

**YENEPOYA (DEEMED TO BE UNIVERSITY)**  
**Yenepoya Ethics Committee 2**  
**Annual report for the year January 2023- December-2023**

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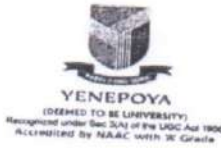
**YENEPOYA (DEEMED TO BE UNIVERSITY)**  
**Yenepoya Ethics committee 2**  
**Annual report for the year January 2023- December-2023**

**Introduction**

This committee was established on 18 December 2017 named as  
**“Institutional ethics committee”** for review the research protocol.



Under the direction of Honourable vice chancellor the **“Institutional ethics committee”** renamed as **“Yenepoya Ethics committee 2”** notification dated on 14.05.2018



Office of the Registrar  
University Road  
Deralakatte, Mangalore - 575 018  
Ph: 0824 - 2204667/68/69/70/71  
Fax: 0824 - 2203943

Ref: No. YU/REG/ACA/Committees/2018

14.05.2018

**NOTIFICATION-13/2018**

Sub: Renaming of the Ethics Committees  
\*\*\*\*\*

Under the directions of the Hon'ble Vice Chancellor the existing Yenepoya University Ethics Committee has been renamed as **“Yenepoya Ethics Committee 1”** while Institutional Ethics Committee of Yenepoya has been renamed as **“Yenepoya Ethics Committee 2”** and is hereby notified. Bye-Law no.578 and sub-clauses from 1 to 11 are hereby amended accordingly.

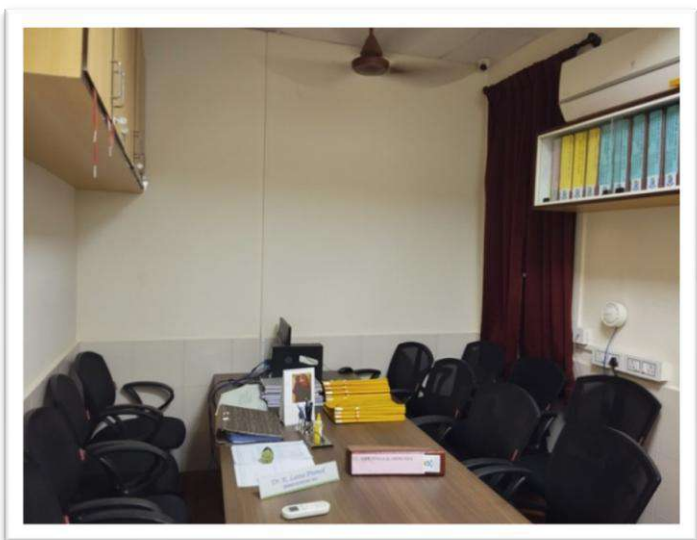
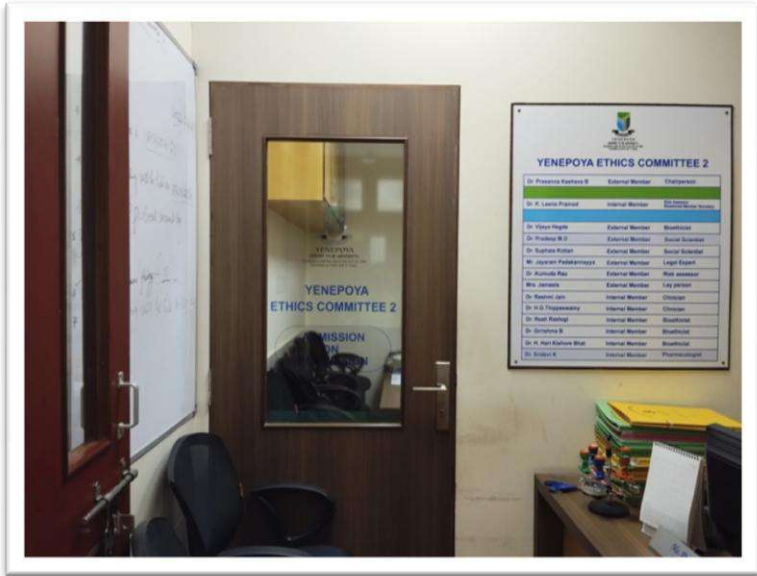
  
(Dr. G. Shreekumar Menon)  
REGISTRAR

To: Principals of all constituent Colleges .....for information  
Chairman and Secretary of Ethics Committee 1 and 2.....for needful action  
Controller of Examinations  
Finance Officer  
Chief Operating Officer  
P A to Vice Chancellor  
P A to Registrar

**INFRASTRUCTURE**

Address: Basement (-2 floor) , Yenepoya Dental college,  
 Yenepoya Deemed to be University)

<b>Secretariat Room with waiting</b>	<b>8 * 4 sq feet</b>
<b>Meeting room and Protocol review room</b>	<b>10*10 sq feet</b>
<b>Record room</b>	<b>10* 6 sq feet</b>



## **Scope of Yenepoya Ethics committee 2**

Yenepoya ethics committee 2 will review the research proposal from Yenepoya Dental College, Yenepoya Medical college, Yenepoya Nursing college, Yenepoya Physiotherapy college, Yenepoya Institute of allied health science, Yenepoya Institute of Arts, Science and Commerce, Ph.D., proposal, Yenepoya Ayurveda College, and Centres of Yenepoya (Deemed to be University).

As per the YU notification dated on 30.08.2019 (Ref.NO. YU/REG/ACA/CFE/Protocols 2019) the recent implantation of the New drugs and Clinical trial rules 2019, the protocol allotment for Yenepoya ethics committee is:

1. Post graduate Dissertation/Thesis(Including super speciality)
2. Post graduate Short studies
3. Undergraduate studies(Including ICMR-STs)



**YENEPOYA**  
(DEEMED TO BE UNIVERSITY)  
Accredited by NAAC with A+ Grade

Office of the Registrar  
University Road  
Deralakatte, Mangalore - 575 018  
Ph: 0824 - 2204667/68/69/70/71  
Fax: 0824 - 2203943

Ref: No. YU/REG/ACA/CFE/Protocols/2019 30.08.2019

**NOTIFICATION**  
Sub: Protocols of Yenepoya Ethics Committee - 1 & Yenepoya Ethics Committee -2  
\*\*\*\*\*

In view of the recent implementation of the New Drugs and Clinical Trials Rules 2019, the protocols allotment for Yenepoya Ethics Committee - 1 & Yenepoya Ethics Committee - 2 is hereby notified as follows:-

