



YENEPOYA

(DEEMED TO BE UNIVERSITY)

Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Details of the Collaborative Activity

2020-21

Name of the Collaborating Institute: Narayana Dental College and Narayana Nursing College Nellore, Andhra Pradesh

Name of Collaborating Department: Centre for Ethics, Yenepoya University, Mangalore

Activities:


- A workshop was conducted by the Centre for Ethics titled “Bioethics in Healthcare and Research” at the Narayana Dental College, Nellore, Andhra Pradesh; 17-18 July 2020
- An official MoU was signed by the Narayana Dental College and Narayana Nursing College Nellore, Andhra Pradesh and the Centre for Ethics, Yenepoya University, Mangalore on 14th June 2016


ATTESTED

Dr.Gangadhara Somayaji K.S.
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Centre for Ethics, Yenepoya (deemed to be University)

Workshop report

Title	Good Clinical Practice Workshop for Ethics Committees of Narayana Dental College, Nellore.
Date	17-18 July 2020
Organizers	Centre for Ethics, Yenepoya deemed to be University and Ethics Committee of Narayana Dental College, Nellore. 
Background	<p>Training in Good Clinical Practice Guidelines is mandatory for all ethics committee members for registering the EC with the Director Controller General of India. DCGI registration is essential for ECs to review and approve clinical trials. Therefore, CFE as a part of consultancy program offers EC mentoring and GCP training to enable them to be trained in the guidelines and get registered with the DCGI.</p> <p>So far CFE has trained more than 12 Ethics Committees.</p>
Objectives	<p>The training of the members of the Ethics Committees in Good Clinical Practice Guidelines was conducted with the following objectives</p> <ol style="list-style-type: none">1. To define various terms in relation to clinical trials.2. To define the investigator's role and responsibilities of various stakeholders in a clinical trial.3. To know the components of a research protocol package.4. To know the composition of the ethics committee.5. To understand the functioning of the ethics committee.6. To understand safety and protection of participants.7. To be conversant with reporting of serious adverse events.8. To know the special considerations in clinical trials (AYUSH, medical devices, surgical trials, etc)
Beneficiaries	Ethics Committee members of Narayana Dental College and Hospital, Nellore.
Number of attendees	14
Sessions	<p>The two days workshop with the following sessions:</p> <ol style="list-style-type: none">1. Introduction to GCP guidelines2. Components of protocol3. Ethical principles4. Safety considerations and SAEs5. Vulnerability in research6. Informed consent process7. EC composition8. EC functioning and review process9. Responsibilities of sponsor, CRO, investigators


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10. Data safety and management
11. Special consideration in clinical trials: vaccine trials, contraceptive trails, surgical/medical devices, diagnostics and herbal.

**Training
method**

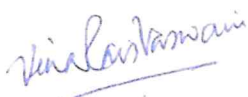
1. The workshop was conducted 'online' in view of the COVID-19 pandemic related lockdown and travel restrictions.
2. The sessions were conducted from the Demo Room 2 of the Department of Forensic Medicine and Toxicology and projected on screen for the participants in the lecture hall of Narayana Dental College using Skype Meeting.
3. The sessions included interactive lectures using powerpoint presentation with appropriate examples.
4. The sessions were interspersed with interaction with the participants and clarification of doubts.

**Resource
persons**

1. **Dr. Vina Vaswani**, Professor, Forensic Medicine and Toxicology; Director, Centre for Ethics, Yenepoya (deemed to be University), Mangalore
2. **Dr. Ravi Vaswani**, Professor, Medicine, Additional Faculty, Centre for Ethics; Joint Secretary, Yenepoya Ethics Committee-1, Yenepoya (deemed to be University), Mangalore
3. **Dr. Uma Kulkarni**, Professor, Ophthalmology, Additional Faculty, Centre for Ethics; Member-Secretary, Yenepoya Ethics Committee-1, Yenepoya (deemed to be University), Mangalore

**Feedback
(Google forms)**

1. The feedback was good for all the sessions in terms of presentation, clarity, duration, pacing and interaction
2. The participants responded that the workshop was beneficial to them to conduct a review process of protocols and had improved their knowledge.
3. The participants also opined that there was a need for such programs to update them with the changing guidelines

