



3.4.1. The Institution has a stated Code of Ethics for research, the implementation of which is ensured by the following:

Minutes of the Relevant Committees with Reference to the Code of Ethics

Sl. No.	Name of the Committee	Page Number
1.	Institutional Ethics Committee (YEC-1)	03 - 128
2.	Institutional Ethics Committee (YEC-2)	129 – 167
3.	Institutional Animal Ethics Committee (IAEC)	168 - 213
4.	Institutional Bio-safety Committee (IBSC)	214 - 222
5.	Institutional Committee for Stem Cell Research (YU-IC-SCR)	223 - 254




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3.4.1. The Institution has a stated Code of Ethics for research, the implementation of which is ensured by the following:

Minutes of the Relevant Committees with Reference to the Code of Ethics

Sl. No.	Name of the Committee	No. of Meetings				
		2020-21	2019-20	2018-19	2017-18	2016-17
1.	Institutional Ethics Committee (YEC-1)	12	14	12	12	12
2.	Institutional Ethics Committee (YEC-2)	11	07	04	03	-
3.	Institutional Animal Ethics Committee (IAEC)	02	02	03	02	03
4.	Institutional Biosafety Committee (IBSC)	01	01	01	-	01
5.	Institutional Committee for Stem Cell Research (YU-IC-SCR)	01	01	-	01	01

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka



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Meeting Details and Minutes of Yenepoya Ethics Committee – 1

Sl. No.	Year	No. of Meetings
1.	2020-21	12
2.	2019-20	14
3.	2018-19	12
4.	2017-18	12
5.	2016-17	12

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka



Core minutes of the 118 Meeting of Yenepoya Ethics Committee- 1

The 118 meeting of the Yenepoya Ethics Committee- 1 was held on 03 June 2021 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC. In view of the COVID pandemic, the meeting was held in hybrid mode (both in the Demo Room 2 and online on Google Meet). Dr. Vikram Shetty, Chairperson and Dr. Uma Kulkarni, Member-Secretary conducted the online meeting from the Secretariat, YEC-1, Academic Block, YMC.

The following members were present:

No	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson	External	Demo 2
2.	Mr. Saduddin Salihi (SS)	Legal Expert	External	Online
3.	Fr. Teji Thomas (TT)	Priest	External	Online
4.	Dr. Sayeegeetha (SH)	Layperson	External	Demo 2
5.	Dr. Scahidanda Adiga (SA)	Basic Science	External	Demo 2
6.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Online
7.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Online
8.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
9.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence:

10.	Ms. Viji Prasad (VP)	Nurse	Internal
11.	Mr. YM Khurshid	Layperson	External
12.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal

Secretarial staff: Ms. Jainabu Mufeeda

Guest observers: None


Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the **quorum requirements** were met and declared the meeting open. <https://meet.google.com/oms-xjru-wpf?hs=224>


Secretary

Yenepoya Ethics Committee-1

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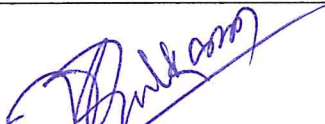

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore- 575 018, Karnataka
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23. List of protocol documents for shredding: (N=13) – for ratification

Sl No	Protocol No	Title	Date of closure	YEC-1 decision
1.	2015/298	Evaluation of efficacy of autologous blood injection for the treatment of chronic recurrent temporomandibular joint dislocation and related MRI changes	03-May-2018 (78 YUEC meeting)	Ratified
2.	2016/162	To study the process of scheduling surgeries operation theatre and reasons for their cancellation in a tertiary care hospitals	03-May-2018 (78 YUEC meeting)	Ratified
3.	2017/340	Clinical interventions and prescribing pattern analysis in hypertensive and diabetes mellitus patients	03-May-2018 (78 YUEC meeting)	Ratified
4.	2017/335	A study on prevalence, risk factors and prescription pattern in pregnancy induced hypertension	03-May-2018 (78 YUEC meeting)	Ratified
5.	2017/342	Evaluation of drug therapy, outcomes and impact of patient counselling in chronic obstructive pulmonary disease patients in a tertiary care hospital	03-May-2018 (78 YUEC meeting)	Ratified
6.	2017/339	Evaluation of drug therapy in breast cancer patients in a tertiary care teaching hospital	03-May-2018 (78 YUEC meeting)	Ratified
7.	2017/337	Study on pain management of Head and neck Cancer in a tertiary care hospital	03-May-2018 (78 YUEC meeting)	Ratified
8.	2017/336	Evaluation of polypharmacy, comorbidities and prescribing pattern in geriatric patients, at a tertiary care hospital	03-May-2018 (78 YUEC meeting)	Ratified
9.	2017/338	Comparison of clinical profiles of osteoarthritis and rheumatoid arthritis and assessment of prescription pattern	03-May-2018 (78 YUEC meeting)	Ratified
10.	2017/341	A study on the drug utilization pattern and medication adherence in patients with chronic kidney disease in a tertiary care teaching hospital	03-May-2018 (78 YUEC meeting)	Ratified
11.	2016/125	Soft tissue tumours: A clinicopathological assessment	03-May-2018 (78 YUEC meeting)	Ratified
12.	2016/214	Comparative evaluation of two desensitizing agents on dentin hypersensitivity reduction: An in vivo study	Short study (Full Review)	Ratified
13.	2016/182	A study of knowledge, attitude and practice (KAP) on ethical issues in authorship among medical and dental researchers	03-May-2018 (78 YUEC meeting)	Ratified

24. Duplicate EC clearance issued (for information of YEC-1) (N=0)

Sl. No	Protocol No.	Name of the PI	Title of the study	Type of study	Date of issue	YEC-1 decision
	Nil					


Secretary

25. Post approval communications: (N=0)

Sl. No	Protocol No.	Name of the PI	Title of the study	Subject	YEC-1 decision

26. Other administrative issues (if any) –Nil

Sl. No	Topic	Objectives	Name of the trainer	YEC-1 decision

27. SOP change request:

Sl No	SOP number & Version	Change request & Justification	Suggested by	Drafted by	Approval	YEC-1 decision
1	SOP7A/v3.1	Full review approval letter template, as suggested by the NABH during Desktop Surveillance Assessment	Dr. Uma Kulkarni	Dr. Uma Kulkarni	All	Ratified
2	SOP3A/v3	Change in Conflict of Interest declaration for researchers template	Dr. Ravi Vaswani	Dr. Ravi Vaswani	All	Ratified

28. Training session of the Members:

Members were briefed about the WHO's Guidelines for Monitored Emergency Use of Unregistered Interventions – Dr. Ravi Vaswani

29. Communications with regulatory authorities/ management or others (if any): Nil

30. Subcommittee reports (if any): Nil

31. Any other matter with permission of the chair:

Copy to: All the Ethics Committee Members
Registrar YU (for information)

Dr. Uma Kulkarni
Secretary
Yenepoya Ethics Committee-1

Dr. Uma Kulkarni
Secretary, YEC -1

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Dr. Gangadhara Somayaji K.S.

Dr. Gangadhara Somayaji K.S.
Page Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Dr. Uma Kulkarni
Secretary



Core minutes of the 117 Meeting of Yenepoya Ethics Committee- 1

The 117 meeting of the Yenepoya Ethics Committee- 1 was held on 06 May 2021 at 11.00 AM. In view of the COVID pandemic, the meeting was held on Google Meet. Dr. Vikram Shetty, Chairperson and Dr. Uma Kulkarni, Member-Secretary conducted the online meeting from the Secretariat, YEC-1, Academic Block, YMC.

The following members were present:

S.No	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson	External	Demo 2
2.	Mr. Saduddin Salihi (SS)	Legal Expert	External	Online
3.	Fr. Teji Thomas (TT)	Priest	External	Online
4.	Dr. Sayeegeetha (SH)	Layperson	External	Online
5.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal	Online
6.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Online
7.	Mr. YM Khurshid	Layperson	Internal	Online
8.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Online
9.	Ms. Viji Prasad (VP)	Nurse	Internal	Online
10.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Online
11.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence:

12.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	
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Secretarial staff: Ms. Jainabu Mufeeda

Guest observers: None

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the **quorum requirements** were met and declared the meeting open. <https://forms.gle/EtpPqXQW3PwbSyxy8>

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
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Secretary

Yenepoya Ethics Committee-1

		0.3%/2.5% (Cipla) with EPIDUO FORTE (adapalene and benzoyl peroxide) gel, 0.3%/2.5% (GALDERMA LABS) in human subjects with acne vulgaris	
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17. Other administrative issues (if any) –

18. Training session of the Members:

Sl.No	Topic	Objectives	Name of the trainer
1	NABH standards	SWOT analysis of NABH desktop assessment and the way forward to improve the standards	Dr. Uma Kulkarni

19. Communications with regulatory authorities/ management or others (if any): Nil

20. SOP change request:

- a. **Suggestion by RV:** To include online meeting attendance and online COI declaration for protocols during EC meetings: Approved by all.