**Yenepoya Ethics Committee - 1**

1. Regulatory clinical trails
2. Funded faculty trails
3. Seed grants from Yenepoya (Deemed to University)
4. Ph.D Dissertation
5. Manuscripts for publications

**Yenepoya Ethics Committee - 2**

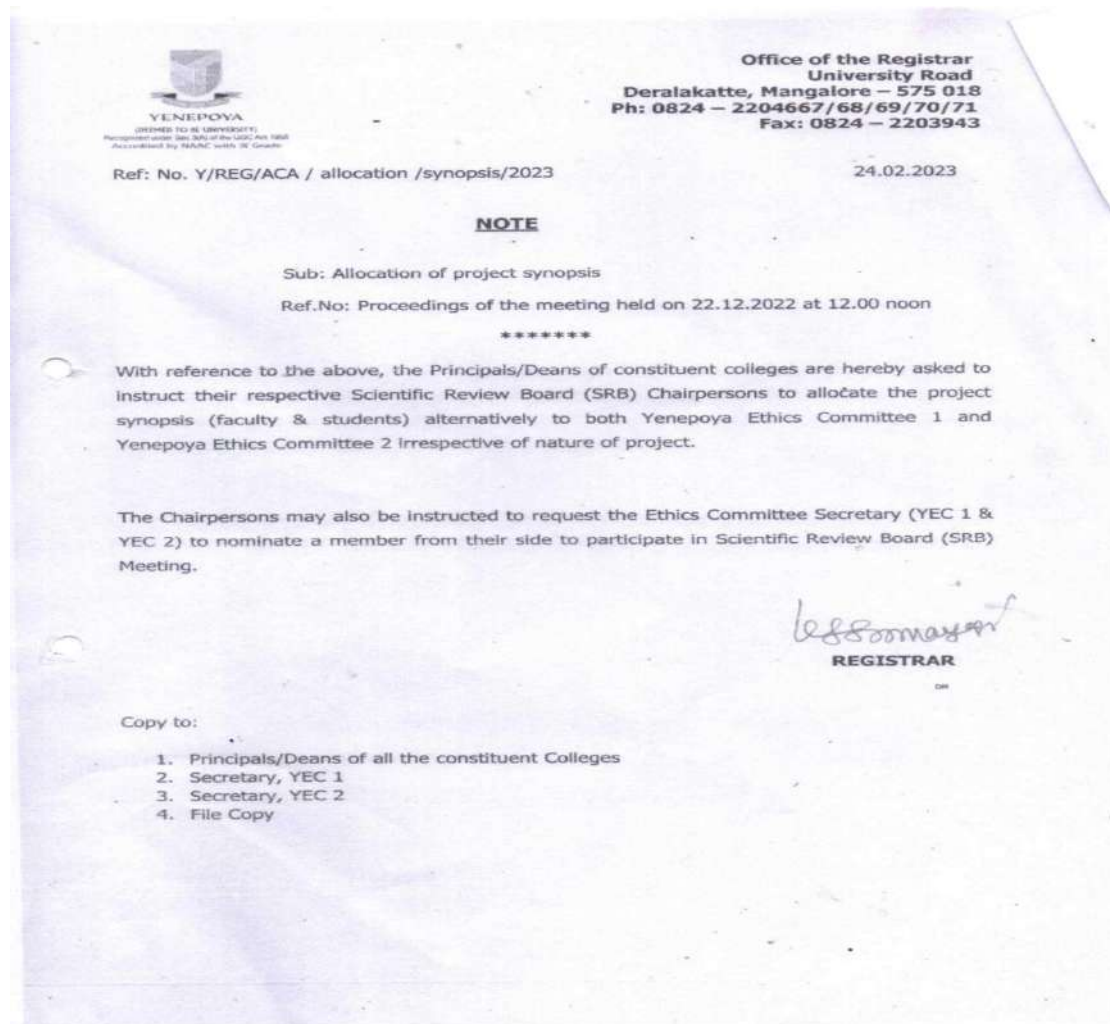
1. Postgraduate Dissertation/thesis( including super speciality)
2. Postgraduate short studies
3. Undergraduate studies (including ICMR-STs)

To, The Chairperson of the committee - YEC-1 & YEC-2  
Copy To:  
1. File copy

By Order  
  
REGISTRAR  
30/8

- The notification issued by the Registrar, Yenepoya(Deemed to be University) Ref: No. Y/REG/ACA/allocation/synopsis/2023 dated 24.02.2023

The respective Scientific review board chairpersons to allocate the project synopsis (Faculty and students) alternatively to both YEC1 and YEC2



- The notification issued by the Principal, Yenepoya Medical College (vide Ref. No. YMC/1034/2022 dated 06.06.2023  
The YEC2 will review proposal submitted by undergraduates, PG dissertation, PG Short study, and Faculty research proposal, MSc and Ph.D., Proposal from the following department:

1. Physiology, 2. Pharmacology, 3. Community medicine, 4. Pathology,

5. General medicine 6. Geriatric medicine, 7. Respiratory medicine,  
8. Psychiatry, 9. Dermatology, 10. Paediatrics 11. Cardiology,  
12. Neurology, 13. Nephrology, 14. Endocrinology 15. Rheumatology  
016. Audiology and speech language pathology.

**Terms of references for Scientific Review Boards A & B**

1. SRB-A will review proposals submitted by undergraduates, PG dissertation, PG sh faculty research proposals, MSc and PhD proposals from all the following departme
  - i. Anatomy
  - ii. Biochemistry
  - iii. Microbiology
  - iv. Forensic medicine
  - v. General surgery
  - vi. Otorhinolaryngology
  - vii. Ophthalmology
  - viii. OBG
  - ix. Radiodiagnosis
  - x. Anesthesia
  - xi. Orthopedics
  - xii. Urology
  - xiii. Surgical oncology
  - xiv. Neurosurgery
  - xv. Plastic surgery
2. SRB-B will review proposals submitted by undergraduates, PG dissertation, PG sh faculty research proposals, MSc and PhD proposals from the following department
  - i. Physiology
  - ii. Pharmacology
  - iii. Community medicine
  - iv. Pathology
  - v. General medicine
  - vi. Geriatric medicine
  - vii. Respiratory medicine
  - viii. Psychiatry
  - ix. Dermatology
  - x. Pediatrics
  - xi. Cardiology
  - xii. Neurology
  - xiii. Nephrology
  - xiv. Endocrinology
  - xv. Rheumatology
  - xvi. Audiology & speech language pathology
3. All proposals approved by SRB-A will be forwarded to EC-1
4. All proposal approved by SRB-B will be forwarded to EC-2

Above terms of above terms of references will be applicable from 06.06.2023.

