--------------------|----------------------|
| Prepared by | Dr. B. Vanaja Kumari, Principal | - | <i>Dr. B. Vanaja</i> |
| | Mrs G. Thejovathi | Member Secretary | <i>Theja</i> |
| Reviewed by | Dr N. Anjani Devi | Member | <i>N Anjani Devi</i> |
| Approved by | Dr Siva Kumar Nuvvula | Chairperson | <i>Siva</i> |
| Noticed by | Dr V. Kumari | Scientific Member | <i>V. Kumari</i> |



Dr. B. Vanaja
Principal
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1. Declaration:

The composition and working procedure of IEC, is based on Operational Guidelines for IEC that review Biomedical Research (WHO, 2000), International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines (1996), New Drugs and Clinical Trials Rules, 2019, Indian GCP guidelines (2016) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017).

2. IEC – Aim & Objectives:

Aim:

IEC, has been constituted with an aim to provide public assurance of protection, reviewing and approving the clinical trial protocol, the suitability of the investigator(s), facilities and the methods and material to conduct interventional research at Narayana College of Nursing, Narayana Medical College and Hospital and Community Areas under compliance of New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR and its requirements.

Objectives:

- These written SOPs were adopted to ensure the protection of the rights and welfare of human participants in biomedical and behavioural research conducted at Narayana College of Nursing.
- The objective of these SOPs of the IEC of Narayana College of Nursing (hereinafter referred to as IEC) for research involving human subjects is to maintain effective functioning of the IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted research proposals and the ongoing approved research projects involving human participants in accordance with the ICMR ethical guidelines for biomedical research on the human subjects.

3. Authority Under Which IEC Constituted:

- Narayana College of Nursing as authorized the formation of IEC, as an independent body which functions independently and as a registered body under CDCSO With respect to decision making and it's working in order to provide public assurance of protection, reviewing and approving the clinical trials.
- Protocols, bioavailability and bioequivalence studies and Biomedical and Health Research projects, the suitability of the investigator(s), facilities and the methods and material to conduct clinical research at Narayana College of Nursing.

In addition to this, the institute will provide all support to the IEC activities which includes training, resources and infrastructure at the same time.



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4. Preparation of Standard Operating Procedures (SOPs) for IEC:

Purpose:

- The purpose of this SOP is to define the process for writing, reviewing, distributing and amending SOPs of IEC.
- The SOPs provide clear, unambiguous instructions so that the related activities of the Committee are conducted in accordance with: New Clinical Trials Rules (2019), National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), Indian GCP Guidelines (Access time 2003) <http://cdsco.nic.in>, WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), The International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines (1996), Declaration of Helsinki and the prevailing amendments from time to time and Amendments from CDSKO office.

Responsibility:

IEC Secretarial staff:

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and past SOPs
- Ensure that all the IEC members and involved staff have access to the SOPs
- Chairperson /Member Secretary appoints coordinating staff to assist IEC Functions.
- Member Secretary shall vote in IEC decisions but coordinating staff of IEC can't vote in any decision making procedure of the IEC.

SOP Team (Member Secretary and one/more members):

- Assess the requests for SOP revision in consultation with the Secretariat and Chairperson
- Propose new / modified SOPs as needed
- Select the format and coding system for SOPs
- Draft the SOP/modify SOP in consultation with the IEC members and involved staff
- Review the draft SOP
- Submit the draft for approval to Chairperson

Chairperson of IEC:

- Chairperson of IEC to appoint the SOP team to formulate the SOPs consisting of Member Secretary, one / more members of IEC and Coordinating staff
- Approve the SOPs
- Sign and date the approved SOPs

Coordinating Staff of IEC:

- Maintain on file all current SOPs and the list of SOPs



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- Maintain an up-to-date distribution list for each SOP distributed
- Maintain the SOPs with a receipt to all users
- Maintain file of all past SOPs of IEC
- Assist in the formulation of SOPs
- Assist Member Secretary

IEC members:

- Sign and date the acknowledgement form when they would receive approved SOP.
- Assist in all decision-making procedures of IEC.
- Assist secretariat for any help in management

Identify the Need for New or Amending SOP:

- Any member of the IEC, Member Secretary would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request.
- The Chairperson will inform all the IEC members about this request in a regular full-committee IEC meeting. If the IEC members agree to the request, an appropriate Member Secretary shall proceed with the revision process/ formulation process of the SOP.
- If the IEC members do not agree, the Chairperson will inform the person/ IEC member who made the request for modification of the SOP in the same meeting.
- The SOPs will be updated regularly at the interval of 3 year or if there are major changes whichever is earlier.

Appoint the SOP Team:

- The Chairperson will identify appropriate members of the IEC who have a thorough understanding of the ethical review process to constitute the SOP writing team.

List of relevant SOPs: (SOP writing team will carry out the subsequent steps)

- Write down step by step all the procedures of the IEC
- Organize, devise and name each process

New Standard Operating Procedures:

- When the need for a new SOP has been identified and agreed, a draft will be written by the Member Secretary and designated IEC members of SOP team, appointed by the Chairperson.

Review by Consultation:

- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team.



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- After incorporating the suggestions put forth by the SOP team members, a copy of the revised draft SOP will be sent to the Member-Secretary, who will circulate it to all the IEC members to invite suggestions.

Preparation and Submission of Final Draft:

- IEC members will review the revised draft SOP in IEC meeting.
- The suggestions agreed upon unanimously, by all the IEC members will be discussed and incorporated in the revised draft SOP and the final draft SOP will be formulated.
- The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

Approve a New/Revised SOP:

- The revised SOPs will be reviewed and approved in the same manner as a new SOP.
- The Chairperson signs and dates the SOP Approval page. Member Secretary shall mention final effective date on SOP, after which SOP need to be made accessible to all stakeholders for reference. Member Secretary or IEC
- Secretariat shall e-mail / share the approved SOP to all members.

Ensure Implementation and File all SOPs:

- The approved SOPs will be implemented from the effective date.
- When the revised version is distributed, old version is retrieved from all members and destroyed for except for one copy; this copy of the earlier version will be placed in the file entitled 'Past SOPs of IEC'.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Member Secretary or IEC coordinating staff, in the IEC office for review and request for a revision of existing SOPs and record the dates of review on the SOP Master file.
- Revision of approved SOPs shall occur at least once a year.

Manage Current and Archive Superseded SOPs:

- IEC office will manage current and archive old versions (superseded) of SOPs
- Superseded SOPs should be retained and clearly marked "superseded" and archived in the file entitled 'Past
- SOPs of IEC by the Member Secretary or IEC coordinating staff.

Glossary:

- Revision date: Date/year by which the SOP may be revised or reviewed.
- Recipients: Stakeholders who would receive a copy of SOP.



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- SOP (Standard Operating Procedure): Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function.
- The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice (GCP).
- IEC: It is an independent body formally designated to review, approve and monitor clinical trials, bioavailability, bioequivalence, biomedical and behavioural research involving humans with the aim to protect the rights and welfare of the participants. It is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a clinical trial and to provide public assurance of that protection.

5. Constitution of the IEC & its Terms of References:

- The IEC is formed by the Dr B. Vanaja Kumari, Principal and Mrs G. Thejovathi, Member Secretary, in accordance with the guidelines laid down in the New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR.
- Appointment / relieving / acceptance of resignation of any member of the IEC would be the prerogative of the principal on the recommendation of IEC.
- The appointment of the IEC member will be confirmed after receipt of their consent to abide by the Good Clinical Practice (GCP) guidelines and maintenance of confidentiality.
- The Principal, IEC will appoint coordinating staff for IEC. They will be supervised by the Member Secretary.
- The IEC, will be multidisciplinary and multi-sectorial in composition and will have 7-9 members from medical, non-medical, scientific and non-scientific areas. At least 50% of members will be non-affiliated to this institute.
- It will have representation that is varied in terms of gender, age and social background. The members representing medical scientist and clinicians should have post graduate qualification & adequate experience in their respective fields.

The Composition shall be as Follows:

- * Chairperson (from outside the institute)
- * One Member Secretary (one of the members representing the institute as designated by the Principal)
- * One or more faculty members of basic medical sciences



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- * One or more faculty members of Dept. of Pharmacology
- * One or more clinicians
- * One or more legal experts
- * One or more independent philosopher or ethicist or theologian
- * One or more lay persons from community
- * One or more woman members
 - The IEC may appoint alternate members who can take part in the IEC activities in absence of regular members to maintain the quorum.
 - The IEC may invite member(s) of specific patient groups or other special interest groups for an IEC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views.
 - Such individuals will have to sign confidentiality agreement and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Observer' and will not have right to vote.

Membership Requirements:

- The Principal, IEC is responsible for appointing new committee members.
- The Chairperson, Member Secretary or any member can suggest names of potential members but the final decision will remain with the Dean, IEC.
- Members will be designated in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience as well as their commitment and willingness to volunteer the necessary time and effort for IEC.
- Members must disclose their interest and involvement by providing a Consent letter and in line with, the Appointment letters will be issued to members along with the Confidentiality agreement which will be required to sign for record of IEC.
- New members will be identified according to the requirement i.e. as per the composition specified.
- New / alternate members will be appointed if deemed necessary by Principal, IEC.

Tenure of Membership:

Dr. B. Anny
Principal

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NELLORE - 524 003.



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- The appointment of the members would be for a period of three years; after which they may be either replaced or reappointed with a fresh appointment letter prior to the end of tenure of members by the IEC secretariat.

Resignation:

- A member can resign by submitting the resignation letter addressing to IEC - Chairperson; and emailed/delivered to Member Secretary. The Member secretary will inform the appointing authority for formal acceptance and to initiate the necessary replacement/recruitment procedure for filling up the vacancy.
- The members if opt to step down due to any genuine cause may do so with prior notice and proper information to the appointing authority.