21. Subcommittee reports (if any)

22. Any other matter with permission of the chair

- a. **Matter 1:** The request letter from Dr. Anurag to approve the compassionate use of Tofacitinib and Bevacizumab for COVID patients in the absence of availability of CDSCO approved drugs like Tocilizumab from government and the market for severe COVID-19 infections in view of the possible therapeutic benefits. It was discussed that compassionate use of these drugs in emergency may be considered on a case to case basis as recommended by the WHO. As per the WHO guidelines (MEURI and scientific brief on emergency use of off-label drugs in pandemic), EC has the authority to approve such use along with approval from regulatory authorities.

Decision: It was unanimously decided to approve Dr. Anurag's request, subject to receiving approval from DCGI and to follow the guidelines of WHO. Member-Secretary to draft the reply and get it approved by Chairperson before communicating with the applicant.

Since there was no other matter, the meeting ended with a vote of thanks.

Uma Kulkarni
Secretary
Yenepoya Ethics Committee-1

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Dr. Uma Kulkarni
Secretary, YEC -1

Uma Kulkarni
Secretary
Yenepoya Ethics Committee-1
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka



Core minutes of the 116 Meeting of Yenepoya Ethics Committee- 1

The 116 meeting of the Yenepoya Ethics Committee- 1 was held on 01 April 2021 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC

The following members were present:

S.No	Name	Designation in YEC-1	Affiliation	Attendance
1.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert (Acting Chairperson)	External	Demo 2
2.	Fr. Teji Thomas (TT)	Priest	External	Demo 2
3.	Dr. Sayeegeetha (SH)	Layperson	External	Demo 2
4.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal	Demo 2
5.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Demo 2
6.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Demo 2
7.	Ms. Viji Prasad (VP)	Nurse	Internal	Demo 2
8.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
9.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence:

10.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External
11.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External
12.	Mr. YM Khurshid	Layperson	External

Secretarial staff: Ms. Jainabu Mufeeda

Guest observers:

1. Dr. Mohammed Naseer Ahamed MSc RE student
2. Dr. Akhila Chandran MSc RE student (Internship)

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the **quorum requirements** were met and declared the meeting open.
3. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. The following members declared conflict of interest: **None**

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Dr. Gangadhara Sopa
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

19.	2017/026	Is Ophthalmology breaking your back? A nationwide survey of musculoskeletal disorders among Ophthalmologists in India?	Ratified
20.	2015/233	Efficacy of different decalcifying agents in preserving the structural integrity of human teeth - a comparative study	Ratified
21.	2017/018	Characterisation of uropathogenic E.coli and its drug resistance pattern in a tertiary care hospital in Mangalore	Ratified

21. Duplicate EC clearance issued for information: (N=0)

Sl. No	Protocol No.	Name of the PI	Title of the study	Type of study	Date of issue	YEC-1 decision
1	Nil					

22. Post approval communications: (N=0)

Sl.No	Protocol No.	Name of the PI	Title of the study	Subject	YEC-1 decision
	Nil				

23. Other administrative issues (if any) –N

24. Training session of the Members: Nil

25. Communications with regulatory authorities/ management or others (if any): Nil

26. SOP change request: Nil

27. Subcommittee reports (if any) –Nil

29. Any other matter with permission of the chair:

Since there was no other matter, the meeting ended with a vote of thanks.

Copy to: All the Ethics Committee Members

Dr. Uma Kulkarni
Secretary
Yenepoya Ethics Committee-1
Dr. Uma Kulkarni
Secretary, YEC -1

Dr. Uma Kulkarni
Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka



Minutes of the 115 Meeting of Yenepoya Ethics Committee- 1

The 115 meeting of the Yenepoya Ethics Committee- 1 was held on 04 March 2021 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC

The following members were present:

S.No	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External	Demo 2
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External	Demo 2
3.	Fr. Teji Thomas (TT)	Priest	External	Demo 2
4.	Dr. Sayeegeetha (SH)	Layperson	External	Demo 2
5.	Mr. YM Khurshid (YK)	Layperson	External	Demo 2
6.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	Demo 2
7.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Demo 2
8.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Demo 2
9.	Ms. Viji Prasad (VP)	Nurse	Internal	Demo 2
10.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
11.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence:

12.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal
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Secretarial staff: Ms. Jainabu Mufeeda

Guest observers: None

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the **quorum requirements** were met and declared the meeting open.
3. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. The following members declared conflict of interest: **None**
4. The minutes of the 114th YEC-1 meeting which were circulated to the members by email, were read out and unanimously approved.

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Secretary

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Yenepoya Ethics Committee-1

Sl.No	Protocol No.	Name of the PI	Title of the study	Subject	YEC-1 decision
1	2019/157	Dr. Manjunath Shenoy	Itraconazole in the management of superficial fungal infections in India: A pilot study	Study status report	Ratified
2	2019/119	Dr. Prashanth RM	Multi centre cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotein (a) levels among patients with established cardiovascular disease	Study status report	Ratified

23. Other administrative issues (if any) –Nil

24. Training session of the Members: Nil

25. Communications with regulatory authorities/ management or others (if any)

26. SOP change request: Nil

27. Subcommittee reports (if any) –Nil

29. Any other matter with permission of the chair

Since there was no other matter, the meeting ended with a vote of thanks.



Dr. Uma Kulkarni
Member-Secretary, YEC -1

Secretary
Yenepoya Ethics Committee-1

To: Registrar, YU



Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



Core Minutes of the 113 Meeting of Yenepoya Ethics Committee- 1

The 113 meeting of the Yenepoya Ethics Committee- 1 was held on 07 January 2021 at 11.00 AM. In view of the COVID pandemic, the meeting was held on Google Meet. Dr. Uma Kulkarni, Member-Secretary conducted the meeting from the Secretariat, YEC-1, Academic Block, YMC. 3 members attended the meeting from the Demo Room 2 and the other members attended the meeting from their homes/hospitals/offices after joining the Google Meet link.

The following members were present:

S.N	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External	Online
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External	Online
3.	Fr. Teji Thomas (TT)	Priest	External	Online
4.	Dr. Sayeegeetha (SH)	Layperson	External	Demo 2
5.	Mr. YM Khurshid (YK)	Layperson	External	Online
6.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	Online
7.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Online
8.	Ms. Viji Prasad (VP)	Nurse	Internal	Online
9.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
10.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence: 2

11.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal
12.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal

Secretarial staff: Ms. Vindhya K

Guest observers: None

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the **quorum requirements** were met and declared the meeting open.


Secretary

Yenepoya Ethics Committee-1
Page 13

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore-575 018, Karnataka

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14	2015/180	Explorative study on the personal experience of workplace harassment among employees of selected institutions in Mangaluru	Ratified
15	2015/286	Comparative evaluation of anesthetic efficacy of two newer and conventional anesthetic solutions for emergency root canal treatment in mandibular teeth with symptomatic irreversible pulpitis - an in vivo study	Ratified
16	2016/301	A study of correlation between glycosylated haemoglobin (HbA1c) and fasting lipid profile (FLP) in diabetic foot wound healing	Ratified
17	2015/256	Assessment of short term electrocardiographic changes induced by three antibiotics viz. levofloxacin, ceftriaxone and amoxicillin/clavulanate	Ratified

Resolution:

21. Duplicate EC clearance issued for information: 0

Sl. No	Protocol No.	Name of the PI	Title of the study	Type of study	Date of issue	YEC-1 decision
1	Nil					

22. Post approval communications: Nil

23. Other administrative issues (if any) – Request by Ms. Sapna Kannan, Yenepoya Research Centre protocol no. 2017/071 titled “Point of care testing platform for early diagnosis of leptospirosis”. Request for change in EC validity date. Regarding ICMR fellowship –deferred.

24. Training session of the Members: Nil

25. Communications with regulatory authorities/ management or others (if any)

26. SOP change request: Nil

27. Subcommittee reports (if any) –Nil

29. Any other matter with permission of the chair

Since there was no other matter, the meeting ended with a vote of thanks.

