

Details of the Collaborative Activity

2020-21

Name of the Collaborating Institute: KLE Academy of Higher Education and Research, Belagavi, Karnataka

Name of Collaborating Department: Yenepoya Ethics Committee, Yenepoya Dental College and Yenepoya Research Centre

Activities:

A MoU was signed in the Year 2017 between Yenepoya and KLE Academy of Higher Education and Research

Course:

- Conducted a Joint online Certification course for ethics committee members during September 2020

Student training

One research scholar (Sreelakshmi) from KLE underwent training at the stem cells division of Yenepoya research centre in the year 2020

ATTESTED

Institutional Ethics Committee



KLE Academy of Higher Education and Research, Belagavi
[Formerly Known as KLE University]

(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)

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Date: 26-Aug-2020

To,

Accreditations:

NABH



FERCAP



Registrations:

DCGI



OHRP



Dr.Ravi Vaswani,

Bioethicist

Yenopoya University

Sub: online certification course to KLE-Ethics Committee Members

Greetings from the KLE Academy of Higher Education and Research, Belagavi

Dear Sir,

With respect to the above-mentioned subject, as per the National and international regulatory guidelines and KLE-IEC SOP the Ethics Committee member and research team should undergo regular or recent guidelines training program. In view of this, you are requested to arrange the half-day online certificate course and also let us know the Certification training fee.

The online training certificate will be issued jointly by Yenopoya University and KLE-Academy of Higher and research, Belagavi.

Audience- Ethics Committee members, Principal Investigators and Research Coordinators

Duration: Half Day Session

Topics: Bioethics-GCP and NDCT rules, 2019

Thanking You

Prof.(Dr)M.S.Ganachari

Dy-Registrar-KLE University

Member Secretary of KLE Ethics Committee

IEC Registrations:

- IEC Reg.No ECR/211/Inst/KA/2013/RR-19- issued under New Drugs and Clinical Trial Rules, 2019.
- OHRP Reg.No:IRB00008025KLEUniversity, IRB00001499
- FWA00024127.

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**Centre for Ethics, Yenepoya (Deemed to be University)
and Yenepoya Ethics Committee-1**

**Report of KAHER EC certification workshop, Belgaum
26-09-2020**

Title	KAHER EC Certification workshop (NDCTR-19 EC training workshop)
Date	26 Sep. 2020
Organizers	Centre for Ethics, Yenepoya (Deemed to be University) Yenepoya Ethics Committee-1
Background	<p>Training in NDCTR-19 is essential for all ethics committee members and researchers. The training of EC members is essential for registering the EC with the Director Controller General of India. DCGI registration is essential for ECs to review and approve clinical trials.</p> <p>Therefore, CFE as a part of consultancy program offers EC mentoring and GCP training/ NDCTR-2019 to enable them to be trained in the guidelines and get registered with the DCGI.</p> <p>So far CFE has trained more than 13 Ethics Committees.</p>
Objectives	<p>The training of the members of the Ethics Committees in NDCTR-19 was conducted with the following objectives</p> <ol style="list-style-type: none">1. Introduction to NDCTR-192. What is new in NDCTR3. EC functioning in accordance with the NDCTR-19
Beneficiaries	Ethics Committee members and researchers from KAHER, Belgaum
Number of attendees	40
Sessions	<p>The two days workshop with the following sessions:</p> <ol style="list-style-type: none">1. Introduction to NDCTR-192. What is new in NDCTR3. Protocol review- role of EC4. Informed consent review-5. Role and responsibilities of EC members
Training method	<ol style="list-style-type: none">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 KAHER and some of the members attended online.3. The sessions included interactive lectures using powerpoint presentation

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with appropriate examples.

4. The sessions were interspersed with interaction with the participants and clarification of doubts.

Resource persons

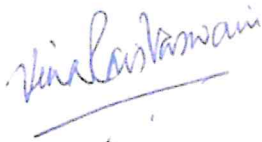
1. **Dr. Vina Vaswani**, Professor, Forensic Medicine and Toxicology; Director, Centre for Ethics, Yenepoya (deemed to be University), Mangalore
2. **Dr. Ravi Vaswani**, Professor, Medicine, Additional Faculty, Centre for Ethics; Joint Secretary, Yenepoya Ethics Committee-1, Yenepoya (deemed to be University),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

Consultancy

15,000 INR paid by KAHER of Yenepoya (Deemed to be University)

Feedback (Google forms)

1. The overall feedback expressed by the participants was good for all the sessions in terms of presentation, clarity, duration, pacing and interaction



Signature and Date

Director
Centre for Ethics
Yenepoya University

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