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

Openday spend of the Control of

(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;

- (v) lay person.
- 5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,
 - (i) one lay person;
 - (ii) one woman member;
 - (iii) one legal expert;
- (iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.
- 6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.
- 7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.
- 8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.
- 9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
- 10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
- 11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.
- 12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.
- 13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any
- 14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.
- 15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.
- 16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.
- 17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.
- 18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

- 19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50kms of the bioavailability or bioequivalence study centre.
- 20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.
- 21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.
- 22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.
- 23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.
- 24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.
- 25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.
- 26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.
- 27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.
- 28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.
- 29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.
- 30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.
- 31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.
- 32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

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

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 (MScNursing)	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

Controller General (I) &

Central Licensing Authority

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



Dr. NTR UNIVERSITY OF HEALTH SCIENCES : AP : VIJAYAWADA - 08

File.No. 3924/EA3/Ph.D/2019-20

Dated. 27.10.2020

To
Dr. S. Indira,
Professor of Medical Surgical Nursing,
Narayana College of Nursing,
C/o Narayana Medical College,
Chintareddy Palem, Nellore-524 002.

Sir,

Sub: Dr.NTR UHS - Admissions - Ph.D course 2019-20 - Reg.

Ref: This office even Proceedings No. dt.20.10.2020.

I am herewith enclosing the MULTI – CITY CHEQUE No. 841377, dt.23.10.2020 of Syndicate Bank for an amount of Rs.19,440/- (Rupees Nineteen Thousand Four Hundred and Forty only) towards payment of remuneration in connection with Ph.D screening committee meeting held from 24.09.2020 to 26.09.2020 at Dr NTR University of Health Sciences, Vijayawada.

Please acknowledge the receipt of the same.

Yours faithfully,

DEPUTY REGISTRAR (ADMISSIONS)

BA

Principal

NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003.

PROCEEDINGS OF THE VICE-CHANCELLOR NTR UNIVERSITY OF HEALTH SCIENCES :: A.P. :: VIJAYAWADA-520 008

Present: Prof. R. Sambasiva Rao, M.D., FAMS, FABMS

Proc.No. 2583/B.Sc.(N)/EA5/2005

Dated: 05-08-2005

Sub: NTR UHS – U.G. Admissions – Constitution of Selection Committee – Admissions into B.Sc.(Nursing) Course for the academic year 2005-06 – 1st Counseling – Orders – Issued.

Ref: This office Notification dated 26-07-2005.

-oCo--

ORDER:

The Vice-Chancellor, NTR University of Health Sciences, Vijayawada is pleased to constitute the Selection Committee with the following members for selection of candidates for provisional admission into B.Sc.(Nursing) Course for the academic year 2005-06 under open method at NTR University of Health Sciences, Vijayawada to be held from 16-08-2005 to 20-08-2005.

 The Principal, Government College of Nursing, Hyderabad.

Chair Person

 The Principal, St. Anns' College of Nursing, Vijayawada.

Member

3. The Principal,
Narayana College of Nursing,
Nellore.

Member

The counseling will be held from 8.30 A.M. on the above dates at the NTR University of Health Sciences, Vijayawada to select the candidates for provisional admission into B.Sc.(Nursing) Course.

The members of the selection committee are requested to attend the selection committee meeting on 16-08-2005 at 8.00A.M. at NTR University of Health Sciences, Vijayawada without fail.

The Selection Committee is further requested to submit the list of candidates selected into B.Sc.(Nursing) Course college wise along with proceedings of the Selection Committee.

The Deputy Registrar (Admissions) i/c., Assistant Registrar (Admissions) and staff of Admissions Section will assist the Selection Committee.

// BY ORDER //

To
The Chair person & Members of the Selection Committee.

Copy to all the Principals of B.Sc.(Nursing) colleges for information.

Copy to the Special Chief Secretary to Government, HM & FW Dept., Govt. of A.P, Hyd.

Copy to the Finance Officer, NTR UHS, Vijayawada.

Copy to the PS to VC / Steno to Registrar, NTR UHS, Vijayawada.

NARAYANA COLLEGE OF NURSING Chinthareddypalem, NELLORE - 524 003.

PROCEEDINGS OF THE VICE-CHANCELLOR

NTR UNIVERSITY OF HEALTH SCIENCES, A.P., VIJAYAWADA-8

PRESENT: PROF R. SAMBA SIVA RAO, VICE-CHANCELLOR

Proc.No.1536/B.Sc., (Nursing)/EA5/2004-05

Dated: 06-11-2004

SUB:- NTR UHS – U.G. ADMISSIONS – B.Sc., (Nursing) 4YDC/2YDC Courses for the academic year 2004-05 – Constitution of Selection Committee for B.Sc., (N) Course – Orders – Issued.