Copy to: All the Ethics Committee Members


Dr. Uma Kulkarni

Secretary, YEC -I

Secretary

Yenepoya Ethics Committee-1


Secretary
Yenepoya Ethics Committee-1

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Page 11 of 11

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



Core minutes of the 112nd Meeting of Yenepoya Ethics Committee- 1

The 112nd meeting of the Yenepoya Ethics Committee- 1 was held on 03 December 2020 at 2.00 PM. In view of the COVID pandemic, the meeting was held on Google Meet. Dr. Uma Kulkarni, Member-Secretary conducted the meeting from the Secretariat, YEC-1, Academic Block, YMC. 2 members attended the meeting from the Demo Room 2 and the other members attended the meeting from their homes/hospitals/offices after joining the Google Meet link.

The following members were present:

S.No	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External	Online
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External	Online
3.	Fr. Teji Thomas (FT)	Priest	External	Online
4.	Mr. YM Khurshid (YK)	Layperson	External	Online
5.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	Online
6.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Online
7.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Online
8.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal	Online
9.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
10.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence: 2

11.	Dr. Sayeegeetha (SH)	Layperson	External
12.	Ms. Viji Prasad (VP)	Nurse	Internal

Guest observers: None

Secretarial staff: Ms. Vindhya

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the **quorum requirements** were met and declared the meeting open.

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Secretary

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Yenepoya
Mangalore-575 018, Karnataka

Page 1 of 10

Sl. No	Protocol No.	Name of the PI	Title of the study	Type of study	Date of issue	YEC-1 decision
1	Nil					

22. Post approval communications: Nil
 23. Other administrative issues (if any) – Nil
 24. Training session of the Members: Nil
 25. Communications with regulatory authorities/ management or others (if any)
 26. SOP change request: Nil
- Conflict of interest form** for validation and approval: Approved
 - Protocol submission application form for validation and approval:** Approved
 - Online meeting SOP for approval: Approved
 - E-Consent review form for validation and approval: Deferred

27. Subcommittee reports (if any) – Nil

28. Annual feedback and assessment- Some forms pending, hence the same will be completed during this month.

- Self assessment form
- Annual feedback

Resolution: All members are requested to fill out the forms and submit to YEC-1 secretariat on or before the next meeting

29. Rapid update - 3 planning of dates : Approved. Member-Secretary may finalize the dates


- CTRI registration procedure
- Conflict of interest
- GCP training for clinical trial investigators

30. Any other matter with permission of the chair:

- Calendar of meetings for 2021: Resolution: First Thursdays of every month to continue. Member-Secretary may draw out the actual dates, circulate and put up on the website and notice board
- Designation of Dr. Uma Kulkarni to attend FERCAP conference on behalf of YEC-1 in response to the email from FERCAP stating that the registration fee of Rs. 7200 would be waived off for one member of FERCAP member ECs to attend the conference starting 7 Dec 2020. The same was approved.

Since there was no other matter, the meeting ended with a vote of thanks.

Copy to: All the Ethics Committee Members


 Dr. Uma Kulkarni
 Secretary, YEC -1

Secretary
 Yenepoya Ethics Committee-1

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Dr. Gangadhar Page 10 of 10
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Deralakatte
 Mangalore- 575 019, Karnataka


 Secretary
 Yenepoya Ethics Committee-1



Core minutes of the 111th Meeting of Yenepoya Ethics Committee- 1

The 111th meeting of the Yenepoya Ethics Committee- 1 was held on 05 November 2020 at 11.00 AM. In view of the COVID pandemic, the meeting was held on Google Meet. Dr. Uma Kulkarni, Member-Secretary conducted the meeting from the Secretariat, YEC-1, Academic Block, YMC. 2 members attended the meeting from the Demo Room 2 and the other members attended the meeting from their homes/hospitals/offices after joining the Google Meet link.

The following members were present on the Google Meet/in the Demo Room 2 during the meeting

S.No	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External	Online
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External	Online
3.	Dr. Sayeegeetha (SH)	Layperson	External	Online
4.	Fr. Teji Thomas (FT)	Priest	External	Online
5.	Mr. YM Khurshid (YK)	Layperson	External	Online
6.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	Online
7.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Online
8.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Online
9.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal	Online
10.	Ms. Viji Prasad (VP)	Nurse	Internal	Online
11.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
12.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence: None

Guest observers: None

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.


 Secretary

Yenepoya Ethics Committee-1

ATTESTED


Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Deralakatte
 Mangalore-575 018, Karnataka

20. List of protocol documents for shredding: Nil

21. Duplicate EC clearance issued for information: 0

Sl. No	Protocol No.	Name of the PI	Title of the study	Type of study	Date of issue	YEC-1 decision
1	Nil					

22. Post approval communications: Nil

23. Other administrative issues (if any) – Nil

24. Training session of the Members: Nil

25. Communications with regulatory authorities/ management or others (if any)

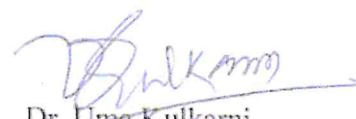
26. SOP change request: Nil

27. Subcommittee reports (if any) – Nil

28. Any other matter with permission of the chair

- Dr. Uma Kulkarni requested the Chairperson and the EC members to approve the scientific paper titled 'A case of neglect of conflict of Interest: An ethics committee experience' authored by Dr. Uma Kulkarni and Dr. Ravi Vaswani. The paper is about the detection of an undisclosed conflict of interest by a researcher identified during routine site monitoring. Anonymity of the department researchers and the protocol have been maintained in the paper. The paper will be presented as an e-poster at Virtual workshop: Advancing Research Ethics in Asia and the Pacific (ARRETI) on 18 and 19 November 2020 (Abstract and E-poster is attached).
- Dr. Uma Kulkarni requested the Chairperson and the EC members to approve the scientific paper titled 'Challenges in review of E-consent in COVID research' authored by Dr. Uma Kulkarni, Dr. Vina Vaswani and Dr. Ravi Vaswani. The paper is about the challenges identified during the review of e-consent and does not specifically involve any single protocol but is a general commentary. There is no reference to any protocol or researcher or department. The paper will be presented as an oral presentation at FERCAP on 07 December 2020 (Abstract is attached).

Copy to: All the Ethics Committee Members



Dr. Uma Kulkarni
Secretary, YEC -1

Secretary

Yenepoya Ethics Committee-1



Secretary

Yenepoya Ethics Committee-1

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Page 9 of 9
Dr. Gangabai Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



Core minutes of the 110th Meeting of Yenepoya Ethics Committee- 1


The 110th meeting of the Yenepoya Ethics Committee- 1 was held on 01 October 2020 from 2.00 PM to 3 PM. In view of the COVID pandemic, the meeting was held on Google Meet. Dr. Uma Kulkarni, Member-Secretary conducted the meeting from the Forensic Demo Room-2, Academic Block, YMC. 2 members attended the meeting from the Demo Room 2 and the other members attended the meeting from their homes/hospitals/offices after joining the Google Meet link.

The following members were present on the Google Meet/in the Demo Room 2 during the meeting

S.N	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External	Online
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External	Online
3.	Dr. Sayeegeetha (SH)	Layperson	External	Online
4.	Fr. Teji Thomas (FT)	Priest	External	Online
5.	Mr. YM Khurshid (YK)	Layperson	External	Online
6.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	Online
7.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Online
8.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Online
9.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal	Online
10.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
11.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

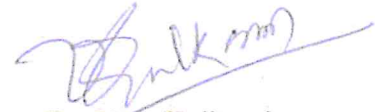
Leave of absence: 1


Secretary
Yenepoya Ethics Committee-1

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Registrar
Yenepoya (Deemed to be University)
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Page 1 of 9

- DCGI approval
- Report on the EC training of KAHER, Belgaum on 26 Sept 2020

Copy to: All the Ethics Committee Members



Dr. Uma Kulkarni
Secretary, YEC -1

Secretary
Yenepoya Ethics Committee-1

SECRETARY



Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Devalakatte
Mangalore-575 018, Karnataka

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Core minutes of the 109th Meeting of Yenepoya Ethics Committee- 1

The 109th meeting of the Yenepoya Ethics Committee- 1 was held on 03 September 2020 from 11 AM to 1 PM. In view of the COVID pandemic, the meeting was held on Google Meet. Dr. Uma Kulkarni, Member-Secretary conducted the meeting from the Forensic Demo Room-2, Academic Block, YMC. 4 members attended the meeting from the Demo Room 2 and the other members attended the meeting from their homes/hospitals/offices after joining the Google Meet link.