### **DCGI REGISTRATION:**

The Yenepoya Ethics committee 2 has been registered under DCGI (Drug controller General of India) on 30<sup>th</sup> January 2020. The registration is valid for a period of 5 years from the date of issue ( 30<sup>th</sup> January 2025

The YEC2 receives the protocol as per the DCGI norms.

DCGI registration number is ECR/1337/Inst/KA/2020



File No. EC/19/000466  
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: 30-Jan-2020

To

The Chairman  
YENEPOYA ETHICS COMMITTEE 2  
YENEPOYA BASEMENT (-2FLOOR),  
YENEPOYA DENTAL COLLEGE  
UNIVERSITY ROAD, NITHYANANDA  
NAGARA, DERALAKATTE  
MANGALORE Dakshina  
Kannada Karnataka - 575018 India

Subject: Ethics Committee Registration No. ECR/1337/Inst/KA/2020 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2019/5820 dated 26-Aug-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/1337/Inst/KA/2020. The said registration is subject to the conditions as mentioned below:

Yours faithfully

V G  
SOMANI

(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 Licensing Authority. Provided that if the application for renewal of registration is received by the Central Licensing 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;




## **DHR REGISTRATION:**

The YenePOYA Ethics committee 2 has been provisionally registered under DHR (Department of health research ) on 23<sup>rd</sup> December 2020. The provisional certificate is valid for a period of 2 years from the date of issue (23.12.2022)

The YEC2 receives the protocol as per the DHR norms.

DHR registration number is EC/NEW/INST/2023/KA/0276

File No. - EC/NEW/INST/2020/1216

**Government of India**  
**Ministry of Health & Family Welfare**  
**Department of Health Research**

2nd Floor, IRCS Building,  
New Delhi - 110001  
Dated : 23-Dec-2020

**Provisional Certificate**

**Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECBHR), Department of Health Research (DHR).**

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter-IV of the New Drugs and Clinical Trials Rules, 2019.

**Name :** YENEPOYA ETHICS COMMITTEE 2  
**Address :** YENEPOYA DEEMED TO BE UNIVERSITY, BASEMENT(-2 FLOOR),YENEPOYA DENTAL COLLEGE, UNIVERSITY ROAD,NITHYANANDA NAGARA,DERALAKATTE MANGALORE , Dakshina Kannada, Karnataka - 575018  
**Contact No:** 0824-2206000,2204668  
**Fax :** 0824-2204663

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

ANU Digitally signed  
by ANU NAGAR  
DN: cn=ANU NAGAR  
(Anu Nagar)  
Joint Secretary  
Department of Health Research  
Designated Authority

In the month of January 2023 YEC2 has renewed the DHR registration , and final certificate received in the month of 24<sup>th</sup> May 2023.The final certificate bearing number is EC/NEW/INST/2023/KA/0276

The registration is valid for a period of 5 years from the date of issue (24 May 2028)



Government of India  
Ministry of Health & Family Welfare  
Department of Health Research  
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,  
Red Cross Road, New Delhi – 110001  
Date : 24-May-2023

To

The Chairperson  
YENEPOYA ETHICS COMMITTEE 2  
YENEPOYA DEEMED TO BE UNIVERSITY BASEMENT(-2 FLOOR),YENEPOYA DENTAL COLLEGE  
UNIVERSITY ROAD,NITHYANANDA NAGARA,DERALAKATTE, City-MANGALORE , District-Dakshina  
Kannada - Karnataka - 575018

Subject: Ethics Committee Registration No. EC/NEW/INST/2023/KA/0276 issued under New Drugs and Clinical Trials Rules, 2019

Sir/Madam,

Please refer to your file No. EC/NEW/INST/2020/1216, dated 16-Sep-2020 submitted to this National Ethics Committee Registry for Biomedical and Health Research (NECRBHR, Department of Health Research) for the Registration of Ethics committee.

Please find the enclosed registration of the Ethics committee in form CT-03 vide Registration No. EC/NEW/INST/2023/KA/0276, dated 16-May-2023. The said registration is subjected to the conditions as mentioned below.

Yours faithfully,

**BISWABANDA** Digitally signed by  
**N SENAPATI** / BISWABANDA SENAPATI  
Date: 2023.05.24 12:44:26  
+05'30'  
(B. Senapati)  
Deputy Secretary to Govt. of India

#### Conditions of Registration

The following include few of the conditions to be followed by the Ethics Committees (ECs) registered with the Designated Authority (NECRBHR, DHR).

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Designated Authority, NECRBHR, DHR. The EC has been registered for the purpose of reviewing Biomedical and Health Research. For Clinical Trials review, registration with CDSCO is required.
2. This certificate is issued to you on the basis of declaration/submission made by you.
3. An institution or organization or any person shall conduct any Biomedical and Health Research with the approval of the Ethics Committee registered under rule 17, Chapter IV of New Drugs and Clinical Trials Rules 2019.
4. The Ethics Committee should be constituted in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 as may be specified by the Indian Council of Medical Research from time to time and shall function in accordance with said guidelines.
  - a) EC composition should be as follows:
    - i) ECs should be multi-disciplinary and multi-sectoral.
    - ii) There should be adequate representation of age and gender.
    - iii) Preferably 50% of the members should be non-affiliated or from outside the institution.

### **Composition of YEC2 members**

The YEC2 consists of members who collectively have the qualifications and experience to review and evaluate the scientific and ethical aspects of a proposed research projects.

Selection of the Chairperson and Member Secretary as per the YU byelaws, ICMR guidelines and DHR, DCGI criteria.

- **Composition shall be follows:**

- a. Chairperson
- b. Member secretary
- c. At least two person from basic medical sciences
- d. At least two clinician
- e. At least one Social scientist
- f. At least lay person from the community
- g. At least one legal expert

- **Resignation of Dr. Sahana Devadas Acharya (Pharmacologist)**

Due to some personal reason Dr.Sahana Devadas Acharya resigned from YEC2 on 25.04.2023

- **Resignation of Dr. Prasanna Keshava B**

Dr. Prasanna Keshava B (Chairperson) of YEC2 from 23.07.2022 to 15.12.2023) had resigned as he joined in Yenepoya Ayurveda College in the month of December . As per the ICMR guidelines ,DCG&DHR criteria chairperson should not be affiliated to the institution . So Dr. Prasanna Keshava B had resigned from the position of Chairperson on 15.12.2023

- **Adding Dr. Sridevi K as a Pharmacologist**

According to ICMR ,DHR& DCGI criteria ethics should have one pharmacologist. It was decided to appoint Dr. Sridevi K as a Pharmacologist for YEC2

Dr. Sridevi K Joined as Pharmacologist on 22.05.2023

- **Adding Dr. Pradeep M.D as a Social scientist**

Dr. Pradeep M D joined as a social scientist on 22<sup>nd</sup> May 2023 for balancing the Members ratio.