Disqualification:

- If Principal, IEC Chairperson or member secretary received a communication in writing alleging misconduct by a member.
- A member can be disqualified if fails to attend more than 3 regular consecutive IEC meetings without prior intimation.
- A list of members of the IEC, their appointment letters, bio-data and consent forms would be maintained by Member Secretary of the IEC.
- This list and the copy of the working procedures would be made available to any investigator, for the purpose of filing of research projects, upon written request for the same to the Chairperson.

Chairperson:

- The Chairperson will be appointed by the Principal, Narayana College of Nursing
- The Chairperson will be the Head of the EC.
- The Member Secretary will be the guardian of all documents and records of the EC.
- Other IEC members will be regular committee members with equal ranking.
- The Chairperson will be responsible for conducting committee meetings and will lead all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson will sign documents and communications related to IEC functioning.
- In case of anticipated absence, the Chairperson will nominate a committee member as acting Chairperson.

Member Secretary:

- To accept research study / project proposals.
- To prepare, maintain and distribute of study files.



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- To schedule and organize IEC meetings after consultation with the Chairperson.
- To prepare and maintain meeting agenda and minutes.
- To maintain IEC record and archive them.
- To sign documents and communications related to IEC functioning.
- To communicate with the IEC members and applicants/investigators.
- To notify the Principal Investigator (PI) regarding IEC decisions related to the submitted research proposal.
- To arrange for training of personnel and IEC members.
- To organize the preparations, review, revision and distribution of SOPs and guidelines.
- To provide necessary administrative support for IEC related activities to the Chairperson.
- To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- To receive fees and issue official receipts for the same.
- To delegate various responsibilities to appropriate and authorized persons.
- To ensure adherence of IEC functioning as per SOPs.

Coordinating Staff:

- To support the Member Secretary in executing functions of the IEC.
- Correspondence with the IEC members and investigators.
- Arranging IEC meetings.
- Receiving all research proposals.
- Assisting in preparing agenda and minutes of the meetings.
- Maintaining and archiving study documents.
- To perform any other functions as instructed by Member Secretary/Chairperson.

Responsibilities of IEC members:

- To attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- To review, discuss and consider research proposals submitted for evaluation.
- To monitor Serious Adverse Event (SAE) reports and recommend appropriate action(s).
- To review the progress reports and monitor ongoing studies.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest, if any.
- To participate in continuing education activities in biomedical ethics and biomedical research.



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- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.
- To provide an updated CV when requested for by the IEC secretariat.
- To carry out the work delegated by Chairperson and Member Secretary.
- To assist the Chairperson and Member Secretary in carrying out IEC work as per SOP.

However, following members should be held responsible for specific activities:

- **Clinician:** To provide medical inputs on protocol: Informed consent forms and other aspects like standard of care, Placebo, Sample size, dosing, Concomitant medications, Prohibited medications, risk & benefit to patients, Age group, and Inclusion / exclusion criteria.
- To take clinical judgment for the trial.

Basic Medical Scientist:

- To provide scientist aspects of the study: Investigator's brochure, safety of drug, Pharmacodynamics and
- pharmacokinetics of drug, lab procedures, study design, sample size, use of biological samples.
- Preclinical data and whether protocol adequately address issue of all this matter or not, Qualification of PI and GCP training certificate, Details of SAEs and reporting time limit from PI, all ethics issues and other procedures involved in the study.

Legal Expert:

- To review Clinical Trial Agreement (CTA): Parties involved, scope of agreement, responsibilities of parties and payment details.
- To review incidence of SAE included or not, Adequacy of amount.
- To see whether any clause is violating the norm, Confidentiality, dispute resolution, updated with regulatory requirements and interpretation of the same, Insurance policy: it should cover the participants for injury due to all clauses mentioned in Rule 122DAB, Validity, Countries for which the policy provides cover and Liability limit- per person and total.
- Indemnity: it should cover the liability of investigator and sponsor and could be part of CTA or separated document.
- To see informed consent document.

Social Scientist / NGO representative / Philosopher / Ethicist:

- To see Community perspective, Informed consent process, Compensation, Design of trial whether it is discomfort to subjects, Number of blood samples, post-trial access to involved community, Confidentiality, Vulnerable population, Recruitment process.



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Layperson:

- To see Informed Consent Process, Trial procedures, Post-trial access, Compensation, Confidentiality, Think from the subject's perspective, No exploitation of subject, Subject diary simple or not.

6. Quorum Requirements:

- For clinical trial, the five members of quorum must be from Medical scientist (preferably a pharmacologist), Clinician, Legal expert, Social scientist or representative of a nongovernmental voluntary agency or a philosopher or an ethicist or a theologian or a similar person and one Layperson from the community as per New Drugs and Clinical Trials Rules, 2019.

7. Responsibilities of IEC

- The IEC is to ensure that the research projects carried out or supported by IEC are sound in scientific design, have statistical validity and are carried according to the standard guidelines as prescribed by Good Clinical Practice (GCP), Indian Council of Medical Research (ICMR) guidelines and New Drugs and Clinical Trials Rules, 2019.
- To protect the safety, dignity, rights and wellbeing of the potential research participants.
- To include solely those patients who have given informed consent for participation in the research.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To ensure equitable recruitment of subjects in the study.
- To ensure that the research is conducted under the supervision of the medical persons or scientists with required experience and expertise.
- To assist in the development and the education of a research community responsive to local health care requirements.
- The IEC would review all new research projects and if approval is given it would be for a maximum period of one year (for projects > 1 year).
- After completion of a year, the progress of the project would be reviewed and further extension may be provided. Status of any project can be retrieved by tracking the record document.
- The IEC would maintain a list of all projects submitted, approved, disapproved and outcome of each project with confidentiality.

Dr. B. Anny
Principal

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- The IEC should ensure that patients' rights are not compromised regarding any payments proposed to be made in the study to the patients towards reimbursement of incidental expenses.

8. IEC Members List:

Table-Nine IEC Members Details

| Role in EC | Name and Educational Qualification | Current Organization (Name & Address) | Current Residential Address, Telephone/MobileNo&E-mailID | Affiliated to NCON - Yes/No |
|-------------------------|--|---|--|-----------------------------|
| Chairperson | Dr. Siva Kumar Nuvvula M.D. S (Pedodontics and Preventive Dentistry) | Narayana Dental College & Hospital, Chinthareddypalem, Nellore-524003, A.P | H.No: 56, H Block, Staff Quarters, Narayana Medical College Campus, Nellore-524003, A.P, India, 0861-2317963, Fax:0861-2305092, +91-9441624429, siyakumarn@narayanagroup.com | No |
| Member secretary | Mrs G. Thejovathi, M.Sc. (Nursing) Child Health Nursing | Narayana College of Nursing, Chinthareddypalem, Nellore-524003, A.P | House No: 49, E Block, Staff Quarter, Narayana Medical College Campus, Chinthareddypalem, Nellore-524003, A.P, India, 0861-2317969 +91-9182385535, tejaswani.987@gmail.com | Yes |
| Clinician | Dr Mahidhar Reddy, MS (General Surgery) | Narayana Medical College & Hospital, Chinthareddypalem, Nellore-524003, A.P | H.No: 34, H Block, Staff Quarter, Narayana Medical College Campus, Chinthareddypalem, Nellore-524003, A.P, India, 0861 - 2317965 0861 - 2317962 Ph no: +91-9703848030 mahiesweb@gmail.com | No |
| Basic Medical Scientist | Dr Sreenivasulu Munna M.Pharm, Ph.D., FAGE | Narayana Pharmacy College, Chinthareddypalem, Nellore-524003, A. P | Plot.No:G1, Varshitha Highlands, Sathyam G Nagar, Vaviletipadu (V) Dhana lakshmi puram, Nellore- 524003, A.P, India, 0861 - 2317966 +91-9505811202, sreenivasulu_munna@yahoo.com | No |
| Social Scientist | Mr Natha Krishna Kumar B. Zc, M.A, Sociology | Not affiliated to any organization | H.No:8/11 Anicut Road, Ranganayakulapet, Nellore-524001, A.P, India, +91-9849082239 kknatha@gmail.com | No |
| Legal Expert | Mr. P. Vijaya Kumara Reddy B.A, B.L | Private Practitioner | H. No: 16-6-206, 3 rd Cross Road, Opp to Sri Nethaji Subhash Chandra Bose Statue, Mini Bypass Road, Srinivasa Agraharam, Nellore-524001, +91-9849527270, pvkreddy@gmail.com . | No |
| Scientific Member | Dr. V. Kumari M.Sc. (Nursing), Ph.D. in Nursing | Narayana College of Nursing, Chinthareddypalem, Nellore-524003, A.P | House No: 117, H Block, Fourth Floor, Staff Quarter, Narayana Medical College Campus, Chinthareddypalem, Nellore-524003, A.P, India, 0861-2317969, +91-9677043530 | Yes |

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| | | | | |
|------------|--|---|---|-----|
| | | | kumarivelu1960@gmail.com , | |
| Member | Dr. Anjani Devi Nelavala M.Sc. (Nursing), Ph.D. in Nursing | Narayana College of Nursing, Chinthareddypalem, Nellore-524003, A.P | H. No:17, Staff Quarter, Narayana Medical College Campus, Chinthareddypalem, Nellore-524003, A.P, India, 0861-2317969 , +91-7093655848, nelavalaanjani@gmail.com | Yes |
| Lay Person | Mr. Sudhakar Bandhila M.A, Telugu, M.Sc. Zoology | Telugu Lecturer in ZPHS MulkalPudi | House No: 1-2-16, CB Nagar Colony, Naidupeta-524126, A.P, India,+91-9441232050 SudhakarBandhila1975@gmail.com | NO |

9. Policy for Updating/Training of IEC Members:

- Member Secretary will notify - all relevant information on ethics to the IEC – members
- All IEC members shall be required to undergo refresher course in Good clinical practice (GCP) annually.
- The Chairperson, Member Secretary and members will be encouraged by the appointing authority to attend national and international training programs/conferences/workshops / seminars/courses at least once in a year in the field of research ethics (over and above his own discipline) to help in improving the quality of review of research protocols/ethics committee submissions and other related activities.