The following members were present on the Google Meet/in the Demo Room 2 during the meeting

S.No	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External	Online
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External	Online
3.	Dr. Sayeegeetha (SH)	Layperson	External	Online
4.	Fr. Teji Thomas (FT)	Priest	External	Online
5.	Mr. YM Khurshid (YK)	Layperson	External	Online
6.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	Online
7.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Demo 2
8.	Ms. Viji Prasad (VP)	Nurse	Internal	Demo 2
9.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
10.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence: None

11.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal
12.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal

Guest observers: None

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.


Secretary

Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 007, Karnataka
Page 1 of 7

						exclusion criteria 4. To ensure mechanisms for follow up visits to avoid protocol deviations	
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18. Serious adverse events/other reports (N=0)

19. Protocol Deviations / Violations – for ratification (n=0)

20. List of protocol documents for shredding: Nil

21. Duplicate EC clearance issued for information: 0

Sl.No	Protocol No.	Name of the PI	Title of the study	Type of study	Date of issue	YEC-1 decision
1	Nil					

22. Post approval communications: Nil

23. Other administrative issues (if any) – Nil

24. Training session of the Members: Nil

25. Communications with regulatory authorities/ management or others (if any)

26. SOP change request: As per DCGI request changed SOP02/v3

27. Subcommittee reports (if any) – Nil

28. Any other matter:

- DCGI re-registration details sent - Noted
- The members placed on record their appreciation of the efforts of Dr. Uma Kulkarni, the Member-Secretary to successfully acquire registration with the Department of Health Research, Government of India for the purpose of review of non-sponsored (academic) clinical trials.

Copy to: All the Ethics Committee Members



Dr. Uma Kulkarni
Secretary, YEC -1
Secretary

Yenepoya Ethics Committee-1



Secretary
Yenepoya Ethics Committee-1

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Page 7 of 7
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



Core minutes of the 108th Meeting of Yenepoya Ethics Committee- 1

The 108th meeting of the Yenepoya Ethics Committee- 1 was held on 06 August 2020 from 11 AM to 1 PM. In view of the COVID pandemic, the meeting was held on Google Meet. Dr. Uma Kulkarni, Member-Secretary conducted the meeting from the Forensic Demo Room-2, Academic Block, YMC. 3 members attended the meeting from the Demo Room 2 and the other members attended the meeting from their homes/hospitals/offices after joining the Google Meet link.

The following members were present on the Google Meet/Demo Room 2 during the meeting

S.N	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External	Online
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External	Online
3.	Dr. Sayeegeetha (SH)	Layperson	External	Online
4.	Fr. Teji Thomas (FT)	Priest	External	Online
5.	Mr. YM Khurshid (YK)	Layperson	External	Online
6.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	Online
7.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Online
8.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Online
9.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal	Online
10.	Ms. Viji Prasad (VP)	Nurse	Internal	Demo 2
11.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
12.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence: None

Guest observers: None

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.


Secretary

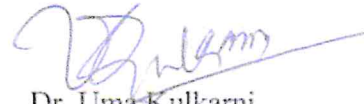
Yenepoya Ethics Committee-1


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatta,
Mangalore-575 011, Karnataka

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		Hussain	undergoing surgery under spinal anaesthesia		on time and decided to chose a new study
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Copy to: All the Ethics Committee Members



Dr. Uma Kulkarni
Secretary, YEC -1

Secretary

Yenepoya Ethics Committee-1

YEC-108/2020



Secretary

Yenepoya Ethics Committee-1

ATTESTED



Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Orakatte
Mangalore-575 018, Karnataka

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Core minutes of the 107th Meeting of Yenepoya Ethics Committee- 1

The 107th meeting of the Yenepoya Ethics Committee- 1 was held on 02 July 2020 from 11 AM to 1 PM. In view of the COVID pandemic, the meeting was held on Google Meet. Dr. Uma Kulkarni, Member-Secretary conducted the meeting from the Forensic Demo Room-2, Academic Block, YMC. 5 members attended the meeting from the Demo Room 2 and the other members attended the meeting from their homes/hospitals/offices after joining the Google Meet link.

The following members were present on the Google Meet/Demo Room 2 during the meeting

S.No	Name	Designation in YEC-1	Affiliation	Attendance
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External	Online
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External	Online
3.	Dr. Sayeegeetha (SH)	Layperson	External	Online
4.	Fr. Teji Thomas (FT)	Priest	External	Online
5.	Mr. YM Khurshid (YK)	Layperson	External	Online
6.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External	Online
7.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal	Demo 2
8.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal	Demo 2
9.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal	Demo 2
10.	Ms. Viji Prasad (VP)	Nurse	Internal	Online
11.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal	Demo 2
12.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal	Demo 2

Leave of absence: None

Guest observers: None

Proceedings of the meeting:

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.
3. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. The following members declared conflict of interest: **None**
4. The Chairperson called upon the Member-Secretary to start the business on the agenda. The minutes of the 106th YEC-1 meetings which were circulated to the members by email, were displayed on-screen and on the Google Meet screen, read out and unanimously approved.
5. **Initial Full Review protocols (N=1)**

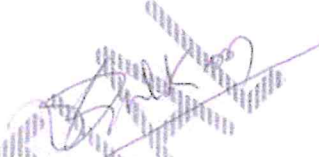
1.	Protocol number:	YEC-1/2020/029
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Secretary

		suppurativa (SUNRISE)				
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- 23. Other administrative issues (if any) – Nil
- 24. Training session of the Members: Nil
- 25. Communications with regulatory authorities/ management or others (if any)
- 26. SOP change request: Nil
- 27. Subcommittee reports (if any) –Nil
- 28. Any other matter:
 - Minutes of the meeting with Koraga community leaders (for information): Noted

Copy to: All the Ethics Committee Members


Dr. Uma Kulkarni
Secretary, YEC -I

Secretary
Yenepoya Ethics Committee-1

YEC-1 CONFIDENTIAL


Secretary

Yenepoya Ethics Committee-1

ATTESTED


Dr. Gangadhara Somayaji K.S.
Page 17 of 17
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



Core minutes of the 106th Meeting of Yenepoya Ethics Committee- 1

The 106th meeting of the Yenepoya Ethics Committee- 1 was held on 04 June 2020 from 11 AM to 1 PM. Due to the extension of the lockdown announced in view of the COVID pandemic, and after seeking the approval of all the members, the meeting was held on Google Meet. Dr. Uma Kulkarni, Member-Secretary conducted the meeting from the Forensic Demo Room-2, Academic Block, YMC. Two other members Dr. Ravi Vaswani, Joint Secretary, YEC-1 and Dr. Sachidananda Adiga, Basic Scientist, were also present. All the other members attended the meeting from their homes/hospitals/offices.

The following members were present on the Google Meet/Demo Room 2 during the meeting

S. No	Name	Designation in YEC-1	Affiliation
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External
3.	Dr. Sayeegeetha (SH)	Layperson	External
4.	Fr. Teji Thomas (FT)	Priest	External
5.	Mr. YM Khurshid (YK)	Layperson	External
6.	Dr. Sachidananda Adiga (SA)	Basic Scientist	External
7.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal
8.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal
9.	Ms. Viji Prasad (VP)	Nurse	Internal
10.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal
11.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal

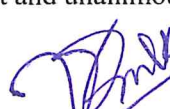
Leave of absence:

1	Dr. Laxminarayan Sonde (LS)	Clinician	Internal
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Guest observers: None

Proceedings of the meeting:

1. The meeting was conducted on Google Meet with each member signing in. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.
3. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. The following members declared conflict of interest: **None**
4. The Chairperson called upon the Member-Secretary to start the business on the agenda. The minutes of the 105th YEC-1 meetings which were circulated to the members by email were displayed on-screen, read out and unanimously approved.


Secretary

Yenepoya Ethics Committee-1
Page 27

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Dr. Ganesh Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
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Mangalore - 575 018, Karnataka
Page 1 of 10

			Impaired Renal Function		
2	2019/119	Dr. Prashanth RM	Multi-centre cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotein(a) levels among patients with established cardiovascular disease	Clinical Trial	Coronavirus (COVID-19) outbreak: Novartis Clinical Trial Continuity for Trial # CTQJ230A12001 (Heritage) letter from Sponsor.