- **Adding Dr. Animesh Jain as a Chairperson**

YEC2 proposed Dr. Animesh Jain (Professor, Community medicine , KMC Mangalore) as the Chairperson to replace the position of Dr. Prasanna Keshava B , Dr.Animesh Jain joined as a Chairperson On 19.12.2023

The Yenepoya Ethics Committee 2 of Yenepoya (Deemed to be) University is re-notified with the following members on 19.12.2023

SL. NO	MEMBERS	DEGREE	ROLE IN ETHICS COMMITTEE
1.	Dr. Animesh Jain	MD (Community Medicine) , PGDBEME	Chairperson
2.	Dr. K. Leena Pramod	M. Sc(Zoology), PGDBEME, PGDFAO(Forensic),Ph.D.	Member Secretary
3.	Dr. Vijaya Hegde	MDS, PGDBEME	Bioethicist,
4.	Mr. Jayarama Padakannaya	B.Com, LLB	Lawyer
5.	Ms. Jameela	BA	Lay person
6.	Dr. Kumuda Rao	MDS(Oral Medicine and Radiology), PGDMLE	Clinician
7.	Dr. Suphala Kotian	MSW, Ph.D	Social Scientist
8.	Dr. Pradeep M.D	MA (Sociology), LLB, Ph.D (in Law)	Social Scientist
9.	Dr. H.G. Thippeswamy	MBBS, MD(Anesthesia)	Clinician
10.	Dr. Rashmi Jain	MBBS, MS (Ophthalmology), PGDBEME	Clinician
11.	Dr. H.Hari Kishore Bhat	MDS(Oral and Maxillofacial Surgery), PGDBEME, PGDCE	Bioethicist, Member

<b>12.</b>	Dr. Grrishma.B	M.B.B.S., M.D.(Physiology) PGDBEME ,DNB	Bioethicist
<b>13.</b>	Ms. Reeti Rastogi	BA, MA (Psychology, M. Phil/ PGDBEME	Bioethicist- HIV Counsellor
<b>14</b>	Dr. Sridevi K	M.B.B.S, MD- (Pharmacology)	Basic Medical Scientist



Dr. Animesh Jain,  
(Chairperson)



Dr. K. Leena Pramod,  
(Member Secretary)



Dr. Rashmi Jain  
(Clinician)



Dr.H.Hari Kishore Bhat  
(Bioethicist)



Dr. Sridevi K  
(Pharmacologist)



Dr. Grrishma B  
(Bioethicist)



**Dr. Thippeswamy H G**  
(Clinician)



**Dr. Kumuda Rao**  
(Clinician)



**Dr. Vijaya Hegde**  
(Bioethicist)



**Mrs. Reeti Rastogi**  
(Bioethicist-  
HIV-Counsellor)



**Dr. Pradeep M D**  
(Social Scientist)



**Dr. Suphala S Kotian**  
(Social Scientist)



**Mr. Jayaram Padakanayya**  
(Lawyer)



**Mrs. Jameela**  
(Lay person)

## **YENEPOYA ETHICS COMMITTEE 2 CHAIRPERSON**



**Dr. Vijaya Hegde**  
(From 18.12.2017  
to 22.07.2022)

**Tenure**  
(4 years 6 months 22 days)



**Dr. Prasanna Keshava B**  
(From 23.07.2022 to  
15.12.2023)

**Tenure**  
(1 year 3 months 15 days)



**Dr. Animesh Jain**  
Present Chairperson

**Present**

## **YENEPOYA ETHICS COMMITTEE 2 MEMBER SECRETARY**



**Dr. H. Hari Kishore Bhat**  
From 18.12.2017 to  
22.07.2022

**Tenure**  
(4 years 7 months 22 days)



**Dr. Padmini Thalanjeri**  
From 23.07.2022 to  
06.12.2022

**Tenure**  
(4 months 13 days)



**Dr. K. Leena Pramod**  
From 06.12.2022 to  
Till date

**Present**

## **YEC2 MEETING**

The YEC 2 meeting dates are tentatively scheduled on the 2<sup>nd</sup> Saturday of every month to ensure regularity.

The Online meet of YEC2 2 meeting dates are tentatively scheduled on the 4<sup>th</sup> Friday of every month .

Every 4<sup>th</sup> Friday an online meet may be conducted if the number of protocols are more.

The YEC 2 will hold regular meetings at least once in every month and the interval between any two meetings will not exceed 60days.

The calendar of meetings will be prepared by the Member-Secretary and approved by the Chairperson and circulated among all the members of the YEC2

The calendar of meetings will be displayed on the YEC2 website and the notice board of YEC2 office for easy access by the researchers planning their protocol submissions.

### **Proposed date of YEC2 meeting for the year 2023**

<b>Proposed dates of YEC2 scheduled meeting for 2023</b>	
<b>Meeting No:39</b>	<b>14.01.2023</b>
<b>Meeting No:40</b>	<b>11.02.2023</b>
<b>Meeting No:41</b>	<b>11.03.2023</b>
<b>Meeting No:42</b>	<b>08.04.2023</b>
<b>Meeting No:43</b>	<b>13.05.2023</b>
<b>Meeting No:44</b>	<b>10.06.2023</b>
<b>Meeting No:45</b>	<b>08.07.2023</b>
<b>Meeting No:46</b>	<b>12.08.2023</b>
<b>Meeting No:47</b>	<b>09.09.2023</b>
<b>Meeting No:48</b>	<b>14.10.2023</b>
<b>Meeting No:49</b>	<b>11.11.2023</b>
<b>Meeting No:50</b>	<b>09.12.2023</b>