Evaluation of IEC:

- The committee will conduct periodic self-assessment annually through internal meeting of the members using the Self-Assessment Tool. The individual feedback will be provided to all members by Member Secretary.

10. Selection and Responsibilities of Subject Expert:

Purpose:

- To invite a subject expert either affiliated or non-affiliated to IEC, NMC to review the proposed study protocol; if the complexity of the issue(s) are not within the collective expertise of all IEC members.

Responsibility:

- Upon the advice or recommendation of the secretary or any IEC member, it is the responsibility of the IEC to nominate the name of one or more special subject experts and be endorsed by the Chairperson for the given project.

Recommendation:



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- The IEC will designate subject experts from the different specialties and the Chairperson / Member Secretary on behalf of the IEC will invite subject expert selected by the IEC in writing to assist in the review of the project and provide his/ her independent opinion.

Selection:

- IEC Chairperson approves the invited subject expert and review the research project.

Co-ordination with Subject Expert:

- Subject experts will participate after they agree to the confidentiality clause and abide by the rules & regulations of IEC whose opinion would be valuable but they would not be involved in the decision making process of the EC.
- The expert opinion should be obtained in writing within 30 working days' post EC meeting.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the subject experts if any doubts or questions are raised.
- The Chairperson / Legal expert / IEC members can provide any further explanations. If deemed necessary, subject expert may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet, incidental expenses, etc.

11. Research Proposal Submission Procedure:

- All research proposals are to be submitted to the EC- Member Secretary in the prescribed Application format along with check list in the prescribed format and detailed study protocol at least 1 to 2 weeks in advance, especially for all clinical trials.
- Covering letter addressed to the IEC - Chairperson / Member Secretary

The protocol would include the following:

- I. Title; Name and contact details of a) Principal Investigator (PI); b) Study Sponsor.
- II. Protocol - Summary; research objectives and rationale for the study involving human subjects.
- III. Recent curriculum vitae (CV) of the investigators indicating qualification and experience; GCP certificate (< 3 years) of PI and his team members.
- IV. Details of Funding agency / Sponsors and fund allocation for the proposed work. *
- V. Investigator's Brochure. *
- VI. Undertaking by the Investigator. *
- VII. Subject recruitment procedures or proposed methods / advertisement / notices.



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- VIII. Study subjects - Inclusion and exclusion criteria.
- IX. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any.
- X. Statistical analysis in detail.
- XI. Procedure for seeking and obtaining informed consent; with sample of patient information sheet and information consent forms in English and vernacular languages and the validity of the translation and back translation (certificate).
- XII. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research. *
- XIII. For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over-dosage should be included.
- XIV. Case Record Form (CRF) / Proforma / Questionnaire.
- XV. Proposed compensation for participation and reimbursement of incidental expenses/ serious adverse events occurring during the study participation. *
- XVI. Plans - a) for storage and maintenance of all data collected during the trial; b) publication of results - positive/negative while maintaining the privacy & confidentiality of the study participants.
- XVII. Activity plan / Timeline; Amendments to protocol (if any).
- XVIII. Protocol signature page; signed by the study PI and all other relevant documents related to the study protocol including a) regulatory clearances; b) insurance documents as applicable.
- XIX. Investigator's agreement with the sponsor / Clinical Trial Agreement (CTA) / Agreement to comply with national and international GCP protocols for clinical trials. *
- XX. Memorandum of Understanding (MOU) between collaborative institutions.
- XXI. CTRI registration* and DCGI Approval letter. *
- XXII. FDA marketing/manufacturing license for herbal drugs. *
- XXIII. Ethics Committee clearance of other centres (if applicable).
- XXIV. Any additional document(s), as required by IEC.

Code of Ethics for Research



CODE OF ETHICS FOR RESEARCH

The Ethics Committee and Research Committee of Narayana College of Nursing are strictly ensuring that undergraduate, postgraduate, Ph.D. students, and faculty adhere to research ethics throughout their projects.

The **Code of Ethics in Research** provides a framework of principles that researchers should follow to conduct ethical, responsible, and morally sound research. It emphasizes the protection of human rights, integrity, and the accuracy of scientific endeavors.

1. Respect for Persons

- **Informed Consent:**

Researchers must ensure voluntary and informed consent from participants. Participants should understand the purpose of the research, potential risks, benefits, and their right to withdraw at any time.

- **Autonomy:**

Researchers must respect the autonomy of participants, ensuring they make informed decisions free from coercion or undue influence.

2. Beneficence and Non-Maleficence

- **Minimizing Harm:** Researchers must aim to maximize the benefits of research while minimizing potential harm to participants. Risks must be assessed and mitigated before research begins.
- **Do No Harm:** Researchers are responsible for protecting the well-being of participants, ensuring that no physical, psychological, or emotional harm comes to them as a result of their participation.

Dr. B. D. Devi
Principal



3. Justice

- **Fair Participant Selection:** Research participants should be selected equitably. Vulnerable populations should not be exploited, and the benefits of research should be fairly distributed among all groups.
- **Equitable Access:** The benefits of research (e.g., access to new treatments) should be accessible to all participants after the study, especially those from marginalized groups.

4. Confidentiality and Privacy

- **Data Protection:** Researchers must safeguard the privacy and confidentiality of participants' data. Personal information should be anonymized or encrypted to protect participants' identities.
- **Restricted Access:** Only authorized personnel should have access to sensitive data collected during the research.

5. Integrity and Honesty

- **Honesty in Reporting:** Researchers should report research findings honestly, without fabrication, falsification, or misrepresentation of data.
- **Plagiarism:** Researchers must avoid plagiarism by giving proper credit to original sources, ideas, and research materials.
- **Conflict of Interest:** Any potential conflicts of interest must be declared upfront to ensure the integrity of the research process.

6. Accountability and Responsibility

- **Ethical Review:** Research involving human participants must be reviewed and approved by an Institutional Ethics Committee (IEC) or an equivalent body to ensure compliance with ethical standards.



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- **Supervision:** Researchers must ensure proper supervision of research activities, especially if students or junior researchers are involved.
- **Adherence to Laws and Regulations:** Researchers must follow all relevant national, institutional, and international laws, guidelines, and ethical standards.

7. Transparency

- **Transparency in Methods:** Research methods and procedures should be transparent and reproducible, ensuring that other researchers can replicate or verify the findings.
- **Public Disclosure:** Results, both positive and negative, should be publicly disclosed to advance knowledge and avoid unnecessary duplication of research.

8. Protection of Vulnerable Populations

- **Special Considerations:** Vulnerable populations, such as children, pregnant women, prisoners, and those with disabilities, should be given special protections. Their participation in research should be justified with clear benefits and minimal risks.

9. Compensation and Remuneration

- **Fair Compensation:** Participants should be fairly compensated for their time and contributions to the research, particularly in case of research-related injury or harm.
- **Research-Related Injury:** If any injury or adverse event occurs during the research, the participant should be entitled to proper treatment and compensation.

10. Social Responsibility

- **Benefit to Society:** Researchers have a duty to ensure that their research benefits society and contributes to the advancement of science and public good.
- **Environmental Impact:** Researchers should consider the environmental impact of their research and strive to minimize any negative effects.



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11. Post-Trial Responsibilities

- **Post-Trial Access:** If a research study involves the development of new treatments, participants should have access to these interventions after the trial concludes, especially if no other effective alternatives exist.

12. Publication Ethics

- **Accurate Authorship:** Only individuals who have made significant intellectual contributions to the research should be listed as authors.
- **Data Integrity:** Researchers must not manipulate or falsify data, and should publish accurate findings, whether the results are favorable or not.
- **Acknowledging Contributions:** Proper acknowledgment should be given to all contributors, including funding agencies, research assistants, and collaborators.

13. Global Ethical Considerations

- **International Research:** Researchers conducting cross-border studies should ensure that ethical standards are maintained globally, and that research conducted in developing countries or low-resource settings follows the same ethical standards as in developed countries.

Research Promotion

- **Collaboration:** Encourage interdisciplinary and collaborative research within and outside the institution.
- **Training:** Facilitate workshops and training sessions on research methodologies, ethics, and writing skills.

Narayana College of Nursing offers financial support through its research committee for various research and academic activities, including:

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1. Publication of Papers:

- **Amount:** ₹15,000
- **Purpose:** To support faculty and students in publishing research articles in reputable journals.

2. Useful Projects Beneficial to the Public:

- **Amount:** ₹25,000
- **Purpose:** For projects that have practical applications and can contribute positively to the community.

3. Participation in International Conferences:

- **Amount:** ₹5,000
- **Purpose:** To encourage faculty and students to present their research and gain international exposure.

Guidelines for Availing the Support:

1. Eligibility:

- Faculty and students of Narayana College of Nursing.
- Projects or publications should align with the strategic goals of the college and contribute to the academic environment or community welfare.

2. Application Procedure:

- Submit a formal request to the Research Committee along with a detailed proposal, including objectives, expected outcomes, budget, and impact.
- For publications, include the manuscript and details of the journal where it will be published.
- For conferences, provide proof of acceptance and a brief description of the research to be presented.

