



YENEPOYA

(DEEMED TO BE UNIVERSITY)

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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


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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**

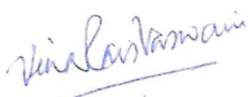
1. The workshop was conducted 'online' in view of the COVID-19 pandemic related lockdown and travel restrictions.
2. The sessions were conducted from the Demo Room 2 of the Department of Forensic Medicine and Toxicology and projected on screen for the participants in the lecture hall of Narayana Dental 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

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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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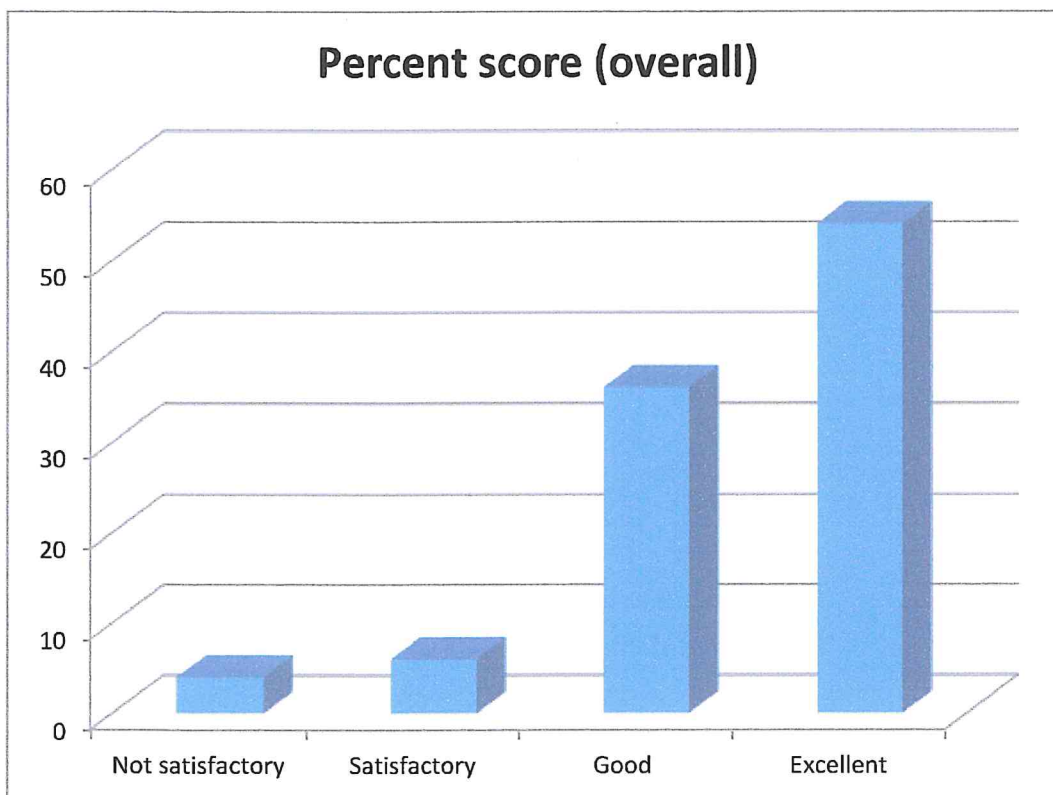


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The overall feedback by the participants was very good. Ninety percent of the participants rated the workshop as good or excellent. Some of the participants have expressed their willingness to pursue the PGDBEME course in Yenepoya University. The EC 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



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