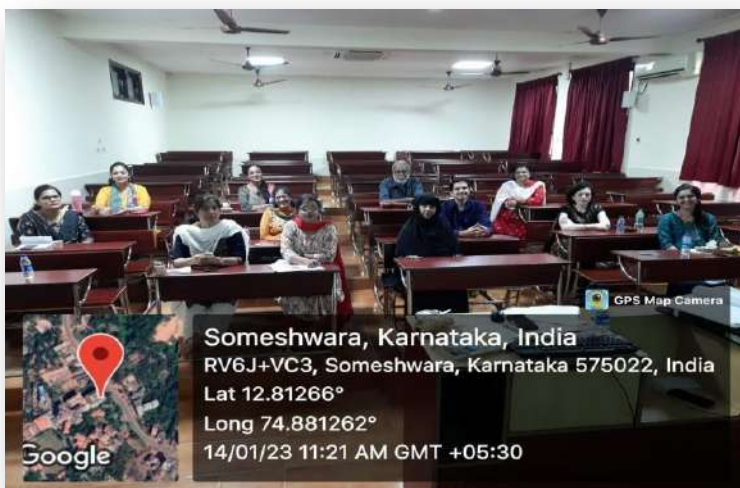


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### **Procedure of the meeting**

- The Member-Secretary assisted by the Secretariat will prepare the agenda of the next YEC 2 meeting
- The agenda is prepared at least 1 weeks before the scheduled day
- The agenda is sent to the Chairperson at least 7 calendar days before the meeting.
- The Chairperson will review the agenda and approve it
- Once approved, the agenda is circulated to all the YEC2 members at least 5 calendar days before the scheduled meeting.
- The secretarial staff will list and schedule the protocols in the agenda as per their receipt
- In the case of regulatory clinical trials, if the complete protocol package is received and verified, at least 21 calendar days before the next meeting, the Secretariat will add the protocol details in the agenda. Otherwise, the Secretariat will not table the protocol, but will keep it for tabling in the meeting after the next.
- In the case of all other protocols categorized as full review, if the complete protocol package is received and verified, at least 14 calendar days before the next meeting, the Secretariat will add the protocol details in the agenda. Otherwise, the Secretariat will not table the protocol, but will keep it for tabling in the meeting after the next.
- YEC2 members will approve the agenda, at the start of the meeting.
- The meeting will be conducted only after the quorum is ensured by the Chairperson, as per the NDCTR-19 and the Indian GCP guidelines (whenever regulatory clinical trial protocols are for review) or the ICMR National Ethical Guidelines, 2017 (for all other types of trials)
- The meeting will be conducted only after the quorum is ensured by the Chairperson.

- The quorum will consist of
  - One basic medical scientist (preferably a pharmacologist)
  - One social worker (or a social scientist, theologian, ethicist, Philosopher, member or representative of a non-governmental voluntary agency or a similar person)
  - A clinician
  - A lay person
  - A legal expert
  - If a guest is permitted to observe the meeting, then he should have obtained the permission from the Chairperson and Member-Secretary and should have signed the Confidentiality agreement form prior to attending the meeting as per **YEC2/SOP05/v2**
  - The Secretariat will mark the attendance of the members and guests present in the meeting and take their signatures on the attendance sheet.



**39<sup>th</sup>meetingheld on 14.01.2023**



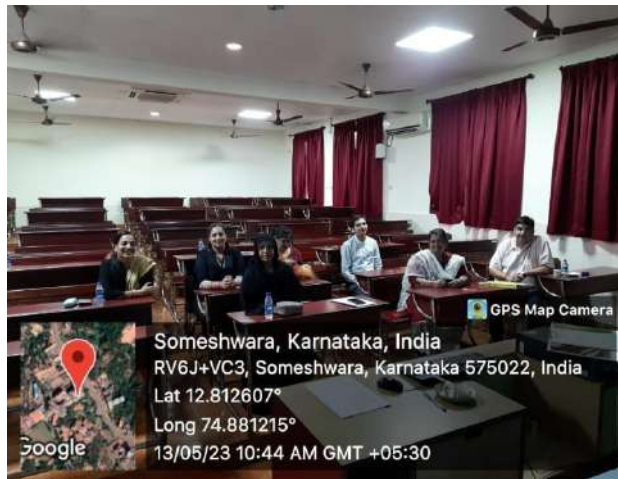
**40<sup>th</sup> meeting held on 11.02.2023**



**41<sup>st</sup> Meeting held on 11.03.2023**



**42<sup>nd</sup> Meeting held on 08.04.2023**



**43<sup>rd</sup> Meeting held on 13.05.2023**



**44<sup>th</sup> meeting held on 10.06.2023**



**45<sup>th</sup> meeting held on 08.07.2023**



**46<sup>th</sup> meeting held on 12.08.2023**



**47<sup>th</sup> meeting held on 09.09.2023**



**48<sup>th</sup> meeting held on 14.10.2023**



**49<sup>th</sup> meeting held on 10.11.2023**



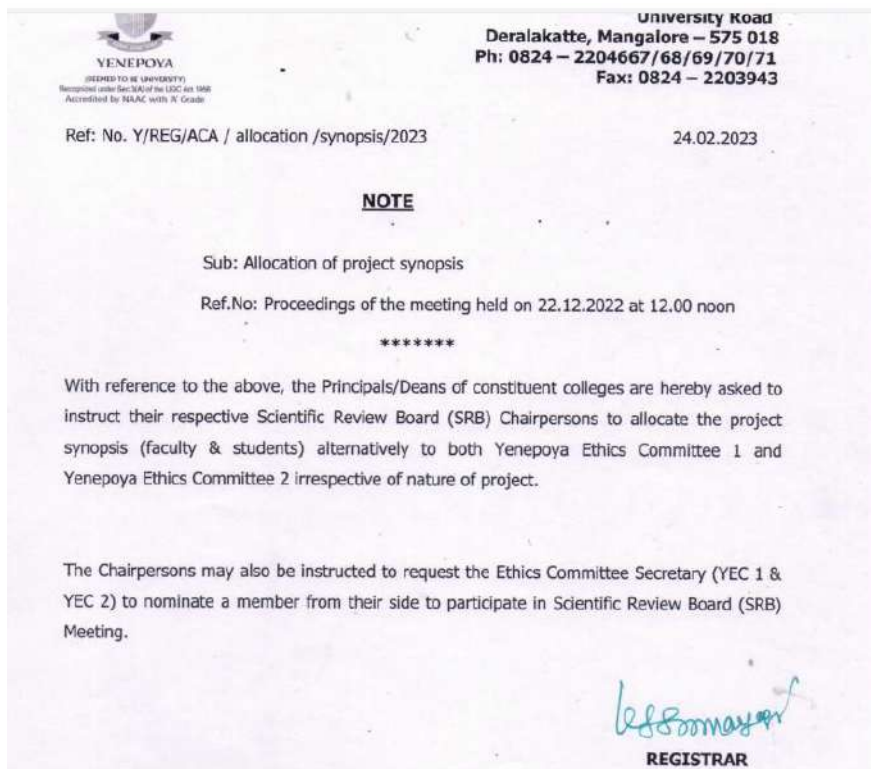
**50<sup>th</sup> meeting held on 09.12.2023**

**SRB MEETING**

As per the YU Notification dated on 24.02.2023

(Ref:no.Y/REG/ACA/allocation/synopsis/2023)

The Yenepoya ethics committee 2 member secretary to nominate a member from their side to participate in Scientific review board meeting.