3. Review and Approval:

- The Ethics Committee will review the application based on its relevance, innovation, and potential impact.



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- Upon approval, the funds will be disbursed as per the guidelines set by the committee.

4. Reporting and Accountability:

- After receiving the grant, a report detailing how the funds were utilized, along with outcomes and any publications or conference presentations, should be submitted to the committee.

2.5 Dissemination

- **Publication:** Support and facilitate the publication of research findings in peer-reviewed journals.
- **Presentation:** Encourage presentation of research findings at conferences and seminars.

3. Roles and Responsibilities

3.1 Chairperson

- **Leadership:** Lead the committee, ensuring effective functioning and adherence to guidelines.
- **Decision-Making:** Make final decisions on research approvals and ethical matters.
- **Coordination:** Liaise with the Institutional Ethics Committee and other relevant bodies.

3.2 Committee Members

- **Review:** Critically review research proposals and manuscripts.
- **Guidance:** Provide feedback and support on research design, methodology, and analysis.
- **Ethics:** Ensure compliance with ethical standards and guidelines.

Dr. B. D. Srinivas
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3.3 Secretary

- **Documentation:** Prepare and maintain minutes of meetings, agendas, and correspondence.
- **Organization:** Schedule meetings and manage logistics.
- **Communication:** Disseminate decisions and feedback to researchers.

3.4 Biostatistician/Subject Expert

- **Expertise:** Offer statistical and methodological support to enhance research quality.
- **Analysis:** Assist in the design of statistical analyses and interpretation of data.

3.5 External Members

- **Impartiality:** Provide an objective perspective and additional expertise.
- **Advice:** Offer guidance on emerging trends and best practices in research.

4. Guidelines for Meetings

4.1 Frequency

- Meetings should be held regularly (e.g., quarterly) or as needed based on research submissions and progress.

4.2 Agenda

- **Preparation:** Prepare an agenda in advance, including:
 - Review of new research proposals.
 - Discussion of ongoing projects.
 - Updates on ethical issues and compliance.
 - Planning for upcoming events or training.

Dr. B. D. Dey
Principal

NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003



NARAYANA COLLEGE OF NURSING

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website: <https://www.narayanannursingcollege.com>



4.3 Quorum

- A quorum (typically at least 50% of the committee members) must be present for decisions to be made.

4.4 Decision-Making

- **Consensus:** Aim for decisions through consensus. If needed, decisions can be made by majority vote.
- **Documentation:** Record all decisions and action items clearly in the minutes.

4.5 Minutes of Meeting (MoM)

- **Content:**
 - Date, time, and venue.
 - Attendees and absentees.
 - Summary of discussions.
 - Decisions made and action items.
 - Next meeting details.
- **Distribution:** Share minutes with all members for review and feedback before finalizing.
- **Storage:** Keep minutes in a secure location for future reference.

5. Research Committee Guidelines

5.1 Ethical Standards

- **Compliance:** Ensure all research adheres to ICMR's ethical guidelines and institutional policies.

Dr. B. D. D. D.
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5.2 Reporting and Documentation

- **Records:** Maintain comprehensive records of all research proposals, approvals, and correspondence.
- **Transparency:** Ensure transparency in decision-making processes and documentation.

5.3 Conflict of Interest

- **Disclosure:** Members must disclose any conflicts of interest that could affect their judgment.

5.4 Training and Development

- **Continuing Education:** Encourage ongoing professional development in research methodologies and ethics for committee members and researchers.

By adhering to these guidelines, the Research Committee at Narayana College of Nursing ensures that research activities are conducted ethically, scientifically rigorous, and aligned with institutional and national standards.

Publication Guidelines

The publication guidelines for project publication at Narayana College of Nursing would typically align with broader academic and professional standards for publishing in nursing and healthcare. These guidelines are likely influenced by frameworks from agencies such as the Indian Council of Medical Research (ICMR), the Central Drugs Standard Control Organization (CDSCO), and institutional regulations. Below is a detailed outline of standard **publication guidelines** that adopted for project publications at Narayana College of Nursing:



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1. Research Ethics and Approval

- **Ethical Approval:** Every research project must obtain approval from an **Institutional Ethics Committee (IEC)** before starting. This is crucial, particularly for research involving human subjects.

Narayana College of Nursing has Institutional Ethics Committee from CDSCO, New Delhi.

- **Informed Consent:** Ensure that written informed consent is obtained from all participants in accordance with ICMR's ethical guidelines. This should be documented and kept securely.
- **Adherence to Good Clinical Practices (GCP):** For clinical studies, researchers should follow ICMR guidelines on GCP, ensuring safety, quality, and integrity in data collection and patient care.

2. Manuscript Preparation

- **Title:** The title should be concise and reflect the study's main purpose, methodology, and outcomes. Avoid abbreviations and jargon.
- **Abstract:** The abstract should be structured (250-300 words) and include sections like:
 - Background
 - Objectives
 - Methods
 - Results
 - Conclusion
- **Introduction:** The introduction must describe the background, rationale, objectives, and significance of the research. It should provide context through a brief review of existing literature.

Dr. B. D. Srinivas
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- **Materials and Methods:** This section should provide a detailed description of the study design, methodology, sample size calculation, and statistical tools used. It should also highlight how ethical approval was obtained.
- **Results:** Results should be presented clearly using appropriate figures, tables, and graphs. No interpretation should be included here.
- **Discussion:** The discussion should interpret the results in relation to existing literature, study limitations, and future implications. Mention any unexpected findings and offer potential explanations.
- **Conclusion:** Summarize key findings, emphasizing their relevance to healthcare and nursing. Do not introduce new information.
- **References:** Follow a standardized referencing format (Vancouver or APA) as per ICMR or the target journal's guidelines.

3. Data Integrity and Confidentiality

- **Data Sharing:** ICMR encourages transparency in data sharing, with appropriate safeguards to protect patient confidentiality. Researchers should obtain necessary permissions before sharing data.
- **Data Protection:** Ensure that all participant data is anonymized to maintain confidentiality in compliance with ICMR's ethical guidelines.
- **Plagiarism Check:** All manuscripts should undergo a plagiarism check to maintain the originality of the work.

4. Conflict of Interest and Funding Disclosure

- **Declaration of Funding Sources:** Clearly mention any financial or institutional support received for the research. Acknowledge ICMR funding if applicable.
- **Conflict of Interest:** Disclose any potential conflicts of interest that might influence the research results or interpretation.

Dr. B. D. Devi
Principal



5. Authorship Criteria

- **ICMR Authorship Norms:** Only those who have significantly contributed to the research's conception, design, data collection, analysis, or writing should be listed as authors. All authors must approve the final version of the manuscript.
- **Acknowledgments:** Credit should be given to individuals or organizations who contributed to the research but do not meet the authorship criteria.

6. Publication Ethics and Open Access

- **ICMR Open Access Policy:** ICMR encourages open access publication to ensure that the public benefits from scientific advancements. Manuscripts should be published in peer-reviewed journals that offer open access or ensure broad dissemination.
- **Reporting Standards:** The manuscript should follow standard reporting guidelines like CONSORT for clinical trials or STROBE for observational studies, as applicable. ICMR emphasizes transparency and reproducibility in research reporting.

7. Study Registration

- **Clinical Trials Registry:** If the research involves a clinical trial, it must be registered with the **Clinical Trials Registry- India (CTRI)**, as per ICMR guidelines.
- **Reporting of Negative Findings:** ICMR encourages the reporting of all findings, including negative or inconclusive results, to maintain scientific integrity and avoid publication bias.

8. Format and Submission

- **Font and Layout:** Use a standard font like Times New Roman, 12-point, with 1-inch margins. The manuscript should be double-spaced.



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- **Word Limit:** Follow the recommended word count as per the target journal or publication. For ICMR publications, typical manuscripts range from 3000 to 5000 words, excluding references, tables, and figures.
- **Figures and Tables:** All figures and tables should be labeled and integrated within the manuscript. They should be cited sequentially and placed after the relevant text.
- **Headings and Subheadings:** Use appropriate heading levels to organize the manuscript logically, with clear sections for Methods, Results, Discussion, etc.

9. Review Process

- **Peer Review:** Manuscripts submitted for publication under ICMR-affiliated projects typically undergo peer review. Ensure that the manuscript meets high-quality research standards before submission.
- **Response to Reviewers:** Be prepared to address comments and revisions suggested by peer reviewers in a clear and timely manner.

10. Dissemination of Research Findings

- **Public Access:** ICMR encourages wide dissemination of research findings to the public, policymakers, and other researchers. This includes making the research publicly accessible in institutional repositories or via open-access journals.
- **Community Engagement:** Research findings that may impact local communities should be communicated back to those communities in a manner they understand, maintaining transparency and trust.

Dr. B. D. Dey
Principal

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The Research Committee at Narayana College of Nursing is a critical body responsible for overseeing and supporting research activities within the institution. It ensures that research is conducted ethically, meets high scientific standards, and aligns with both institutional and national guidelines.

Dr. B. D. D. D.
Principal

NARAYANA COLLEGE OF NURSING
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ANAYANAN

COLLEGE OF BUSINESS



1. The meeting was held on 10/10/2023 at 10:00 AM in the IEC meeting room. The meeting was presided over by the IEC Chairperson, Mr. [Name]. The meeting was attended by the IEC members, Mr. [Name], Mr. [Name], and Mr. [Name]. The meeting was held in a friendly and cooperative atmosphere. The meeting was held in a friendly and cooperative atmosphere.