RFF:- This Office Notification dt. 28-10-2004.

ORDER:

This Vice-Chancellor, NTR University of Health Sciences, Vijayawada is pleased to constitute the Selection Committee with the following members to select the candidates for provisional admission into B.Sc., (Nursing) 4/2 Years Degree Courses in all Nursing Colleges affiliated to NTR UHS for the academic year 2004-05 at NTR University of Health Sciences, Vijayawada from 9th to 11th November, 2004.

Principal, Govt. College of Nursing, Hyderabad
 Principal, St. Anns College of Nursing, Vijayawada
 Principal, Narayana College of Nursing, Nellore
 MEMBER
 MEMBER
 MEMBER

Dr. D. Vijaya Kumar, Prof., GGHMC, Gudivada
 Smt. P.S. Rama Devi, Assistant Registrar (Admissions)
 MEMBER

6. Sri G.K. Choudary, Deputy Registrar (Admissions) - MEMBER/SECRETARY

The Selection will be at 8-30 A.M. on 09-11-2004 at the Office of NTR University of Health Sciences, Vijayawada to select the candidates for admission into B.Sc., (Nursing) 4/2 Years Degree Course.

The members of the Selection Committee are requested to attend the Selection Committee meeting on 9-11-2004 at 8-00 AM without fail.

The selection committee is further requested to submit the list of candidates selected

// BY ORDER //

REGISTRAR

To The Chairman and Members of the Selection Committee.

Copy to Director of Medical Education, A.P., Hyderabad.

Copy to Principals of College of Nursing, Hyderabad, Visakhapatnam and Kurnool.

Copy to Deputy Registrar (Exams), NTR UHS, Vijayawada.

Copy to Finance Officer, NTR UHS, Vijayawada.

Copy to OSD, NTR UHS Camp Office, DME's Building, Koti, Hyderabd.

Copy to PS to VC / Steno to Registrar, NTR UHS, Vijayawada.

NARAYANA COLLEGE OF NURSING
Chinthareddypalem,
NELLORE - 524 003.

PROCEEDINGS OF THE VICE-CHANCELLOR NTR UNIVERSITY OF HEALTH SCIENCES :: A.P. :: VIJAYAWADA-520 008

Present: Prof. R. Sambasiva Rao, M.D., FAMS, FABMS

Proc.No. 2583/B.Sc.(N)/EA5/2005

Dated: 05-08-2005

Sub: NTR UHS - U.G. Admissions - Constitution of Selection Committee - Admissions into B.Sc.(Nursing) Course for the academic year 2005-06 - 1st Counseling -Orders - Issued.

Ref: This office Notification dated 26-07-2005.

ORDER:

The Vice-Chancellor, NTR University of Health Sciences, Vijayawada is pleased to constitute the Selection Committee with the following members for selection of candidates for provisional admission into B.Sc.(Nursing) Course for the academic year 2005-06 under open method at NTR University of Health Sciences, Vijayawada to be held from 16-08-2005 to 20-08-2005.

The Principal, Government College of Nursing, Hyderabad.

Chair Person

The Principal, St. Anns' College of Nursing, Vijayawada.

Member

The Principal, 3. Narayana College of Nursing, Nellore.

Member

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The members of the selection committee are requested to attend the selection committee meeting on 16-08-2005 at 8.00A.M. at NTR University of Health Sciences, Vijayawada without fail.

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The Deputy Registrar (Admissions) i/c., Assistant Registrar (Admissions) and staff of Admissions Section will assist the Selection Committee.

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The Chair person & Members of the Selection Committee.

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Copy to the PS to VC / Steno to Registrar, NTR UHS, Vijayawada.

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

PROCEEDINGS OF THE VICE-CHANCELLOR NTR UNIVERSITY OF HEALTH SCIENCES, A.P., VIJAYAWADA-8 PRESENT: PROF R. SAMBA SIVA RAO, VICE-CHANCELLOR

Proc.No.1536/B.Sc., (Nursing)/EA5/2004-05

Dated: 06-11-2004

SUB:- NTR UHS – U.G. ADMISSIONS – B.Sc., (Nursing) 4YDC/2YDC Courses for the academic year 2004-05 – Constitution of Selection Committee for B.Sc., (N) Course – Orders – Issued.

REF:- This Office Notification dt. 28-10-2004.

ORDER:

This Vice-Chancellor, NTR University of Health Sciences, Vijayawada is pleased to constitute the Selection Committee with the following members to select the candidates for provisional admission into B.Sc., (Nursing) 4/2 Years Degree Courses in all Nursing Colleges affiliated to NTR UHS for the academic year 2004-05 at NTR University of Health Sciences, Vijayawada from 9th to 11th November, 2004.