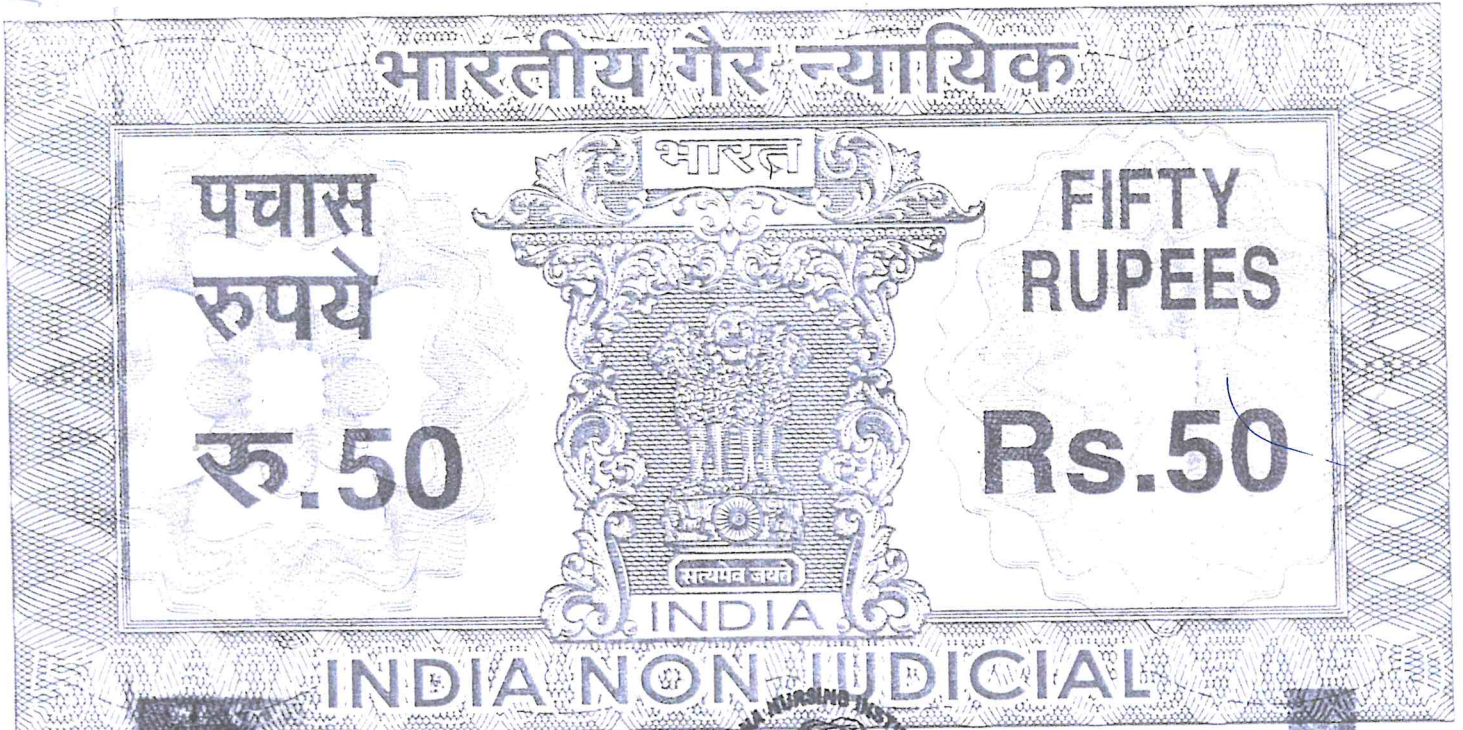


Signature and Date

Director
Centre for Ethics
Yenepoya University



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ఆంధ్రప్రదేశ్ ఆంధ్ర ప్రదేశ్ ANDHRA PRADESH
 SL No: 75 Date: 16-6-2016 Rs. 50
 Sold To: నారాయణ దేవాలయం కోడల్ కె. కె. సుబ్బారావు
 For Whom: నారాయణ దేవాలయం కోడల్ కె. కె. సుబ్బారావు
 MEMORANDUM OF UNDERSTANDING
 Between

Narayana Dental College & Hospital ; Narayana Nursing College, Nellore
 AND
 Centre for Ethics, Yenepoya University, Mangalore

This Memorandum of Understanding (Agreement) is made and entered into by Narayana Dental College and Hospital and Narayana Nursing College located in Chinthareddypalem, Nellore with the Center for Ethics, Yenepoya University located at Deralakatte, Mangalore.

RECITALS

Whereas the institutions are linked by common academic and healthcare interests;
 Whereas the institutions wish to enable cooperation and exchange in all academic and healthcare areas of mutual interests; and

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TO: NAAC office, YU
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Whereas the institutions wish to enable cooperation and exchange in all academic and healthcare areas of mutual interests; and

Whereas the institutions wish to develop the basis for better understanding of bioethics, their implementation in research protocols & processes utilizing the faculty and facilities available in both the institutions;

Therefore, in consideration of their mutual interests and the covenants set forth herein, the institutions agree as follows:

ARTICLE 1

PURPOSE AND SCOPE OF THE AGREEMENT

1.01 **Purpose.** The purposes of this agreement include, but are not limited to the following:

- a) Training of Staff in different aspects of Bioethics ;
- b) Guidance & Support for Development of Bioethics Center in Narayana Dental & Nursing Institutions;
- c) Organizing joint academic and scientific activities such as courses, conferences, seminars, symposia, or lectures;
- d) Exchange of research and teaching personnel;
- e) Exchange of publications and other materials of common interest.