IEC MINUTES



INSTITUTIONAL ETHICS COMMITTEE
NARAYANA COLLEGE OF NURSING

Chinthareddypalem, Nellore. Ph : 0861 - 2317969, Fax : 0861 - 2311968.
Reg Approved by: Central Drugs Standard Control Organization
Reg. No ECR/1348/Inst/AP/2020 New Delhi, dated : 20.Feb.2020.



NCON/IEC/ACD/2020-21/01

08/02/2021

CIRCULAR

Narayana College of Nursing -Institutional Ethics Committee meeting is tentatively scheduled on 17th&18thFeb 202, from 2pm to 5pm, in Seminar hall, Ph.D Scholars & UG selected funded project students are instructed to present their proposals for ethics committee approval, the Proposal should be submitted to the Member Secretary before one week of presentation. All the committee members to be present in time as per mentioned Date&time and Scheduled was attached.

A. S. Sali
Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003.

Copy to:

- IEC Members
- Guides
- I M.Sc.(N) Class coordinator

D. B. S. S. S.
Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
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INSTITUTIONAL ETHICS COMMITTEE NARAYANA COLLEGE OF NURSING

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Schedule for Presentation

| S No | Ph D Scholar & IV year B.Sc.(N) Student (UGSRS) | Date & time | Sign |
|------|---|---------------------|-----------|
| 1. | Prof Latha. A, Ph.D. Scholar | 17/2/21, 2pm to 5pm | Latha |
| 2. | Prof Saritha, Ph.D. Scholar | 17/2/21, 2pm to 5pm | Saritha |
| 3 | Mrs Kantha. K, Assoc. Prof, PhD Scholar | 17/2/21, 2pm to 5pm | Kantha |
| 4 | Mrs Aruna Kumari, Assoc. Prof, PhD Scholar | 17/2/21, 2pm to 5pm | Aruna |
| 5 | Ms. Akshita Joy | 17/2/21, 2pm to 5pm | Joy |
| 6 | Ms. Sumi Sabu | 17/2/21, 2pm to 5pm | Sumi |
| 7 | Ms. Athira Kunjumon | 17/2/21, 2pm to 5pm | Athira |
| 8 | Ms. Simi Thomas | 17/2/21, 2pm to 5pm | Simi |
| 9 | Ms. Chinju. T.J | 17/2/21, 2pm to 5pm | Chinju |
| 10 | Varsha Sunil kumar | 17/2/21, 2pm to 5pm | Varsha |
| 11 | Ashy Kuriakose | 17/2/21, 2pm to 5pm | Ashy |
| 12 | Anumol Biju | 17/2/21, 2pm to 5pm | Anumol |
| 18 | Aneeta. S. Titus | 17/2/21, 2pm to 5pm | Aneeta |
| 19 | Sheena Thomas | 18/2/21, 2pm to 5pm | Sheena |
| 20 | Anujamol Thomas | 18/2/21, 2pm to 5pm | Anujamol |
| 21 | Deepthi Tomy | 18/2/21, 2pm to 5pm | Deepthi |
| 22 | Anjaly Thankachan | 18/2/21, 2pm to 5pm | Anjaly |
| 23 | Sandra. V. Saji | 18/2/21, 2pm to 5pm | Sandra |
| 24 | Alida Franchis | 18/2/21, 2pm to 5pm | Alida |
| 25 | Rosy Raj | 18/2/21, 2pm to 5pm | Rosy |
| 26 | Teena P Mathew | 18/2/21, 2pm to 5pm | Teena |
| 27 | Limna George | 18/2/21, 2pm to 5pm | Limna |
| 28 | Ann Maria Babu | 18/2/21, 2pm to 5pm | Ann Maria |
| 29 | Anugraha Antony | 18/2/21, 2pm to 5pm | Anugraha |

The list of documents to be submitted by the investigator to the IEC for review:

1. Covering letter
2. Application for Initial review
3. Complete Proposal
4. Informed Consent Document in English and local language
5. Questionnaire if any

K. Kantha

Member secretary

Member Secretary

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

Dr. Raju

Chairperson

Chairperson

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.
Dr. Raju
Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
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INSTITUTIONAL ETHICS COMMITTEE NARAYANA COLLEGE OF NURSING

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Institutional Ethics Committee Minutes

An Institutional ethics committee meeting was held on 24th & 25th Feb 2021 from 10 am at Seminar hall in Narayana College of Nursing for proposal presentation by PhD scholars & UG selected funded project students to get IEC clearance. The committee has assessed 4 PhD scholar & 22 UG proposals and provided suggestions according to the ethical norms and Title of the dissertation. The committee has also appreciated researchers for their efforts in developing and presenting their proposals. At the end of the meeting, everyone was thanked by member secretary for commitment and active participation.

The Following Members was present

| S.No | Name of Member | Qualification | Designation in Ethics Committee | Sign |
|---|---------------------------|---------------------------|---------------------------------|--------------------|
| 1. | Dr. Nuvvula Siva Kumar | BDS (M.D.S) | Chair Person | <i>[Signature]</i> |
| 2. | Dr. V Mahidhar Reddy | MBBS (MS) General Surgery | Clinician | <i>[Signature]</i> |
| 3. | Dr. Arumugam Indira | BSc (MSc.PhD) | Scientific Member | <i>[Signature]</i> |
| 4. | Ms. Kantha Katari | BSc (MSc.Nursing) | Member Secretary | <i>[Signature]</i> |
| 5. | Dr. H Rajeswari | BSc (MSc.,PhD Nursing) | Member | <i>[Signature]</i> |
| 6. | Mr. Kandati Jithendra | MBBS (MD-Microbiology) | Basic Medical Scientist | <i>[Signature]</i> |
| 7. | Mr. P Vijaya Kumara Reddy | B.A (LLB) | Legal Expert | <i>[Signature]</i> |
| 8. | Mr. Nath Krishna Kumar | BSc (MA) | Social scientist | <i>[Signature]</i> |
| 9. | Ms. K Padma | 10 th class | Lay person | <i>[Signature]</i> |
| Others presented in Presentation | | | | |
| 10. | Dr Kumari.V | BSc (MSc.,PhD Nursing) | HOD of OBG | <i>[Signature]</i> |
| 11. | Prof Latha.A | BSc (MSc.Nursing) | HOD of MSN | <i>[Signature]</i> |
| 12. | Mrs Ramya | BSc (MSc.Nursing) | HOD of CHN | <i>[Signature]</i> |
| 13. | MrsSmitha.P.M | BSc (MSc.Nursing) | HOD of MHN | <i>[Signature]</i> |
| 14. | Dr Mangala Gowri | BSc (MSc.,PhD Nursing) | HOD of COHN | <i>[Signature]</i> |

Dr. [Signature]
Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
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INSTITUTIONAL ETHICS COMMITTEE
NARAYANA COLLEGE OF NURSING

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The following proposals was presented and approved on 24th Feb 2021

| SNo | Ph.D. Scholar&UGSRS Students | Thesis |
|-----|------------------------------|--|
| 1. | Prof Latha. A | Effectiveness of Cutaneous stimulation by Cryotherapy on pain and fatigue among Chronic Kidney Disease patient with AV fistula undergoing Hemodialysis at Narayana Medical College & Hospital Nellore. |
| 2. | Prof Saritha | Effect of self Management promotional Program on Glycemic Control among Type II DM patients in Rural areas, Nellore. |
| 3 | Kantha.K, Assoc. Prof | A Study to Evaluate the effectiveness VAT on Hypertension Safety bundle care therapy (HSBCT) on prevention of risk for CAD among hypertensive adults at selected villages of Nellore, Andhra Pradesh. |
| 4 | Aruna Kumari, Assoc. Prof | A Study to Compare Knowledge on diabetic foot ulcer and practice of foot care among Diabetic Patients residing in selected Rural and Urban Areas of Vijayawada, Andhra Pradesh. |
| 5 | Akshita Joy | A study to explore coping measures related to management of examination stress among adolescents studying 10th standard at selected schools in Nellore, Andhra Pradesh. |
| 6 | Sumi Sabu | Descriptive Study to find Association between Smart Phone usage and Academic Performance among Graduate Nursing Students at selected colleges of Nellore district, Andhra Pradesh. |
| 7 | Athira Kunjumon | A Descriptive study to Assess the Awareness of Fire Safety Measures among Undergraduate Students in selected colleges at Nellore, Andhra Pradesh. |
| 8 | Simi Thomas | An Observational Survey on Fat Soluble vitamin deficiencies among primary school children in selected Schools at Nellore, Andhra Pradesh. |
| 9 | Chinju .T.J | A Cohort Study To Assess The Attitude' And Practice Of Breast Self Examination Among Premenopausal Women |

D. S. S. S.
Principal
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| At Selected Areas in Nellore, Andhra Pradesh | | |
|--|--------------------|---|
| 10 | Varsha Sunil kumar | A prospective study to assess knowledge regarding disaster management among adolescents at selected schools, Andhra Pradesh. |
| 11 | Ashy Kuriakose | A Study to assess the knowledge, attitude and practice regarding dental care among school children's in selected schools, Nellore, Andhra Pradesh. |
| 12 | Anumol Biju | An Explorative Study to Assess the Effectiveness of Self-instructional Module on Knowledge regarding Prevention of Needle Stick injury among Staff Nurses at NMCH Nellore, Andhra Pradesh. |
| 13. | Aneeta. S. Titus | An Explorative Study to Effectiveness of Skill Training on First Aid For Selected Minor injuries among Accredited Social Health Activists (ASHA) at selected Health centers of Andhra Pradesh |