**List of members attended in SRB meeting from March 2023 to December 2023**

Sl. no	Name of the members	SRB meeting date	Name of the college	Venue
1	Dr. H.Hari Kishore Bhat	27.02.2023	YDC	5 <sup>th</sup> floor , YDC
2.	Dr. K. Leena Pramod	28.02.2023	YDC	5 <sup>th</sup> floor , YDC
3.	Dr. K. Leena Pramod	01.03.2023	YDC	5 <sup>th</sup> floor , YDC
4	Dr. K. Leena Pramod	16.03.2023	YMC, SRB-B	Psychiatry OPD demo room, YMCH (SRB - B)

5	Dr. K. Leena Pramod	27.03.2023	YSAHS	Google meet
6	Dr. K. Leena Pramod	29.03.2023	YSAHS	Google meet
7	Ms. Reeti rastogi	29.03.2023	YSAHS	Yenepoya School of allied health and sciences, mudipu
8	Dr. Rashmi jain	29.03.2023	YMC, SRB-A	ENT Seminar hall, YMCH 5 <sup>th</sup> floor
9	Dr. Thippeswamy HG	31.03.2023	YMC, SRB-A	ENT Seminar hall, YMCH 5 <sup>th</sup> floor
10	Dr. Rashmi Jain	27.03.2023	YMC, SRB-A	ENT Seminar hall, YMCH 5 <sup>th</sup> floor
11	Dr. Rashmi Jain	28.03.2023	YMC, SRB-A	ENT Seminar hall, YMCH 5 <sup>th</sup> floor
12	Dr. K. Leena Pramod	27.04.2023	YMC, SRB-B	Psychiatry OPD demo room, YMCH (SRB -
13	Dr. H.Hari Kishore Bhat	25.04.2023	YMC, SRB-A	ENT Seminar hall, YMCH 5 <sup>th</sup> floor
14	Dr. Thippeswamy HG	12.05.2023	YMC, SRB-A	ENT Seminar hall, YMCH 5 <sup>th</sup> floor
15	Dr. Rashmi Jain	20.05.2023	YMC, SRB-A	ENT Seminar hall, YMCH 5 <sup>th</sup> floor
16	Dr. Thippeswamy HG	29.05.2023	YMC, SRB-A	ENT Seminar hall, YMCH 5 <sup>th</sup> floor
17	Dr. K. Leena Pramod	27.06.2023	YMC, SRB-B	Psychiatry OPD demo room, YMCH (SRB - B)
18	Ms. Reeti rastogi	04.07.2023	YSAHS	Yenepoya School of allied health and sciences, mudipu
19	Dr. Sridevi K	28.07.2023	YMC, SRB-B	Psychiatry OPD demo room, YMCH (SRB - B)
	Dr. Sridevi K	08.09.2023	YMC, SRB-B	Psychiatry OPD demo room, YMCH (SRB - B)
20	Dr. K. Leena Pramod	29.09.2023	YMC, SRB-B	Psychiatry OPD demo room, YMCH (SRB -B)
21	Dr. Thippeswamy HG	31.10.2023	YMC, SRB-B	Psychiatry OPD demo room, YMCH (SRB -B)
22	Dr. Rashmi jain	30.11.2023	YMC, SRB-A	Psychiatry OPD demo



23	Dr. Grrishma B	22.12.2023	YMC, SRB-A	room, YMCH (SRB -B Psychiatry OPD demo room, YMCH (SRB -B
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### **YEC2 LIBRARY**

The main aim of the ethics committee is research on human participants pertains to a broad range of scientific enquiry aimed at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value. Every research has some inherent risks and probabilities of harm or inconvenience to participants/communities.

To learn about more on research guidelines YEC2 is maintaining some guidelines books in YEC2 library.

The following books are maintained:

Sl. no	Title of the book	Code no
1	National ethical guidelines for biomedical and health research involving human participants -2006	YEC2/Lib01
2	National ethical guidelines for biomedical and health research involving human participants -2017	YEC2/Lib02
3	National ethical guidelines for biomedical Involving children-2017	YEC2/Lib03
4	Biomedical ethics perspectives in the Indian context- Vol.1	YEC2/Lib04
5	Application form for initial review	YEC2/Lib05
6	Clinical trial and biomedical research in India -2023	YEC2/Lib06

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### **Student visiting to YEC2:**

The students are visiting the YEC2 for clarification regarding Submission clarification, resubmission review clarification and other matter related to research.

SO YEC2 maintaining the student movement registrar book from April 2023

Total number of Principal investigator visited to the YEC2 department is  
**130**

### **Colour coding for files**

YEC2 is maintaining the colour coding system for each research files to easily identify and access the research file for YEC2 secretariat and attender

The following files are being used in YEC2:

- Blue file for faculty projects
- Pink for Academic clinical trial
- Green for funded projects
- Yellow for Dissertation/Short study of Postgraduates student  
YMC, YDC, YPC, YNC, YPRPC, YSAHS

Dissertation/Short studies received from different colleges are labelled with different colour sticker

- Yenepoya Dental college- Blue sticker
- Yenepoya Medical college – Orange sticker
- Yenepoya Nursing College- Red sticker
- Yenepoya Physiotherapy College - Green Sticker
- Ph.D., proposal - Violet sticker
- Yenepoya allied health and science college – White sticker
- Master of Health and Administration - White and Red Sticker
- PGDBEME proposal - White and Blue sticker
- Yenepoya Research centre - Yellow and White sticker

- Master of Social Work - White and brown sticker
- Yenepoya Pharmacy and Research centre college- Brown sticker

\*One strip of colour sticker for Dissertation

\* Two strip of colour sticker for Short study



**YENEPOYA ETHICS COMMITTEE 2**  
 Yenepoya (Deemed to be University)  
 Floor -2(Basement), Yenepoya Dental College, Mangalore-575018  
 yec2@yenepoya.edu.in,(0824)2206000- Extension Number - 2063  
 DCGI Registration No.: ECR/1337/Inst/KA/2020  
 DHR registration No.: EC/NEW/INST/2023/KA/0276

