



Yenepoya Ethics Committee-1  
Yenepoya deemed to be University

# Rapid Updates: *New* GUIDELINES & SOPs for Ethics Committee members

Conducted by Yenepoya Ethics Committee-1, Yenepoya deemed to be University, Mangalore



## BACKGROUND

In March 2019, The Government of India has notified the New Drugs and Clinical Trials Rules (NDCTR-2019) superseding the previous rules. This necessitates revision of the Standard Operating Procedures of the Ethics committee to align the functioning of the Ethics Committees with the current applicable guidelines. On the other hand, ethics committee accreditation has been an essential step for ensuring quality of ethical review and recognition of Ethics Committees.

Therefore, this workshop has been planned to update the Ethics Committee members in NDCTR-2019 and the updated SOPs.

## Program Details:

Resource persons:

Dr. Ravi Vaswani & Dr. Uma Kulkarni, Members, Yenepoya Ethics Committee-1

Date: 16 Oct 2019

Time: 8:30 AM to 2:30 PM

Venue: Forensic Demo Room-2

## Program schedule:

|                       |  |
|-----------------------|--|
| 8:30 AM:              | Registration   |
| 9:00 AM to 9:30 AM:   | What is new in NDCTR-2109?   |
| 9:30 AM to 10:30 AM:  | Understanding SOPs through flowcharts and timelines:<br>Part 1: Pre-approval activities  |
| 10:30 AM to 10:45 AM: | Tea break and discussion   |
| 10:45 AM to 11:30 AM: | Ethics committee meetings: Quorum and decision making                                    |
| 11:30 AM to 12:30 PM: | Understanding SOPs through flowcharts and timelines:<br>Part 2: Post-approval activities |
| 12:30 PM to 1:00 PM:  | Lunch break  |
| 1:00 PM to 1:30 PM:   | Roles and responsibilities of Ethics Committee members                                   |
| 2:00 PM to 3:00 PM:   | Hands-on: Review forms- effective utilization  |
| 3:00 PM to 3:30 PM    | Feedback, valedictory and distribution of certificates                                   |

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**Registration:** To register, please send the following details to [ethcom@yenepoya.edu.in](mailto:ethcom@yenepoya.edu.in)

Name:

Designation:

Role in the ethics committee:

Name of the Ethics Committee:

Contact Number:

Food preference: Veg/ Non-veg:

---- Registration is open to Ethics Committee members ----