23. Other administrative issues (if any) – Nil

24. Training session of the Members: Rapid Update-2 report

25. Communications with regulatory authorities/ management or others (if any)

26. SOP change request

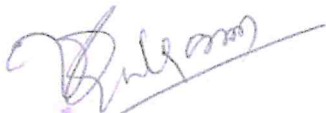
- Change of extension request form: The copy will be circulated among all the members for approval of the changes
- SOP 8A/v3.1 for approval: online meeting: The copy will be circulated among all the members for approval of the changes. Voting will be done for some of the decisions
- SOP 7A/v3 minor modification (As suggested by Dr. Vikram Shetty): The copy will be circulated among all the members for approval of the changes
- SOP 18- Soft copy of EC clearance to be maintained: The copy will be circulated among all the members for approval of the changes
- Initial application form version 3.1 effective date 04-06-2020: The copy will be circulated among all the members for approval of the changes

27. Subcommittee reports (if any) –

28. Any other matter:

Copy to: All the Ethics Committee Members

Registrar YU (for information)



Dr. Uma Kulkarni

Yenepoya Ethics Committee-1
Secretary, YEC -1

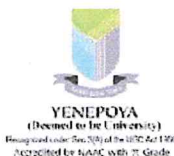

Secretary

Yenepoya Ethics Committee-1

ATTESTED


Dr. Gangadhara Somayaji K.S.
Page 10 of 10
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

105 YEC-1 Meeting Core Minutes



Core minutes of the 105th Meeting of Yenepoya Ethics Committee- 1

The 105th meeting of the Yenepoya Ethics Committee- 1 was held on 07 May 2020 from 11 AM to 1 PM. Due to the extension of the lockdown announced in view of the COVID pandemic, and after seeking the approval of all the members, the meeting was held on Google Meet. The Member-Secretary conducted the meeting from the Forensic Demo Room-1, Academic Block, YMC, whereas all the other members attended the meeting from their homes/hospitals.

The following members were present on the Google Meet during the meeting

S. No	Name	Designation in YEC-1	Affiliation
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External
3.	Dr. Sayeegeetha(SH)	Layperson	External
4.	Fr. Teji Thomas (FT)	Priest	External
5.	Mr. YM Khurshid (YK)	Layperson	External
6.	Dr. Sachidananda Adiga (SA)	Pharmacologist	External
7.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal
8.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal
9.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal
10.	Ms. Viji Prasad (VP)	Nurse	Internal
11.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal
12.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal

Leave of absence:

The following members were granted leave of absence: None.


Since Mr. Saduddin Salihi was unable to vote on Google form for technical problems, his vote was communicated to the Member-Secretary who registered his vote on the Google forms on his behalf

Guest observers: None

Proceedings of the meeting:

1. The meeting was conducted on Google Meet with each member signing in. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.
3. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. The following members declared conflict of interest:


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

105 YEC-1 Meeting Core Minutes

in order to expedite the process of approval and also for conducting online meetings for the same.


This permission being a one-time measure: All members informed about the same

25. SOP change request

- a. SOP 18- Soft copy of EC clearance to be maintained: Agreed by all members
- b. SOP for online meeting: It was unanimously resolved to constitute an SOP sub-committee to prepare and review the SOP for online meetings of YEC-1 and get it approved by the Chairperson and the University at the earliest.

26. Subcommittee reports(if any) -- NIL

27. Any other matter: Since there was no other matter, the meeting ended with a vote of thanks.


Secretary
Yenepoya Ethics Committee-1

Dr. Uma Kulkarni

Secretary, YEC - 1

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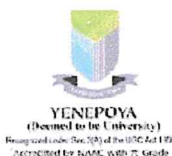
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Secretary
Yenepoya Ethics Committee-1

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Page 12 of 12

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

104 Emergency YEC-1 Core Meeting Minutes



Core minutes of the 104thEmergency E-Meeting of Yenepoya Ethics Committee- 1

The 104th emergency meeting of the Yenepoya Ethics Committee- 1 was held on 19 April 2020. Due to the lockdown announced in view of the COVID pandemic, the meeting was held on Google Hangouts.

The following members were present


S.No	Name	Designation in YEC-1	Affiliation
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External
3.	Dr. Sayeegeetha (SH)	Layperson	External
4.	Fr. Teji Thomas (FT)	Priest	External
5.	Mr. YM Khurshid (YK)	Layperson	External
6.	Dr. Sachidananda Adiga (SA)	Pharmacologist	External
7.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal
8.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal
9.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal
10.	Ms. Viji Prasad (VP)	Nurse	Internal
11.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal
12.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal

The following members were granted leave of absence: None

Proceedings of the meeting:

1. The meeting was conducted on Google Hangout
2. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
3. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.
4. The Chairperson asked the members to declare a conflict of interest - if any - for the protocol tabled in the agenda for the meeting. None of the members had a conflict of interest for the protocol.
5. The Chairperson called upon the Member-Secretary to start the business on the agenda.



Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Page 1 of 3

104 Emergency YEC-1 Core Meeting Minutes


11. Any other matter: Since there was no other matter, meeting ended with a vote of thanks.


Secretary
Yenepoya Ethics Committee-1
Dr. Uma Kulkarni
Member-Secretary, YEC - 1
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SECRET


Secretary
Yenepoya Ethics Committee-1

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Page 3 of 3
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

103 Emergency YEC-1 Core Meeting Minutes



Core minutes of the 103rd Meeting of Yenepoya Ethics Committee- 1

The 103rd Emergency meeting of the Yenepoya Ethics Committee- 1 was held on 17 April 2020. Due to the Lockdown announced in view of the COVID pandemic, the meeting was held on google hangouts. The member-secretary conducted the meeting from the Forensic Demo Room-1, Academic Block, YMC, whereas all the other members attended the meeting from their homes/hospitals.

The following members were present on the google hangout during the meeting

S.No	Name	Designation in YEC-1	Affiliation
1.	Dr.Vikram Shetty (VS)	Chairperson/Clinician	External
2.	Dr. Sayeegeetha(SH)	Layperson	External
3.	Fr. Teji Thomas (FT)	Priest	External
4.	Mr. YM Khurshid (YK)	Layperson	External
5.	Dr.Sachidananda Adiga (SA)	Pharmacologist	External
6.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal
7.	Dr. LaxminarayanSonde (LS)	Clinician	Internal
8.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal
9.	Ms. Viji Prasad (VP)	Nurse	Internal
10.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal
11.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal

The following members were granted leave of absence:

1.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External
----	--------------------------	-----------------------------	----------

Proceedings of the meeting:

1. The meeting was conducted on google hangout with each member signing into google hangout.


Secretary
Yenepoya Ethics Committee-1

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Dr.Gangadhara Somayaji R.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

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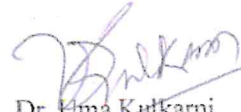
103 Emergency YEC-1 Core Meeting Minutes

11. Any other matter:

Since there was no other matter, the meeting ended with a vote of thanks.

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Dr. Uma Kulkarni
Secretary, YEC - 1

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Yenepoya Ethics Committee-1

YEC-1 CONFIDENTIAL



Secretary
Yenepoya Ethics Committee-1

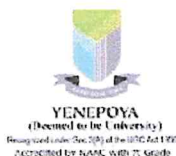
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Dr. Gangadhara Somayaji K.S.
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Mangalore-575 018, Karnataka

102 YEC-1 Meeting Core Minutes



Core minutes of the 102nd Meeting of Yenepoya Ethics Committee- 1

The 102nd meeting of the Yenepoya Ethics Committee- 1 was held on 09 April 2020 at 11 am. Due to the lockdown announced in view of the COVID pandemic, and after seeking the approval of all the members, the meeting was held on Google hangouts. The Member-Secretary conducted the meeting from the Forensic Demo Room-1, Academic Block, YMC, whereas all the other members attended the meeting from their homes/hospitals.

The following members were present on the Google hangout during the meeting

S.No	Name	Designation in YEC-1	Affiliation
1.	Dr. Vikram Shetty (VS)	Chairperson/Clinician	External
2.	Mr. Saduddin Salihi (SS)	Co-Chairperson/Legal Expert	External
3.	Dr. Sayeegetha (SH)	Layperson	External
4.	Fr. Teji Thomas (FT)	Priest	External
5.	Mr. YM Khurshid (YK)	Layperson	External
6.	Dr. Sachidananda Adiga (SA)	Pharmacologist	External
7.	Dr. Nagapathi Bhat (NB)	Pharmacologist	Internal
8.	Dr. Laxminarayan Sonde (LS)	Clinician	Internal
9.	Dr. Mohammed Guthigar (MG)	Social Scientist	Internal
10.	Ms. Viji Prasad (VP)	Nurse	Internal
11.	Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	Internal
12.	Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	Internal

Leave of absence:

The following members were granted leave of absence: None.