1. Principal, Govt. College of Nursing, Hyderabad

CHAIRPERSON

2. Principal, St. Anns College of Nursing, Vijayawada

MEMBER

3. Principal, Narayana College of Nursing, Nellore

MEMBER

4. Dr. D. Vijaya Kumar, Prof., GGHMC, Gudivada

MEMBER

Smt. P.S. Rama Devi, Assistant Registrar (Admissions)
 Sri G.K. Choudary, Deputy Registrar (Admissions)

MEMBER/SECRETARY

The Selection will be at 8-30 A.M. on 09-11-2004 at the Office of NTR University of Health Sciences, Vijayawada to select the candidates for admission into B.Sc., (Nursing) 4/2 Years Degree Course.

The members of the Selection Committee are requested to attend the Selection Committee meeting on 9-11-2004 at 8-00 AM without fail.

The selection committee is further requested to submit the list of candidates selected

// BY ORDER //

REGISTRAR

To

The Chairman and Members of the Selection Committee.

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Copy to OSD, NTR UHS Camp Office, DME's Builling, Koti, Hyderabd.

Copy to PS to VC / Steno to Registrar, NTR UHS, Vijayawada.

Principal

NARAYANA COLLEGE OF NURSING
Chinthareddypalem,

PROCEEDINGS OF THE VICE-CHANCELLOR, Dr. NTR UNIVERSITY OF HEALTH SCIENCES::AP::VIJAYAWADA-520 008 PRESENT Dr. A.V. KRISHNAM RAJU, M.D., FICP.

Procgs.No. 1414/A5/Nsg/09

Dt.18-06-2009

Sub:- Dr. NTRUHS - Acad. - Affiliation - To consider to grant Certificate of Registration to the Pulipati College of Nursing, Ammapalem(V), Konizeria (M), Khammam Disteict for the year 2009-10 - Inspection Committee constituted - Orders - Issued -Reg.

Read:- Orders of the Vice-Chancellor, dt.11-06-2009.

ORDER:

The Vice-Chancellor is pleased to constitute an Inspection Committee with the following members to inspect physical, infrastructural facilities like Land, buildings, equipment, clinical facilities and teaching staff available as per norms of Dr. NTR UHS stipulated in its Statute on affiliation of college of nursing together with norms of Indian Nursing Council, New Delhi and considering the affiliated hospitals at Khammam 1) CIMS Maternity and Emergency Hospital, Station Road, 2) Cure Emergency Hospital Critical Care & Tranuma Centre, NST Road 3) Yalamanchili Pali Clinic and Multy Speciality Hospital, Water Tank Road for the number of beds considering the documentary evidence produced for grant of Certificate of Registration for starting of B.Sc. Nursing Course for the academic year 2009-10.

The following members are requested to inspect the Pulipati College of Nursing, Sri Balaji Nagar, Ammapalem(V), Konizeria (M), Khammam Disteict and affiliated hospitals as per G.O. on 29th June 2009 as already agreed for, duly following the norms of by Dr. NTR UHS & INC., New Delhi for issuance of Certificate of Registration.

 Dr. Niranjan Paul, Registrar, Chairman Rajiv Gandhi Institute Of Medical Sciences, Putlampally, Kadapa – 516 002

Mrs. Indira, Principal, Member
 Narayana College of Nursing, C/o Narayana Medical College,
 Chintareddy Palem, NELLORE-524 002

The committee is requested to submit the Inspection report in a sealed cover duly signing on each paper to the undersigned soon after the Inspection is over.

The members are requested to seal the report inperson and handover the cover inperson to the Registrar or send by speed post by signing on pasted part of the sealed cover. A copy of the postal receipt is kept with you for future reference.

The committee members will be paid TA, DA and Sitting Fee of Rs.1,000/- by the Principal of the college from the amount sent by this office to meet the inspection charges.

// BY ORDER//

Encl: 1 Inspection report proforma & Form – VI
2. Guidelines to be followed during inspection

Sd/-REGISTRAR

//ATTESTED//

DEPUT PRESINTARIACADEMIC)

To

The Members of the Committee.

The Secretary & Correspondent, S.S.C.J.S Educational Society, Pulipati Bharathi Enclave,
Beside Shanthi Lodge, Station Road, Khammam.

Copy to

The Principal, Govt. CON, (RIMS), Kadapa
 The Principal, Narayana CON, Nellore
 Staff and to treat them as O.D.

Principal

NARAYANA COLLEGE OF NURS NG
Chinthareddypalem,
NELLORE - 524 003