The following proposals was presented and approved on 25th Feb 2021

| S No | Ph.D. Scholar &UGSRS Students | Thesis |
|------|-------------------------------|--|
| 14. | Sheena Thomas | A cross sectional study to assess prevalence of skin problems among worker in sea food industries at selected areas of Nellore. |
| 15 | Anujamol Thomas | A cross sectional study to evaluate the prevalence and risk factors of computer vision syndrome(CVS) among computer users at selected colleges, A.P |
| 16 | Deepthi Tomy | An explorative study to assess the competency on trauma care among nurses at selected hospitals, Nellore Andhra Pradesh |
| 17 | Anjaly Thankachan | A cross sectional study to assess the Prevalence of respiratory problems among rice mill workers at selected rice mills in Nellore, Andhra Pradesh. |
| 18 | Sandra.V.Saji | An evaluative study to assess the Impact of smart phone on social life among young generation at selected colleges in Nellore, Andhra Pradesh. |
| 19 | Alida Franchis | A comparative study to identify the medication adherence among patients with hypertension in selected urban and rural areas of Nellore district, Andhra Pradesh. |

Dr. Rajam
Principal
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| | | |
|----|-----------------|--|
| 19 | Rosy Raj | An evaluative study to estimate the Documentation Protocol Compliance among staff nurses working in critical care units at selected hospitals, Nellore, Andhra Pradesh. |
| 20 | Teena P Mathew | An Observational Study to Assess the Emotional Problems and Coping Strategies of Senior Citizens living in old age home with a view to develop an information booklet at selected old age homes, Andhra Pradesh. |
| 21 | Limna George | A descriptive study to assess knowledge regarding road safety among small scale vendors riding two wheelers at selected areas of Andhra Pradesh |
| 22 | Ann Maria Babu | A Descriptive Study to Assess the perception on COVID-19 vaccination among Middle aged People between 45-55 year in Dakkilivaripalem at Nellore, Andhra Pradesh." |
| 23 | Anugraha Antony | A descriptive study to assess the knowledge regarding complications and life style modification among the clients in cardiology OPD at selected hospitals, Nellore, Andhra Pradesh. |

Member secretary

Member Secretary

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

Chairperson

Chairperson

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

Principal

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NCON/IEC/ACD/2020-21/02

30/09/2021

CIRCULAR

Narayana College of Nursing -Institutional Ethics Committee meeting is tentatively scheduled on 8th&9th October2021, from 2pm to 5pm, in Seminarhall, M.Sc.(N) students are instructed to present proposals for ethics committee approval, the Proposal should be submitted to the Member Secretary before one week of presentation. All the committee members to be present in time as per mentioned Date& time, schedule was attached

A. S. S. S.
Principal
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NELLORE - 524 003.

Copy to:

IEC Members
Guides
I M.Sc.(N) Class coordinator

D. B. S. S.
Principal
NARAYANA COLLEGE OF NURSING
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NELLORE - 524 003



INSTITUTIONAL ETHICS COMMITTEE NARAYANA COLLEGE OF NURSING

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Institutional Ethics Committee Minutes

The Institutional ethics committee meeting was held on 08th&09th October 2021 from 2pm at Seminar hall, Narayana College of Nursing. The member secretary welcomed the committee members for proposal presentation by P.G students 2018-20 batch to get IEC clearance. The committee has assessed seventeen dissertations and provided suggestions according to the ethical norms and Title of the dissertation. The committee has also appreciated researchers for their efforts in developing and presenting their proposals. The meeting ended with the appreciation of research guides & students for their commitment and active participation.

The Following Members was present

| S.No | Name of Member | Qualification | Designation in Ethics Committee | Sign |
|---|---------------------------|---------------------------|---------------------------------|------|
| 1. | Dr. Nuvvula Siva Kumar | BDS (M.D.S) | Chair Person | |
| 2. | Dr. V Mahidhar Reddy | MBBS (MS) General Surgery | Clinician | |
| 3. | Dr. Arumugam Indira | BSc (MSc. Nursing, PhD) | Scientific Member | |
| 4. | Ms. Kantha Katari | BSc (MSc. Nursing) | Member Secretary | |
| 5. | Dr. H Rajeswari | BSc (MSc. Nursing, PhD) | 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 (M.A) | Social scientist | |
| 9. | Ms. K Padma | 10 th class | Lay person | |
| Others presented in Presentation | | | | |
| 10. | Dr Kumari V | B.Sc. (MSc. Nursing, PhD) | HOD of OBG | |
| 11. | Prof Latha A | BSc (MSc, Nursing) | HOD of MSN | |
| 12. | Mrs Ramya | BSc (MSc, Nursing) | HOD of CHN | |
| 13. | Mrs Smitha P.M | BSc (MSc, Nursing) | HOD of MHN | |
| 14. | Dr Mangala Gowri | BSc (MSc. PhD Nursing) | HOD of COHN | |

Principal
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Reg. No ECR/1348/Inst/AP/2020 New Delhi, dated : 20.Feb.2020.



SCHEDULE

PG students are instructed to present research proposals as per below mentioned schedule.

| S No | Student Name | Date& Time | Sign |
|------|---------------------------------|-----------------------|--------------------|
| 1. | Ms A Sravanthi | 8/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 2. | MsBellamkonda Indrajaya | 8/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 3 | MsKurapati Indira Priyadarshini | 8/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 4 | Ms PB Sowmya | 8/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 5 | MsBRajamani | 8/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 6 | MsMayengbamJennidevi | 8/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 7 | MsPanguluri Rajitha | 8/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 8 | MsSaroja Wahengbam | 8/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 9 | Ms Mounika | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 10 | Ms G Bharathi | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 11 | Ms Vidya N | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 12 | Ms D Bhanupriya | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 13 | Ms V Meena | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 14 | MsThoudam Ranjana Chanu | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 15 | Ms V Sakthi | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 16 | Ms J Vandana | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |
| 17 | Ms T Chandana | 9/10/2021, 2pm to 5pm | <i>[Signature]</i> |

The following documents are to be submitted for the approval:

1. Covering letter
2. Application form
3. Complete Proposal
4. Informed Consent Document in English and local language
5. Structured tool

[Signature]
Member secretary
Member Secretary
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

[Signature]
Chairperson
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
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[Signature]
Principal
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Chinthareddypalem,
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INSTITUTIONAL ETHICS COMMITTEE
NARAYANA COLLEGE OF NURSING

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Reg Approved by: Central Drugs Standard Control Organization
Reg. No ECR/1348/Inst/AP/2020 New Delhi, dated : 20.Feb.2020.



The following Dissertation topics presented by I year M.Sc.(N) students and approved by committee after few modifications.

| S.No | PG Student | Dissertation |
|------|-----------------------------------|---|
| 1. | Ms .A. Sravanthi | A Study to Assess the Problems Encountered in Establishing Breastfeeding among Primi Para Mothers Admitted in Postnatal Wards in NMCH, Nellore. |
| 2. | Ms . Bellamkonda Indraja | A Study to Assess the Effectiveness of Progressive Muscle Relaxation Verses Oral Intake of Ginger Powder on Selected Symptoms of Dysmenorrheal among adolescent Nursing Students in Narayana College of Nursing, Nellore Andhra Pradesh |
| 3 | Ms. Kurapati Indira Priyadarshini | A Study to Assess the Effectiveness of Structured Teaching Program on Knowledge regarding Polycystic Ovary Syndrome among Nursing students, Narayana College of Nursing, Nellore. |
| 4 | Ms. P.B. Sowmya | A Study to Assess the Factors influencing Malnutrition among Women in Reproductive age group at Selected Villages, Nellore. |
| 5 | Ms.B. Rajamani | A Study to assess the Impact of School based Nutritional Education on Dietary Knowledge, Attitude and Behavior among School Children at Nellore. |
| 6 | Ms .MayengbamJenidevi | A Study to Assess the Effectiveness of Skill Training Program on CPR among the Adolescents in a Selected School at Nellore" |
| 7 | Ms. Panguluri Rajitha | A Study to Assess the Correlation of Anger Stress and Blood Pressure among Over Weight School Children (6-12years) at Selected Schools Nellore. |
| 8 | Ms. Saroja Wahengbam | A Study to Assess the Effectiveness of Game Based Learning on Knowledge regarding Health Promotion among Primary School Children in Sravanthi English Medium High School at Saraswathi Nagar,Nellore. |

Dr. S. S. Srinivas
Principal

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| 9/10/22 | | |
|---------|--------------------------|---|
| 9 | MsG. Bharathi | A Study to assess the Prevalence of Anemia and its Associated Factors among Adolescent Girls in Selected School at Nellore. |
| 10 | Ms. Vidya . N | A Study to Assess the Effectiveness of Peer Group Behavior Change communication on Lifestyle Modification among Hypertensive adults in Selected areas, Nellore. |
| 11 | Ms. D. Bhanupriya | A Study to Assess the Effectiveness of Patency Program on CPR among Staff Nurses in NMCH, Nellore. |
| 12 | Ms.V. Meena | Effectiveness of Planned Teaching Program on Knowledge Regarding Arterial Blood Gas Analysis among Nurses Working in Intensive Care Unit at NMCH. Nellore. |
| 12 | Ms.Thoudam Ranjana Chanu | A Comparative study to Assess the Effectiveness of Magnesium Sulphate with Glycerine Versus Cold Press among Patients with Peripheral Intravenous Cannula Induced Phlebitis At NMCH, Nellore. |
| 14 | Ms.V.Sakthi | A Study to assess the Knowledge regarding Modified early warning Score among Staff Nurses at NMCH, Nellore. |
| 15 | Ms.J.Vandana | A Study to assess the Effectiveness of Standardized Bed side report on accountability and work Effectiveness among Staff Nurses at NMCH, Nellore. |
| 16 | Ms. Mounika | A Study to Evaluate the Effect of Positive Psychological Interventions on Burnout among the Nurses and Nursing Students in Narayana Medical College Hospital & Narayana College of Nursing Nellore. |
| 17 | Ms.T.Chandana | A Study to find the Correlation between Hypothyroidism and Depression among Women in NMCH Nellore. |


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Member Secretary

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NCON/IEC/ACD/2023-24/01

21/08/2023

CIRCULAR

Narayana College of Nursing -Institutional Ethics Committee meeting is tentatively scheduled on 28th August 2pm to 5pm, in Smart classroom, all M.Sc.(N) Students are informed to present their proposals for ethics committee approval, the proposal should be submitted to the Member Secretary before one week of presentation. All the committee members to be present in time as per mentioned Date & time and scheduled was attached.