Since Mr. Saduddin Salihi was unable to join the meeting on Google Hangout, he communicated with YEC-1 through telephone and submitted the Google form responses.

Guest observers: None

Proceedings of the meeting:

1. The meeting was conducted on Google hangout with each member signing into Google hangout.
2. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
3. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.
4. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. The following members declared conflict of interest:

S. No	Name of the EC member	Agenda No.	Agenda details	Protocol number for which CoI was declared
1.	Dr. Mohammed Guthigar	7 (1)	Full review protocol	2020/013
2.	Dr. Ravi Vaswani	8 (3)	Ratification of expedited review approval	2020/015
3.	Dr. Uma Kulkarni	8 (3)	Ratification of expedited review approval	2020/015
4.	Dr. Uma Kulkarni	11 (18)	Ratification of approval of study competition report	2019/117

The Chairperson requested the members who declared a conflict of interest to sign out of the Google Hangout meeting when the concerned protocol came up for discussion and the same was followed.

Secretary

Yenepoya Ethics Committee-1

Dr. Gangadhara Somayaji K.S.
Registrar Page 1 of 11
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Core 101 YEC-1 Meeting Minutes

Since there was no other matter, the meeting ended with a vote of thanks.



Dr. Uma Kulkarni
Secretary, YEC - 1

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Yenepoya Ethics Committee-1


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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Core 101 YEC-1 Meeting Minutes

Since there was no other matter, the meeting ended with a vote of thanks.


Dr. Uma Kulkarni
Secretary, YEC - 1

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Secretary
Yenepoya Ethics Committee-1

Core 100th YEC-1 Meeting Minutes



Core minutes of the 100th Meeting of Yenepoya Ethics Committee- 1

The 100th meeting of the Yenepoya Ethics Committee- 1 was held on 06 February 2020 at 10.30 AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

- | | | |
|--------------------------------|-----------------------------|------------|
| 1. Dr. Vikram Shetty (VS) | Chairperson/Clinician | (External) |
| 2. Mr. Saduddin Salihi (SS) | Co-Chairperson/Legal Expert | (External) |
| 3. Dr. Sayeegeetha (SH) | Layperson | (External) |
| 4. Dr. Sachidananda Adiga (SA) | Pharmacologist | (External) |
| 5. Dr. Nagapathi Bhat (NB) | Pharmacologist | (Internal) |
| 6. Dr. Laxminarayan Sonde (LS) | Clinician | (Internal) |
| 7. Dr. Mohammed Guthigar (MG) | Social Scientist | (Internal) |
| 8. Ms. Viji Prasad (VP) | Nurse | (Internal) |
| 9. Dr. Uma Kulkarni (UK) | Member-Secretary/Clinician | (Internal) |

The following members were granted leave of absence:


- | | | |
|--------------------------|---------------------------|------------|
| 1. Fr. Teji Thomas (FT) | Priest | (External) |
| 2. Dr. Ravi Vaswani (RV) | Joint Secretary/Clinician | (Internal) |
| 3. Mr. YM Khurshid (YK) | Layperson | (External) |

Guest observers: 15 students of the Masters in Research Ethics program attended the meeting for educational purpose with prior approval by the Chairperson of YEC-1 and after signing confidentiality agreement.

1. Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.
3. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. None of the members had a conflict of interest for any of the protocols.
4. The Chairperson called upon the Member-Secretary to start the business on the agenda.
5. The minutes of the 99th meeting which were circulated to the members by email, were displayed on-screen, read out and unanimously approved.


Secretary

Yenepoya Ethics Committee-1


Dr. Gangadhara Somayaji K.S.
Registrar
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Mangalore-575 018, Karnataka

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Core 100th YEC-1 Meeting Minutes

3	(2019/072)	Centre for Ethics	To assess the extent to which homeopathy researchers, postgraduate students and research guides in West Bengal are aware of the requirements of consent, addressing privacy and confidentiality and needs providing for protection of specific vulnerabilities among research participants	Dissertation	27-1-2020
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17. List of protocol documents for shredding: Nil

18. Other administrative issues (if any): Nil

19. Training session: Nil

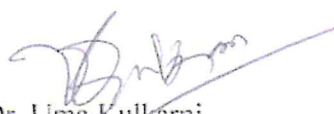
20. Communications with regulatory authorities/ management or others (if any): Nil

21. Subcommittee reports (if any): Nil

22. Any other matter with the permission of the chair:

1. Notification of Investigators undertaking for the reason of change in the central lab at Singapore (protocol no. 2019/051)
2. Notification of site initiation visit – protocol no. 2019/157
3. Notification of final signed CTA – 2019/157
4. Notification of Itraconazole SUSAR GAP PACK SDA10729073

Since there was no other matter, the meeting ended with a vote of thanks.


Dr. Uma Kulkarni
Secretary, YEC – 1

Secretary
Yenepoya Ethics Committee-1

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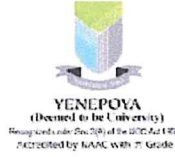

Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayajulu
Registrar
Yenepoya (Deemed to be University)
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Mangalore-575 018, Karnataka

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99th YEC-1 Minutes of the Meeting



Core minutes of the 99th Meeting of Yenepoya Ethics Committee- 1

The 99th meeting of the Yenepoya Ethics Committee- 1 was held on 02 January 2020 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

- | | | |
|-------------------------------|-----------------------------|------------|
| 1. Dr. Vikram Shetty (VS) | Chairperson/Clinician | (External) |
| 2. Mr. SaduddinSalihi (SS) | Co-Chairperson/Legal Expert | (External) |
| 3. Dr. Sayeegeetha(SH) | Layperson | (External) |
| 4. Mr. YM Khurshid (YK) | Layperson | (External) |
| 5. Dr.Nagapathi Bhat (NB) | Pharmacologist | (Internal) |
| 6. Dr. LaxminarayanSonde (LS) | Clinician | (Internal) |
| 7. Ms. Viji Prasad (VP) | Nurse | (Internal) |
| 8. Dr. Ravi Vaswani (RV) | Joint Secretary/Clinician | (Internal) |
| 9. Dr. Uma Kulkarni (UK) | Member-Secretary/Clinician | (Internal) |

The following members were granted leave of absence:

- | | | |
|--------------------------------|------------------|------------|
| 1. Dr. Sachidananda Adiga (SA) | Pharmacologist | (External) |
| 2. Fr. Teji Thomas (FT) | Priest | (External) |
| 3. Dr. Mohammed Guthigar (MG) | Social Scientist | (Internal) |

Guest observers: Seven students of the Masters in Research Ethics attended the meeting for educational purpose with their request being approved beforehand by the Chairperson of YEC-1 and after signing confidentiality agreement.

1. Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that a quorum was present and declared the meeting open.

Secretary

Yenepoya Ethics Committee-1

Dr.Gangadhara S...Page 1 of 6
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99th YEC-1 Minutes of the Meeting

2	(2019/212)	Paediatrics	Bacteriological profile and antimicrobial susceptibility pattern of clinical isolates from children in a tertiary care hospital, Mangalore: A retrospective review of laboratory reports – Increase in Sample size	Funded	19-12-19
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16. List of protocol documents for shredding: Nil

17. Other administrative issues (if any): Nil

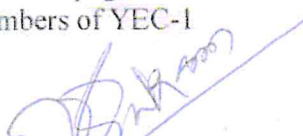
18. Training session: Site monitoring and responsibilities of the monitors

19. Communications with regulatory authorities/ management or others (if any): Nil

20. Subcommittee reports (if any): Nil

21. Any other matter with the permission of the chair:

1. NABH accreditation: The YEC-1 NABH accreditation certificate which was received in the month of December 2019 with effect from 08 December 2019 was presented to the YEC-1 members with appreciation of efforts and hard work of each and every member of YEC-1. A copy of the certificate was forward to the Vice-Chancellor, Yenepoya deemed to be University along with the FERCAP recognition certificate. The certificates were uploaded on the YEC-1 website and the same was informed to the members.
2. DHR registration: The DHR registration of YEC-1 is in process and the same was informed to the members
3. DCGI re-registration of YEC-1 through SUGAM portal: The DCGI re-registration of YEC-1 through SUGAM portal was completed and the same was informed to the members and uploaded on the YEC-1 webpage.
4. Annual Feedback forms were collected from the members of YEC-1


Dr. Uma Kulkarni

Secretary, YEC – 1
Secretary

Yenepoya Ethics Committee-1

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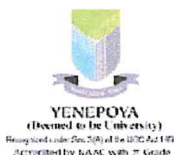
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Yenepoya Ethics Committee-1

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Mangalore-575 018, Karnataka
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98th YEC-1 core Minutes of the Meeting



Core Minutes of the 98th Meeting of Yenepoya Ethics Committee- 1

The 98th meeting of the Yenepoya Ethics Committee- 1 was held on 05 December 2019 at 10.00AM in the Forensic Demo Room-2, Academic Block, YMC.