COLLEGES	COLOUR CODING FOR FILES	
	Dissertation	Short Study
Yenepoya Medical College (YMC)	Orange	
Yenepoya Dental College (YDC)	Blue	
Yenepoya Physiotherapy College (YPC)	Green	
Yenepoya Nursing College (YNC)	Red	
Yenepoya Allied and Health Science (YSAHS)	White	
Yenepoya Pharmacy and Research Centre (YPRPC)	Brown	
Master of Social Work (MSW)	White	No short study
	Brown	
Master of health administration (MHA)	White	No short study
	Brown	



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PGDBEME	White	No short study
YRC proposal	White	No short study
Academic clinical trial	Pink	
Faculty project	Blue	
Funded Project	Green	
Ph. D. Proposal	Purple	

## Protocol numbering

In the 39<sup>th</sup> meeting it was decided the protocols received by YEC2 will be labelled as YEC2/2023/001.

## SOP revision regarding

The Yenepoya ethics committee 2 has been revised the SOP's with effect from 25.02.2023(Notification: Ref: NO/YU/REG/ACA/YEC-2/SOP/2023).

Ref: No/YU/REG/ACA/YEC-2/SOP/2023

25.02.2023

### NOTIFICATION

Sub: Yenepoya Ethics Committee 2 Standard operating Procedure Manual (SOPM)

Reg. No: Your letter no 17.02.2023

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The Standard Operating Procedure Manual of the Yenepoya Ethics Committee 2, Yenepoya (Deemed to be University), Deralakatte, Mangalore, version 02(Referred to shore YEC2/SOP/v2) is hereby notified with effect from 25.02.2023.

Sl. no	Title of the standard operating Procedure (SOPs)	SOP no
1.	Preparation of Standard Operating Procedures for Yenepoya Ethics Committee 2	SOP01/v2
2.	Constitution of Yenepoya Ethics Committee (YEC 2), Selection, Roles and Responsibilities of the Members of the YEC 2	SOP02/v3
3.	Handling Conflict of Interest among Ethics Committee Members	SOP03/ v2
4.	Selection and Responsibilities of Independent Consultants	SOP04/ v2
5.	Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee 2 or attend YEC 2 meeting	SOP05/ v2
6.	Management of Submission of Research Study Protocol and Study Related Documents	SOP06/ v2
7.	Categorization of Submitted Protocols for Ethics Review	SOP07/ v2
7A	Initial Full Review of Research Study Protocols	SOP7A/ v2
7B	Expedited Review of Research Study Protocols	SOP7B/ v2
7C	Exemption from Ethics Review of Research Study Protocols	SOP7C/ v2
8.	Agenda Preparation, Meeting Procedures and Recording of Minutes	SOP08/ v2
9.	Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol	SOP09/v2
10.	Continuing Review of Study Protocols	SOP10/ v2
11.	Review of Protocol Deviations / Violations	SOP11/ v2
12.	Review of Serious Adverse Events (SAE) Reports	SOP12 /v2
13.	Review of Study Completion Reports	SOP13 /v2



14.	Management of Premature Termination / Suspension/ Discontinuation of the Study	SOP14/ v2
15.	Request for Waiver of Written Informed Consent and Waiver of Consent	SOP15/ v2
16.	Site Monitoring and Post-Monitoring Activities	SOP16/ v2
17.	Dealing with Participants Requests and Complaints Coming to Ethics Committee	SOP17 /v2
18.	Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents	SOP18/ v2
19.	Reviewing Proposals involving Vulnerable Populations	SOP19/ v2
20.	Preparing for Ethics Committee Audit/ Inspection	SOP20/ v2
21.	Training and Assessment of Ethics Committee Members	SOP21/v2
22.	Special consideration for Clinical trials in Ayurveda, Siddha,Unani,Yoga and Naturopathy protocol submission in Yenepoya Ethics Committee -2	SOP22/v2

*kesarimayal*  
REGISTRAR

Copy to:

- Secretary, YEC - 2
- File Copy

### **Protocol Statistics from January 2023 to December 2023**

<b>Total number of protocol received by YEC2 (From 2018 to December 2023)</b>	<b>1395</b>
<b>Number of protocol received in the year 2023</b>	<b>213</b>
<b>Total number of protocol approved by YEC2</b>	<b>191</b>
<b>Awaiting for Principal investigator reply</b>	<b>14</b>
<b>Total number of protocol pending for review from YEC2</b>	<b>08</b>
<b>Total number of Expedited review protocol</b>	<b>157</b>
<b>Total number of Full board review protocol</b>	<b>17</b>
<b>Total number of Academic Clinical trial protocol</b>	<b>25</b>
<b>Total number of Sponsored clinical trial protocol</b>	<b>04</b>
<b>Total Number of protocol received from YMC</b>	<b>46</b>
<b>Total Number of protocol received from YDC</b>	<b>55</b>
<b>Total Number of protocol received from YNC</b>	<b>23</b>
<b>Total Number of protocol received from YPC</b>	<b>23</b>
<b>Total Number of protocol received from YSAHS</b>	<b>21</b>
<b>Total Number of protocol received from YIASM</b>	<b>15</b>

<b>Total Number of protocol received from Ph.D., proposal</b>	<b>04</b>
<b>Total Number of protocol received from YRC</b>	<b>02</b>
<b>Total number of protocol received from Faculty project</b>	<b>3</b>
<b>Total number of protocol received from MSW</b>	<b>8</b>
<b>Total number protocol received from centre from clinical research</b>	<b>03</b>
<b>Total number protocol received from Yenepoya Pharmacy and research centre college research</b>	<b>2</b>
<b>Total protocol received from Centre for ethics</b>	<b>04</b>

## **YEC2 Finance:**

### ***Processing Fees for YEC 2 review***

The fees for reviewing various categories of research study proposals in Indian Rupees (INR); non-refundable are as given in the following table:

<b>Sl. No</b>	<b>Category of review</b>	<b>Pharma industry sponsored Research</b>	<b>Govt sponsored/ NGO Research</b>	<b>Academic or Investigator initiated Research</b>
1.	New study protocol	Rs. 25,000 /-	Rs. 20,000 /-	Nil
2.	Continuing review (per review)	Rs. 15,000 /-	Rs.10,000 /-	Nil
3.	Protocol Amendment (per amendment review) (if applicable)	Rs. 15,000 /-	Rs. 10,000 /-	Nil