A. S. S. S.
Principal
NARAYANA COLLEGE OF NURSING
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Copy to:

- IEC Members
- Guides
- I M.Sc.(N) Class coordinator

D. R. S. S.
Principal
NARAYANA COLLEGE OF NURSING
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INSTITUTIONAL ETHICS COMMITTEE NARAYANA COLLEGE OF NURSING

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Schedule for Presentation

| S No | M.Sc.(N) I year students | Specialty | Date & time | Sign |
|------|------------------------------|--------------------------------------|---------------------|------------|
| 1. | Ms. K Nadiya | Medical Surgical Nursing | 28/8/23, 2pm to 5pm | Nadiya |
| 2. | Ms. D Rajya Lakshmi | Medical Surgical Nursing | 28/8/23, 2pm to 5pm | Rajya |
| 3 | Ms. N. Mary Swarna Sulochana | Medical Surgical Nursing | 28/8/23, 2pm to 5pm | Mary |
| 4 | Ms. P. Nissi | Community Health Nursing | 28/8/23, 2pm to 5pm | Nissi |
| 5 | Ms.T. Srilakshmi | Community Health Nursing | 28/8/23, 2pm to 5pm | Srilakshmi |
| 6 | Ms. K Revathi | Obstetrics and Gynecological Nursing | 28/8/23, 2pm to 5pm | Revathi |
| 7 | Ms.TPersis | Obstetrics and Gynecological Nursing | 28/8/23, 2pm to 5pm | Persis |
| 8 | MsY Tejaswini | Obstetrics and Gynecological Nursing | 28/8/23, 2pm to 5pm | Tejaswini |

The following is a list of documents to be submitted by the investigator to the IEC for review:

1. Covering letter
2. Application for Initial review
3. Complete Proposal
4. Informed Consent Document in English and local language
5. Questionnaire if any

Kaatha

Member secretary

Member Secretary

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

Asfa

Chairperson

Chairperson

Institutional Ethics Committee
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Dr. B. Anuj

Principal

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Institutional Ethics Committee Minutes

An Institutional ethics committee meeting was held on 28th August 2023 from 2pm to 5pm at Seminar hall in Narayana College of Nursing for proposal presentation by M.Sc.(N) students to get IEC clearance. The committee has assessed 8 PG proposals and provided suggestions according to the ethical norms and Title of the dissertation. The committee has also appreciated researchers for their efforts in developing and presenting their proposals. At the end of the meeting, everyone was thanked by member secretary for commitment and active participation.

The Following Members was present

| S.No | Name of Member | Qualification | Designation in Ethics Committee | Sign |
|---|---------------------------|---------------------------|---------------------------------|--------------------|
| 1. | Dr. Nuvvula Siva Kumar | BDS (M.D.S) | Chair Person | <i>[Signature]</i> |
| 2. | Dr. V Mahidhar Reddy | MBBS (MS) General Surgery | Clinician | <i>[Signature]</i> |
| 3. | Dr B Vanaja Kumari | BSc (MSc. PhD Nursing) | Scientific Member | <i>[Signature]</i> |
| 4. | Ms. Kantha Katari | BSc (MSc.Nursing) | Member Secretary | <i>[Signature]</i> |
| 5. | MrsThejovathi | BSc (MSc. Nursing) | Member | <i>[Signature]</i> |
| 6. | Mr. Kandati Jithendra | MBBS (MD-Microbiology) | Basic Medical Scientist | <i>[Signature]</i> |
| 7. | Mr. P Vijaya Kumara Reddy | B.A (LLB) | Legal Expert | <i>[Signature]</i> |
| 8. | Mr. Nath Krishna Kumar | BSc (MA) | Social scientist | <i>[Signature]</i> |
| 9. | Ms. K Padma | 10 th class | Lay person | <i>[Signature]</i> |
| Others presented in Presentation | | | | |
| 10. | Dr Kumari.V | BSc (MSc.,PhD Nursing) | HOD of OBG | <i>[Signature]</i> |
| 11. | Prof Latha.A | BSc (MSc.Nursing) | HOD of MSN | <i>[Signature]</i> |
| 12. | Prof P Shanmugavadivu | BSc (MSc.Nursing) | HOD of CHN | <i>[Signature]</i> |
| 13. | MrsSmitha.P.M | BSc (MSc.Nursing) | HOD of MHN | <i>[Signature]</i> |
| 14. | Mrs G Pavithra | BSc (MSc.PhD Nursing) | HOD of COHN | <i>[Signature]</i> |

Dr. B. Anny
Principal
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INSTITUTIONAL ETHICS COMMITTEE NARAYANA COLLEGE OF NURSING

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Note:The Chairperson of the Institutional Ethics Committee (IEC) recommends the following temporary appointments due to recent member resignations: Dr. B. Vanaja Kumari will be appointed as a temporary Scientific Member to replace Dr. Indira A. and Mrs. G. Thejovathi will be appointed as a temporary Member to replace Dr. Rajeswari.

The following proposals was presented and approved after few modifications

| S No | M.Sc.(N) I year | Title of the Statement |
|------|------------------------------|--|
| 1. | Ms. K Nadiya | A Study to assess the Effectiveness of MgSO ₄ in glycerin solution dressing on Wound healing process among patients with Diabetic foot ulcer at selected Hospital, Nellore, A.P |
| 2. | Ms. D Rajya Lakshmi | A Correlational study to assess the Leadership styles and Job satisfaction among Staff nurses at selected Hospital, Nellore, A.P |
| 3 | Ms. N. Mary Swarna Sulochana | A Study to assess the Effectiveness of Mouth care with Chlorhexidine on Oral health among Bedridden patients at selected Hospitals, Nellore, A.P.” |
| 4 | Ms. P. Nissi | A study to assess the Knowledge and Attitude regarding Complementary and Alternative medicine among the population from selected rural area, Nellore. A.P |
| 5 | Ms. T. Srilakshmi | A Descriptive study to explore the Prevalence of School absenteeism among Mother’s of Primary school children at selected rural area, Nellore, A.P |
| 6 | Ms. K Revathi | A Descriptive study to assess the Risk factors contributing to Pregnancy loss among Antenatal women at selected hospital, Nellore, A.P. |
| 7 | Ms. T Persis | A Study to assess the Effectiveness of Self Instructional Module regarding Expression and storage of Breast Milk among Employed Postnatal Mothers at selected hospital Nellore, A.P. |

D.V. Raju
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| | | |
|---|----------------|---|
| 8 | Ms Y Tejaswini | A Study to assess the Effectiveness of Midwife Led bundle care among Antenatal women attending Outpatient Department at Tertiary care hospital, Nellore. A.P. |
|---|----------------|---|

Xoatha

Member secretary

Member Secretary

Institutional Ethics Committee
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Asfa

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Chairperson

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DyBCAmy
Principal

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New Delhi dated: 20.Feb.2020.



06 Sep 2024

Ref: NCON/M.Sc. (N)/IEC/2024-002

To


Ms. Swetha,
M.Sc. (N) I year,
Mental Health Nursing
Narayana College of Nursing,
Chinthareddypalem, Nellore, Andhra Pradesh

The members of committee reviewed and discussed the study proposal entitled.

“A Cross-Sectional Study to Assess the Physiological and Psychological Effects of Online Gaming among Adolescents in Selected Colleges of Nellore.”

Ethical committee has approved this study and none of the members voted against the study.


The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.


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New Delhi dated: 20.Feb.2020.



06 Sep 2024

Ref: NCON/M.Sc. (N)/IEC/2024-005

To

Mrs. G. Sushma,
M.Sc. (N) I year,
Community Health Nursing
Narayana College of Nursing,
Chinthareddypalem, Nellore, Andhra Pradesh

The members of committee reviewed and discussed the study proposal entitled.

“A Comparative Study to Assess the Knowledge and Attitude on Female Foeticide among Pregnant women at selected Urban and Rural Community Areas at Nellore.”

Ethical committee has approved this study and none of the members voted against the study.


The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.


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IEC

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06 Sep 2024

Ref: NCON/M.Sc. (N)/IEC/2024-006

To

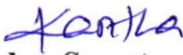
Ms. Varalalakshmi,
M.Sc. (N) I year,
Community Health Nursing
Narayana College of Nursing,
Chinthareddypalem, Nellore, Andhra Pradesh


The members of committee reviewed and discussed the study proposal entitled.


“A Descriptive Study to Assess the Knowledge regarding and Attitude on Female Foeticide among Pregnant women at selected Urban and Rural Community Areas at Nellore.”

Ethical committee has approved this study and none of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.


Member Secretary
IEC
Member Secretary
Institutional Ethics Committee
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Chairperson
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Reg. No. ECR/1348/Inst/AP/2020
New Delhi dated: 20.Feb.2020.