The following members were present:

1. Dr. Vikram Shetty (VS)	Chairperson/Clinician	(External)
2. Mr. SaduddinSalihi (SS)	Co-Chairperson/Legal Expert	(External)
3. Dr. SachidanandaAdiga (SA)	Pharmacologist	(External)
4. Dr. Sayeegeetha(SH)	Layperson	(External)
5. Fr. Teji Thomas (FT)	Priest	(External)
6. Mr. YM Khurshid (YK)	Layperson	(External)
7. Dr.Nagapathi Bhat (NB)	Pharmacologist	(Internal)
8. Dr. LaxminarayanSonde (LS)	Clinician	(Internal)
9. Dr. Mohammed Guthigar(MG)	Social Scientist	(Internal)
10. Ms. Viji Prasad (VP)	Nurse	(Internal)
11. Dr. Ravi Vaswani (RV)	Joint Secretary/Clinician	(Internal)
12. Dr. Uma Kulkarni (UK)	Member-Secretary/Clinician	(Internal)

The following members were granted leave of absence: NIL

1. Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that a quorum was present and declared the meeting open.
3. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. None of the members had a conflict of interest for any of the protocols.
4. The Chairperson called upon the Member-Secretary to start the business on the agenda.


Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhar S. S.
Registrar
Yenepoya (Deemed to be University)
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Mangalore-575 018, Karnataka
Page 1 of 11

98th YEC-1 core Minutes of the Meeting

6	(2019/078)	Centre for Ethics	Perspective about spare embryos among couples who sought IVF: An exploratory study – Change in Objectives	Dissertation	13-11-19
7	(2017/268)	General Medicine	Palliative care needs of geriatric patients in the medical wards of the tertiary care hospital – Change in sample size	Dissertation	13-11-19
8	(2018/163)	Ophthalmology	Factors affecting the follow up of pre term babies screened for ROP – Protocol, Informed consent	Short study	21-11-19

16. List of protocol documents for shredding: Nil

17. Other administrative issues (if any): Nil

18. Training session: Site monitoring and responsibilities of the monitors - Deferred

19. Communications with regulatory authorities/ management or others (if any): Nil

20. Subcommittee reports(if any): Nil

21. Any other matter with the permission of the chair:

FERCAP conference and recognition certificate: The effort of all the YEC-1 members was appreciated. YEC-1 met with the Vice Chancellor and Registrar and informed them of the receipt of the award. A group photo was taken with the University authorities.

EC Software: Template is being prepared with the help of IT department and is being followed up



Dr. Uma Kulkarni

Secretary, YEC – 1

Secretary

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Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar

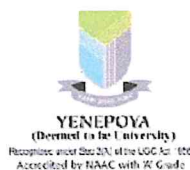
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Secretary

Yenepoya Ethics Committee-1

Core 97th YEC-1 Minutes of the Meeting



Core Minutes of the 97th Meeting of Yenepoya Ethics Committee- 1

The 97th meeting of the Yenepoya Ethics Committee- 1 was held on 07 November 2019 at 11.00AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

- | | |
|--------------------------------|--|
| 1. Dr. Vikram Shetty (VS) | Chairperson/Clinician (External) |
| 2. Mr. Saduddin Salihi (SS) | Co-Chairperson/Legal Expert (External) |
| 3. Dr. Sachidananda Adiga (SA) | Pharmacologist (External) |
| 4. Dr. Sayeegeetha (SH) | Layperson (External) |
| 5. Mr. YM Khurshid (YK) | Layperson (External) |
| 6. Dr. Nagapathi Bhat (NB) | Pharmacologist (Internal) |
| 7. Dr. Laxminarayan Sonde (LS) | Clinician (Internal) |
| 8. Dr. Mohammed Guthigar (MG) | Social Scientist (Internal) |
| 9. Ms. Viji Prasad (VP) | Nurse (Internal) |
| 10. Dr. Ravi Vaswani (RV) | Joint Secretary/Clinician (Internal) |

The following members were granted leave of absence:

- | | |
|--------------------------|---------------------------------------|
| 1. Dr. Uma Kulkarni (UK) | Member-Secretary/Clinician (Internal) |
| 2. Fr. Teji Thomas (FT) | Priest (External) |

1. Since the Member-Secretary was not present, the Joint Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that a quorum was present and declared the meeting open.
3. The Chairperson asked the members to declare a conflict of interest – if any – for any protocol tabled in the agenda for the meeting. None of the members had a conflict of interest for any of the protocols.

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
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Secretary
Yenepoya Ethics Committee-1

Core 97th YEC-1 Minutes of the Meeting

16. List of protocol documents for shredding: Nil
17. Other administrative issues (if any): Nil
18. Training session: A training session on "Risk Benefit analysis" was carried out by Dr. Ravi Vaswani
19. Communications with regulatory authorities/ management or others (if any): Nil
20. Subcommittee reports (if any): Nil
21. Self-assessment: YEC-1 members were informed that the self-assessment and feedback forms are to be submitted on or before 05 December 2019. Soft copies of the same will be emailed to all members.
22. Any other matter with the permission of the chair:
 - a. YEC-1 members were informed that we have received official communication from FERCAP that YEC-1 has been awarded continued recognition for a period of five years. Dr. Uma Kulkarni and Dr. Ravi Vaswani will be attending the conference and will present papers on the functioning of EC and also receive the award on behalf of YEC-1.


Dr. Ravi Vaswani


Jt-Secretary, YEC - 1

Secretary
Yenepoya Ethics Committee-1

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Yenepoya Ethics Committee-1

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Core 96th YEC-1 Minutes of the Meeting



Core minutes of the 96th Meeting of Yenepoya Ethics Committee- 1

The 96th meeting of the Yenepoya Ethics Committee- 1 was held on 03 October 2019 at 11.00AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

1.	Dr. Vikram Shetty (VS)	Chairperson	(External)
2.	Mr. Saduddin Salihi (SS)	Legal expert	(External)
3.	Dr. Sachidananda Adiga (SA)	Pharmacologist	(External)
4.	Fr. Teji Thomas (FT)	Priest	(External)
5.	Dr. Sayeegeetha (SH)	Layperson	(External)
6.	Dr. Mohd Guthigar	Social Scientist	(External)
7.	Dr. Nagapathi Bhat (NB)	Pharmacologist	(Internal)
8.	Dr. Ravi Vaswani (RV)	Clinician	(Internal)
9.	Dr. Laxminarayan Sonde (LS)	Clinician	(Internal)
10.	Ms. Viji Prasad (VP)	Nurse	(Internal)
11.	Dr. Uma Kulkarni (UK)	Member-Secretary	(Internal)


The following member was granted leave of absence:

1.	Mr. YM Khurshid	Layperson	(External)
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1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that a quorum was present and declared the meeting open.
3. The Chairperson asked the members to declare a Conflict of Interest – if any – for any protocol tabled in the agenda for the meeting. None of the members had a conflict of interest for any of the protocols.
4. The Chairperson called upon the Member-Secretary to start the business on the agenda.


Secretary

Yenepoya Ethics Committee-1


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka


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Core 96th YEC-1 Minutes of the Meeting

nominate Dr. Ravi Vaswani, Clinician, Internal Member, Joint Secretary to assist the Member Secretary in the day-to-day functioning of YEC-1

Date: 03/October/2019

Place: Mangalore


Dr. Uma Kulkarni

Member Secretary, YEC-1

Yenepoya Ethics Committee-1

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Secretary
Yenepoya Ethics Committee-1

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Core 95th YEC- meeting minutes



Core Minutes of the 95th Meeting of Yenepoya Ethics Committee– 1

The 95th meeting of the Yenepoya Ethics Committee– 1 was held on 05 September 2019 at 1.30 PM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

1.	Dr. Vikram Shetty (VS)	Chairperson	(External)
2.	Mr. Saduddin Salihi (SS)	Legal expert	(External)
3.	Dr. Sachidananda Adiga (SA)	Pharmacologist	(External)
4.	Mr. YM. Khurshid (YM)	Layperson	(External)
5.	Fr. Teji Thomas (FT)	Priest	(External)
6.	Dr. Nagapathi Bhat (NB)	Pharmacologist	(Internal)
7.	Dr. Ravi Vaswani (RV)	Clinician	(Internal)
8.	Dr. Laxminarayan Sonde (LS)	Clinician	(Internal)
9.	Dr. Mohd Guthigar (MG)	Social Scientist	(Internal)
10.	Dr. Uma Kulkarni (UK)	Member-Secretary	(Internal)

The following members were granted leave of absence:

1.	Dr. Sayeegeetha (SH)	Layperson	(External)
2.	Ms. Viji Prasad (VP)	Nurse	(Internal)

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that a quorum was present and declared the meeting open.
3. The Chairperson asked the members to declare a Conflict of Interest – if any – for any protocol tabled in the agenda for the meeting. None of the members had a conflict of interest for any of the protocols.