1.02 **Scope.** Cooperative projects under this agreement may include any of the academic disciplines represented at either of the institutions.

ARTICLE 2

PROPOSED ACTIVITIES PURSUANT TO THE AGREEMENT

2.01 **Institutional Appointees.** In order to carry out and fulfill the aims of this agreement, each institution will appoint an appropriate person at each of their campuses to coordinate the development and conduct of joint activities. Through these contact persons, either institution may initiate proposals for activities under this agreement. The contact persons will additionally be responsible for evaluation of activities under this agreement according to the practices of their respective institutions.

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2.02 **Supplemental Agreements.** Activities the institutions mutually agree to undertake are subject to further agreement of the institutions & must be set forth in supplemental agreement signed by authorized representatives of each institution. Supplemental agreements should include specific details of the agreed upon activity, including items such as : (a) elaboration of responsibilities of each institution for the agreed upon activity; (b) schedules for specific activities; (c) budgets & sources of financing for each activity; (d) any other items necessary for efficient conduct of the activity and (e) any other items necessary to meet the legal and policy requirements of each institution. Supplemental agreements are subject to approval by each institution according to the normal policies & procedures governing the types of activities proposed therein.

ARTICLE 3

TERM AND TERMINATION

3.01 **Term.** This agreement shall take effect upon signature by both institutions and, unless terminated earlier shall continue for a period of five years from the date of signing this document by the authorities of both Institutions.

3.02 **Extension.** This agreement maybe extended by mutual agreement of concerned institutions in writing and signed by the Head/In charge of both Institutions.

3.03 **Termination.** This agreement may be terminated at any time by either institution after giving written notice of the same to the other institution. Any Supplemental agreements entered into by the institutions maybe continued or terminated at termination of this M.O.U. and specific details of the same must be mentioned in the termination notice along with reasons for the termination.

ARTICLE 4

MISCELLANEOUS

4.01 **Recognition.** Narayana Dental College & Hospital & Narayana Nursing College are recognized as post graduate training centre by the Government of India and by the Dr.N. T. R. University of Health Sciences of Andhra Pradesh.

4.02 The staff from Narayana Dental College & Narayana Nursing College maybe deputed to the Center for Ethics, Yenepoya University, Mangalore to get training in different aspects of Bioethics with information to & approval of Center for Ethics, Yenepoya University, Mangalore.

5.01 **Jurisdiction.** The legal jurisdiction of this agreement shall be interpreted and enforced within Nellore, State of Andhra Pradesh, India. Any claims arising out of this agreement shall be subject to the jurisdiction of Civil court of Nellore.

ATTESTED

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In WITNESS WHEREOF, the institutions have caused their duly authorized representatives to execute this memorandum of Understanding and Agreement to be effective upon signature by both the parties hereto mentioned.

Narayana Dental College & Hospital
By: Dr. G. Subrahmanyam, M.D., D.M. (Card)
Director, Narayana Medical Institutions
Professor of Cardiology, N.M.C.,
Narayana Medical Institutions
Director, Narayana Medical Institutions
Date: NELLORE.

Center for Ethics, Yenepoya University
By: Dr. CV Raghuvver MD
Registrar
Registrar Yenepoya Yenepoya University
Date: 16-6-16 University Road, Deralakatte
Mangalore - 575 018

By: Dr. P. Mahesh
Principal
Narayana Dental College & Hospital
Date: 14/06/2016



By: Dr. Vina Vaswani MD
Director, Center for Ethics,
Yenepoya University
Date: 16-6-16 Director
Centre for Ethics
Yenepoya University

By: Dr. N. Kannan
Institutional Appointee as Coordinator
Center for Ethics,
Narayana Dental College & Hospital
Date: 16/06/2016

By: Ms. Indira S
Dean
Narayana Nursing Institutions
Date: INDIRA. S M.Sc (N)
Narayana Nursing Institute
Chinthereddypalem, Karnataka

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**Centre for Ethics, Yenepoya University
Workshop in Biomedical Ethics in Research
Narayana Dental College and Narayana Nursing College
Nellore, Andhra Pradesh**

The Centre for Ethics, Yenepoya University, as a part of an MoU signed with Narayana Dental College, Nellore, conducted its first Workshop titled Bioethics in Healthcare and Research at Narayana Dental College, Nellore, Andhra Pradesh on 12 and 13 April, 2017.