06 Sep 2024

Ref: NCON/M.Sc. (N)/IEC/2024-004

To

Ms. M. Sireesha,
M.Sc. (N) I year,
Obstetrics and Gynaecological Nursing,
Narayana College of Nursing,
Chinthareddypalem, Nellore, Andhra Pradesh

The members of committee reviewed and discussed the study proposal entitled.

“A True Experimental Study to Assess the Effectiveness of Oketani Breast Massage on Breast Feeding among Postnatal Mothers in Selected Tertiary care Center, Andhra Pradesh.

Ethical committee has approved this study and none of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.

Member Secretary

IEC

Member Secretary

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Chairperson

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Chairperson

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Principal

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New Delhi dated: 20.Feb.2020.



06 Sep 2024

Ref: NCON/M.Sc. (N)/IEC/2024-003

To

Mrs. Kaamadi Rukmini,
M.Sc. (N) I year,
Medical Surgical Nursing,
Narayana College of Nursing,
Chinthareddypalem, Nellore, Andhra Pradesh

The members of committee reviewed and discussed the study proposal entitled.

“A Quasi Experimental Study to Assess the Effectiveness of Hemodialysis Bundle Care on Quality of Life among Hemodialysis Patient in Selected Hospital at Nellore.”

Ethical committee has approved this study and none of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.

Member Secretary
IEC
Member Secretary
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INSTITUTIONAL ETHICS COMMITTEE

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Registration Approved by Central Drugs Standard Control Organization,
Reg. No ECR/1349/Inst/AP/2021 New Delhi, dated : 16 Oct.2021.



16-10-2021

To

KOMMA HIMAJA,
P.G Student,
Dept of Obstetrical & Gynecological Nursing,
Narayana College of Nursing,
Nellore.

The members of committee reviewed and discussed the study proposal entitled "An Experimental Study to Assess Effectiveness of BRIC2 Teaching on Knowledge regarding Partogram among 4th year B.Sc(N) Nursing Students in selected Nursing colleges at Nellore."

Ethical committee has approved this study. None of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.

K. Kanthamma
Member secretary

IEC
Member Secretary
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

P. S. S.
Chairperson

IEC
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Institutional Ethics Committee
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O. B. Raju
Principal
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INSTITUTIONAL ETHICS COMMITTEE

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Registration Approved by Central Drugs Standard Control Organization,
Reg No. ECR/1348/Inst/AP/2021 New Delhi dated 15 Oct 2021



16-10-2021

To

KONDE HARIPRIYA,
P.G Student,
Dept of Medical Surgical Nursing,
Narayana College of Nursing,
Nellore.

The members of committee reviewed and discussed the study proposal entitled "**A Study to Assess the Effectiveness of planned Teaching Programme on Post Hemodialysis Care among caregivers of patients undergoing Hemodialysis at NMCH, Nellore.**"

Ethical committee has approved this study. None of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.

K. Karthi
Member secretary

IEC
Member Secretary
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
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P. K.
Chairperson

IEC
Chairperson
Institutional Ethics Committee
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D. B. Arjun
Principal
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INSTITUTIONAL ETHICS COMMITTEE

NARAYANA COLLEGE OF NURSING

Chinthareddypalem, Nellore. Ph : 0861 - 2317969, Fax : 0861 - 2311968.

Registration Approved by Central Drugs Standard Control Organization,
Reg. No. ECR/1348/inst/AP/2021 New Delhi, dated : 16 Oct 2021



16-10-2021

To

K PADMAJA,
P.G Student,
Dept of Mental Health Nursing
Narayana College of Nursing,
Nellore.

The members of committee reviewed and discussed the study proposal entitled "A Study to Assess the knowledge on Documentation while taking care of Mentally Ill Patients among staff Nurses in psychiatric Ward at Selected Hospital, Nellore."

Ethical committee has approved this study. None of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.

K. Kanth

Member secretary

IEC

Member Secretary

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

R/a

Chairperson

IEC

Chairperson

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

Dr. Radhika
Principal

NARAYANA COLLEGE OF NURSING
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NELLORE - 524 003



INSTITUTIONAL ETHICS COMMITTEE
NARAYANA COLLEGE OF NURSING

Chinthareddypalem, Nellore, Ph : 0861 - 2317969, Fax : 0861 - 2311968

Registration Approved by Central Drugs Standard Control Organization
Reg. No. FCR/1348/Ins/AP/2021 New Delhi dated 16 Oct 2021



16-10-2021

To

PARNAPALLI PRATHIBA,
P.G Student,
Dept of Community Health Nursing,
Narayana College of Nursing,
Nellore.

The members of committee reviewed and discussed the study proposal entitled "**A Study to Assess the Effectiveness of Planned Teaching Program on knowledge regarding Emerging and reemerging diseases among ASHA workers at selected PHC'S and Sub centers, Nellore.**"

Ethical committee has approved this study. None of the members voted against the study

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.


Member secretary

IEC

Member Secretary
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
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INSTITUTIONAL ETHICS COMMITTEE

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Registration Approved by - Central Drugs Standard Control Organization
Reg. No. ECR/0348/Med/AP/2021 New Delhi. Dated: 19 Oct 2021.



16-10-2021

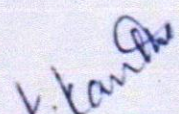
To

A S PUSHPALATHA,
P G Student,
Dept of Medical surgical Nursing,
Narayana College of Nursing,
Nellore.

The members of committee reviewed and discussed the study proposal entitled "**A Study to Assess the Effectiveness of Prone Position in increasing Oxygen Saturation among ARDS Patients at NMCH, Nellore.**"


Ethical committee has approved this study. None of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.


Member secretary

IEC

Member Secretary
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.


Chairperson

IEC
Chairperson

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.


Principal

NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003



INSTITUTIONAL ETHICS COMMITTEE

NARAYANA COLLEGE OF NURSING

Chinthareddypalem, Nellore, Ph - 0861 - 2317968, Fax - 0861 - 2311968.

Registration Approved by Central Drugs Standard Control Organization,

Reg. No. ECR/134850/04/2021 New Delhi, dated: 16 Oct 2021.



16-10-2021

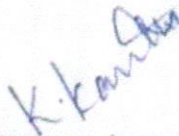
To

LELLA SANDHYA RANI,
P.G Student,
Dept of Mental Health Nursing,
Narayana College of Nursing,
Nellore.

The members of committee reviewed and discussed the study proposal entitled "A study to Assess the Knowledge of Psychiatric drugs and its application in clinical practice among Undergraduate Nursing students in selected nursing colleges, Nellore."

Ethical committee has approved this study. None of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.


Member secretary


IEC

Member Secretary
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.


Chairperson

IEC

Chairperson
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.


Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003

INSTITUTIONAL ETHICS COMMITTEE

NARAYANA COLLEGE OF NURSING

Chinthareddypalem, Nellore, Pin - 524003. Fax: 0861-2411968

Registration Approved by - Central Board of Secondary Education
Reg. No. 572012 dated 07/12/2017, New Delhi, dated: 18.07.2017

16-10-2021

To

SHEELA ROBERT,
P.G Student,
Dept of Child Health Nursing,
Narayana College of Nursing
Nellore.

The members of committee reviewed and discussed the study proposal entitled "A Quasi Experimental Study to Assess the Effect of Swaddling on Management of pain during Heel prick among Neonates admitted in Neonatal Intensive Care Unit at NMCH, Nellore."

Ethical committee has approved this study. None of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.

K. Lakshmi
Member Secretary

IEC

Member Secretary
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

R. S. S.
Chairperson

IEC

Chairperson
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

D. R. Princy
Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003

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INSTITUTIONAL ETHICS COMMITTEE

NARAYANA COLLEGE OF NURSING

Chinthareddypalem, Nellore. Ph : 0861 - 2317969, Fax : 0861 - 2311968.

Registration Approved by : Central Drugs Standard Control Organization.
Reg No. ECR/1348/Inst/AP/2021 New Delhi, dated - 16 Oct 2021.



16-10-2021

To

GURRAMKONDA BHAVYA SREE,
P.G Student,
Dept of Child Health Nursing,
Narayana College of Nursing
Nellore.

The members of committee reviewed and discussed the study proposal entitled "A Study to Assess the Effectiveness of Cluster care on Physiological Parameters among Preterm Newborn admitted in NICU at NMCH, Nellore."

Ethical committee has approved this study. None of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.

K. Karthi
Member secretary

IEC

Member Secretary
Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

S. J. A.
Chairperson

IEC

Chairperson
Institutional Ethics Committee
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D. S. Prasad
Principal

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NELLORE - 524 003.



INSTITUTIONAL ETHICS COMMITTEE

NARAYANA COLLEGE OF NURSING

Chinthareddypalem, Nellore. Ph: 0861-2317969, Fax: 0861-2317968

Registration Approved by - Central Drugs Standard Control Organization
Reg. No. ECR/1348/2016/2021 New Delhi, dated: 15 Oct 2021



16-10-2021

To

PAKALA POOJA,
P.G Student,
Dept of Child Health Nursing,
Narayana College of Nursing,
Nellore.

The members of committee reviewed and discussed the study proposal entitled "A Study to Determine the Effectiveness of Competency Based Teaching Programme on Prevention of Neonatal Hypothermia among Staff Nurses at NMCH, Nellore."

Ethical committee has approved this study. None of the members voted against the study.

The present approval is valid only for three years; the investigator should take the re-approval after three years. Any change, modification or deviation in the protocol, or any event must be informed to ethical committee. Any Protocol modification or amendment must receive IEC approval.

K. Karthi
Member secretary

IEC

Member Secretary

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

Q/a
Chairperson

IEC

Chairperson

Institutional Ethics Committee
NARAYANA COLLEGE OF NURSING
Chinthareddypalem, Nellore-524003.

Dr. B. Chamy
Principal
NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003