➤ Yenepoya ethics committee 2 received 4 sponsored clinical trial protocols

The list is given below:-

<b>Sl. no</b>	<b>Title of the study</b>	<b>Indian funded study/International funded study</b>	<b>Total amount received (Including GST 18% )</b>
<b>1</b>	Reducing the burden of care for Cleft patients: Evaluating the effectiveness of nasoalveolar molding (NAM) in Unilateral Complete Cleft Lip and Palate Patients (NAMUC Study)	<b>Indian sponsored study</b> <b>Indian Alliance</b> <b>DBT welcome</b>	50,000.00 + 9000(GST )
			59, 000
<b>2</b>	A Multicenter, Double-blind, Randomized, Parallel-group, Phase 3 Study to Compare the Efficacy and Safety of the Proposed Biosimilar PERT-IJS and EU-Perjeta® along with Trastuzumab and Chemotherapy	<b>International funded study</b>  <b>Biocon Biologics UK Limited, 16 Great Queen Street, Covent Garden,</b>	75000  +13500(GST)

	(Carboplatin and Docetaxel) as Neoadjuvant Treatment in Patients with Hormone Receptor Negative (HR-ve) Human Epidermal Growth Factor Receptor 2 (HER2)-positive Early Stage or Locally Advanced Breast Cancer.	<b>London WC2B 5AH, United Kingdom</b>	88500
<b>3</b>	A Randomized, double blind, double dummy, active controlled, parallel-group, study to compare the efficacy and safety of Fosravuconazole L-Lysine ethanolate Capsules 169.1mg of Dr. Reddy's Laboratories Limited with Itraconazole 200mg in patients with Onychomycosis	<b>Indian sponsored study</b> <b>Dr. Reddy's Laboratories Ltd</b> <b>Integrated Product Development,</b> <b>Innovation plaza, Survey No: 42, 45 &amp; 46,</b> <b>Bachupally village,</b> <b>Bachupally Mandal,</b> <b>Hyderabad,Medchal -</b> <b>Malkajgiri District - 500</b> <b>090,Telangana, India</b>	50,000.00 + 9000(GST )  59, 000
<b>4.</b>	Evaluation of Efficacy and Safety of Aceclofenac + Paracetamol + Serratiopeptidase Combination After Impacted Lower Third Molar Surgery: A Randomized, Double-Blind Comparison with Aceclofenac + Paracetamol Combination	<b>Indian sponsored study</b>  <b>Ipca Laboratories Limited</b> <b>Clinical Research &amp; Development</b> <b>142 AB, Kandivli</b> <b>Industrial Estate,</b> <b>Kandivli (W),</b> <b>Mumbai: 400067</b>	Not received yet

**Rs. 2,06,500/-**

***Amount in words: Two lakh six thousand five hundred only/-***



**Members Certification details from January 2023 to December 2023**

<b>Sl. no</b>	<b>Members details</b>	<b>Title of the Training Workshop/Conference</b>	<b>Date of attend the training/workshop/conference</b>
1	Dr. K.Leena Pramod	Ethical Horizons: Navigating Artificial Intelligence in Biomedical Research & Healthcare with ICMR Guidelines	08 November 2023
2	Dr. K.Leena Pramod	International Conference of the Forum for Ethics Review Committees in India held at PSG IMSR&H	08 <sup>th</sup> & 9 <sup>th</sup> December 2023
3	Dr. Animesh Jain	On ICH GCP E6 ICMR Ethical guideline and NDTCR 2019	27 <sup>th</sup> October 2023
4	Mr. Jayarama Padakannaya	ICH GCP Guidelines, ICMR Guidelines for Biomedical Research and New Drugs and Clinical Trial Rules 2019	20 <sup>th</sup> May 2023

**YEC2 committees**

A new Severe adverse event (SAE) team is hereby re-notified for Yenepoya Ethics Committee 2 with the following members and is hereby notified. The roles of the members have been laid down in the Standard Operating Procedure YEC2/SOP12/v1

Sl. No.	Members	Role
1	Dr. Sridevi K	Chairperson
2	Dr. H. G Thippeswamy	Executive Secretary
3	Dr. K Leena Pramod	Member
4	Dr. H. Hari Kishore Bhat	Member
5	Dr. Rashmi Jain	Member
6	Dr. Vijaya Hegde	Member
7	Dr. Jayaram Padakanayya	Member
8	Dr. Animesh Jain	Member
9	Dr. Pradeep M.D	Member

A new Standard Operating Procedure (SOP) team is hereby re-notified for Yenepoya Ethics Committee 2 with the following members and is hereby notified. The roles of the members have been laid down in the Standard Operating Procedure YEC2/SOP12/v1.

Sl. No.	Members	Role
1	Dr. K. Leena Pramod	Convenor
2	Dr. Rashmi Jain	Member
3	Dr. Animesh Jain	Member
4	Dr. Vijaya Hegde	Member
5	Dr. H.Hari Kishore Bhat	Member
6	Dr. Sridevi K	Member
7	Dr. Grrishma B	Member

A new CTRI monitoring committee team is hereby re-notified for Yenepoya Ethics Committee 2 with the following members and is hereby notified. The roles of the members have been laid down in the Standard Operating Procedure YEC2/SOP12/v1.

Sl. No.	Members	Role
1	Dr. H.Hari Kishore Bhat	Chairperson
2	Dr. K. Leena Pramod	Member
3	Dr. Vijaya Hegde	Member
4	Dr. Animesh Jain	Member
5	Dr. Rashmi Jain	Member
6	Dr. Sridevi K	Member

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**YEC2 Non -teaching staff**

**YEC2 SECRETARIAT**

**Name:** Ms. Pramitha  
**Qualification:** Bachelor of commerce,  
Diploma In computer application  
Pursuing Master of Commerce



**YEC2 ATTENDER**

**Name:** Mr. Bharath Raj  
**Qualification:** Bachelor of Arts,





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DCGI Registration No.: ECR/1337/Inst/KA/2020  
DHR registration No.: EC/NEW/INST/2023/KA/0276



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**YEC2 Address and Contact details**

Yenepoya Ethics Committee 2

Address: Basement -2 floor

Yenepoya Dental College

Contact Number: 0824-2206000

Extension Number: 2063

**YEC2 website details**

Yenepoya Ethics Committee 2

<https://www.yenepoya.edu.in/you-ethics-commitee.php>

~~~~~**Thank you**~~~~~

*Prepared by:*  
*Dr. K. Leena Pramod*  
*Member Secretary*  
*Yenepoya Ethics Committee 2*