The workshop was attended by about 60 faculty members of the two institutions including the Deans of the two institutions and four ethics committee members. The members actively participated and benefited from the workshop.

The two institutions have undergraduate and postgraduate students who conduct research as a part of their academic training. Although there is an ethics committee (EC) in place, it is not registered with DCGI. Hence both, the dental and nursing institutions are keen on developing ethics committees in their institutions with the guidance of the Centre for Ethics.

The faculty members who went to Nellore as resource persons were Dr. Vina Vaswani, Director, CFE, Dr. Uma Kulkarni, Professor, Ophthalmology, and Dr. Ravi Vaswani, Professor, Internal Medicine, Yenepoya Medical College, Yenepoya University.

Eight sessions were conducted over two full days. Each session had a spectrum of examples of ethical issues pertinent to the topics covered. The sessions were interspersed with interactions with the participants and ended with questions and discussions.

The sessions conducted by the three resource persons included an overview of moral reasoning, ethical principles and theories, ethics of research, vulnerability, guidelines and ethics committee functioning. Each session had a power-point presentation, relevant videos and discussions.

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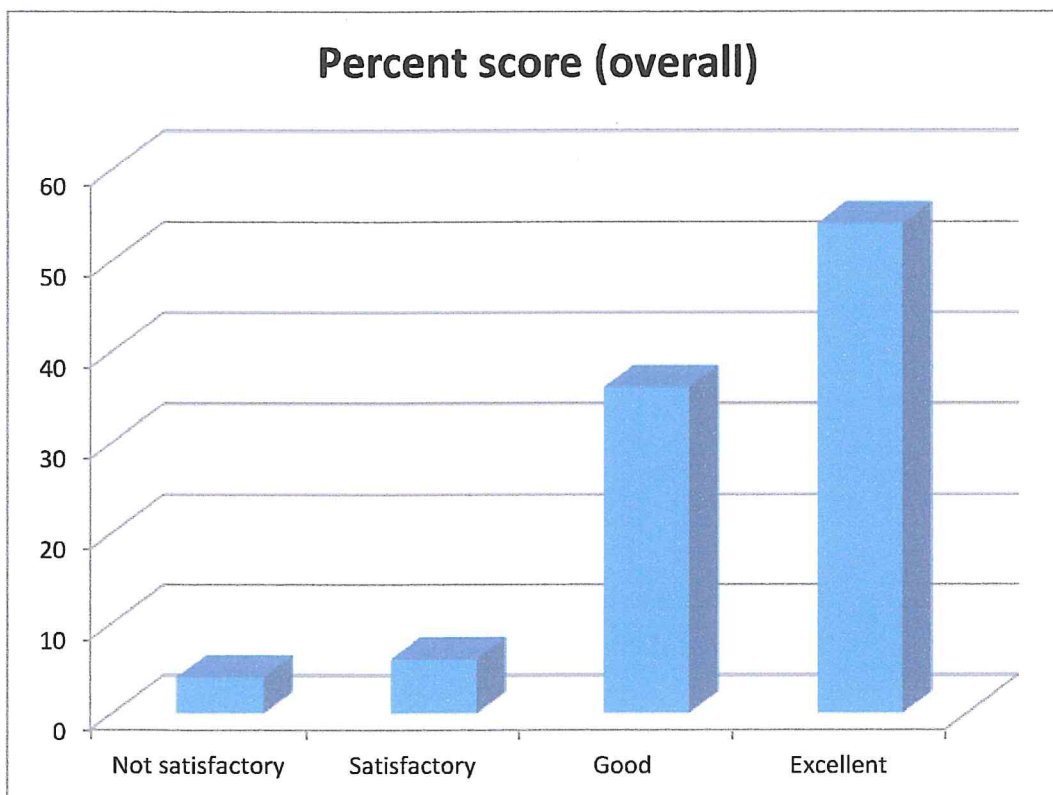


Dr. Anagadhara Somayaji KS
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The overall feedback by the participants was very good. Ninety percent of the participants rated the workshop as good or excellent. Some of the participants have expressed their willingness to pursue the PGDBEME course in Yenepoya University. The EC members have expressed their interest in visiting the YUEC in order to observe the working of the YUEC. The Deans have expressed their interest in establishing ethics committees in their institutions.

A feedback was collected from all the participants and the overall feedback is represented in a chart (see below). The CFE faculty is extremely thankful to the organisers of the workshop for the warm hospitality and valuable feedback. The CFE is looking forward for more training sessions in future.

OVERALL PARTICIPANT SATISFACTION WITH THE WORKSHOP



ATTESTED

(Signature)
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