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Secretary
Yenepoya Ethics Committee-1

Dr. Gangadhara Somayaji K.S.
Registrar
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Core 95th YEC- meeting minutes

Resolution: It was resolved to ratify the minutes of the SAE subcommittee meeting

18. SAE/Safety reports – (n=0)

19. Correspondence from regulatory authorities, university and other communications: (n=1)

Notification from registrar regarding work division of YEC-1 & YEC-2

Resolution: Noted the contents of the letter. Resolved to request the Member-Secretary to widely disseminate the structure to reinforce the message sent by the University.

20. Training Session: - New Drugs and Clinical Trials Rules 2019 – (5 Session) Dr. Ravi Vaswani. PowerPoint slides to be sent to all members

21. Any other matter with the permission of the chair:

- a. Date for one-day training program for YEC 1 and 2 members: It was unanimously resolved to keep Wednesday, 16th October 2019 for the one-day training workshop for YEC 1 and 2 members.

Date: 08 September 2019

Place: Mangalore


Dr. Uma Kulkarni

Member Secretary, YEC-1

Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka


Secretary
Yenepoya Ethics Committee-1



Core minutes of the 94th Meeting of Yenepoya Ethics Committee– 1

The 94th meeting of the Yenepoya Ethics Committee– 1 was held on 01 August 2019 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

1. Dr. Vikram Shetty (VS)	Chairperson	(External)
2. Mr. Saduddin Salihi (SS)	Legal expert	(External)
3. Dr. Sayeegeetha	Layperson	(External)
4. Dr. Sachidanand Adiga	Pharmacologist	(External)
5. Mr. Y. Khurshid	Layperson	(External)
6. Dr. Nagapathi Bhat (NB)	Pharmacologist	(Internal)
7. Dr. Ravi Vaswani (RV)	Clinician	(Internal)
8. Dr. Laxminarayan Sonde (LS)	Clinician	(Internal)
9. Dr. Uma Kulkarni (UK)	Member-Secretary	(Internal)

The following members were granted leave of absence:

1. Father Teji Thomas	Priest	(External)
2. Dr. Mohammed Guthigar (MG)	Social Scientist	(Internal)
3. Dr. Viji Prasad	Nurse	(Internal)

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum was present and declared the meeting open.
3. The Chairperson asked the members to declare Conflict of Interest – if any – for any protocol tabled in the agenda for the meeting. None of the members had conflict of interest for any of the protocols.
4. The Chairperson called upon the Member-Secretary to start the business on the agenda.

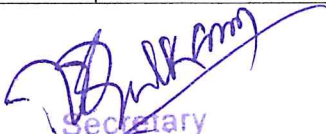
The following items as per the agenda were discussed:

5. The minutes of the 93rd YEC-1 meeting had been circulated to all the members after approval by the Chairperson and no objections/comments/corrections were received. The minutes were projected on the screen, read out in the meeting and approved.

6. Full review protocols (new): n = 2

SI No	Protocol No	Title of the study
1.	2019/172	Title: Biomarker potential of microRNAs in non small cell lung cancer Resolution: It was unanimously resolved to ask the PI to submit the protocol addressing all the recommendations of the YEC-1. The resubmission will be considered to Full review.

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Secretary
Yenepoya Ethics Committee-1
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
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Mangalore- 575 018, Karnataka

			farand the same was found to be in order. Resolution: To schedule site monitoring again after 2 months to ensure protocol adherence
--	--	--	--

17. SAE Subcommittee meetings – (n=1)

18. SAE/Safety reports – (n=0)

- Dear Investigators letter (Protocol no. 2018/084)

19. Correspondence from regulatory authorities, university and other communications: Nil

20. Any other matter for discussion – with permission of the chair.

- Reconstitution of SAE subcommittee for notification by the Registrar
 - Chairperson: Dr. Mohammed Guthigar
 - Secretary: Dr. Ravi Vaswani
 - Members: Dr. Nagapathi Bhat, Dr. Lakshminarayan Sonde
 - Ex-officio member: Dr. Uma Kulkarni
- Reconstitution of SOP subcommittee
 - Dr. Ravi Vaswani
 - Dr. Nagapathi Bhat,
 - Dr. Lakshminarayan Sonde
 - Dr. Uma Kulkarni
- Communicate with the IT regarding software development

21. Training Session: - New Drugs and Clinical Trials Rules 2019 – (4 Session) Dr. Ravi Vaswani.
PowerPoint slides to be sent to all members

22. Any other matter with the permission of the chair:

Since there was no other matter the meeting ended with a vote of thanks.

Date: 01 August 2019
Place: Mangalore


Dr. Uma Kulkarni
Member Secretary, YEC-1
Secretary

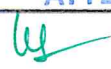
Yenepoya Ethics Committee-1

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Secretary
Yenepoya Ethics Committee-1


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



Core Minutes of the 93rd Meeting of Yenepoya Ethics Committee– 1

The 93rd meeting of the Yenepoya Ethics Committee– 1 was held on 04 July 2019 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

1. Dr. Vikram Shetty (VS)	Chairperson	(External)
2. Dr. Uma Kulkarni (UK)	Member-Secretary	(Internal)
3. Dr. Sayeegeetha (SH)	Layperson	(External)
4. Dr. Nagapathi Bhat (NB)	Pharmacologist	(Internal)
5. Dr. Ravi Vaswani (RV)	Clinician	(Internal)
6. Dr. Grrishma B (GB)	Basic Scientist	(Internal)
7. Dr. Lakshminarayan Sonde (LS)	Clinician	(Internal)
8. Dr. Vijayalaxmi Mogasale (VM)	Clinician	(Internal)
9. Ms. Viji Prasad (VP)	Nurse	(Internal)
10. Ms. Mudasir Baba Rashid (MBR)	Physiotherapy	(Internal)
11. Mr. Saduddin Salihi (SS)	Legal expert	(External)
12. Dr. Mohammed Guthigar (MG)	Social Scientist	(Internal)

The following members were granted leave of absence:


1. Dr. Kiran Kammar (KK)	Homeopath	(Internal)
2. Fr. Teji Thomas (TT)	Theologian	(External)
3. Mr. Moideen Khurshid (MK)	Risk assessor	(Internal)


Dr. Sachidananda Adiga was welcomed as observer for this meeting in preparation for induction to the reconstituted YEC-1 committee from August 2019, after signing the confidentiality agreement.

1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that quorum was present and declared the meeting open.
3. The Chairperson asked the members to declare Conflict of Interest – if any – for any protocol tabled in the agenda for the meeting. None of the members had conflict of interest for any of the protocols.
4. The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

5. The minutes of the 92nd YEC-1 meeting had been circulated to all the members after approval by the Chairperson and no objections/comments/corrections were received. The minutes were read out in the meeting and approved.


Secretary
Yenepoya Ethics Committee-1
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka
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		protocols	based on the merits of the case decided during the meeting. Level A - requires both the primary reviewers and the Chairperson to approve the resubmitted protocol before Secretary communicates the decision to the PI; Level B – requires only the primary reviewers to approve the resubmitted protocol before Secretary communicates the decision to the PI; Level C – requires only Member-Secretary to approve the resubmitted protocol before the decision is communicated to the PI.	may be incorporated in the version 3 of the SOP
g.	Training Session	New Drugs and Clinical Trials Rules 2019 – (3 rd Session)	Dr. Ravi Vaswani	

Since there was no other matter the meeting ended with a vote of thanks.

Date: 05-07-2019

Place: Mangalore


Dr. Uma Kulkarni
Member Secretary, YEC-1

Secretary
Yenepoya Ethics Committee-1

Copy to: Registrar, Yenepoya Deemed to be University

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Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Core Minutes of the 91st Meeting of Yenepoya Ethics Committee- 1

The 91st meeting of the Yenepoya Ethics Committee- 1 was held on 11 June 2019 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

1. Dr. Vikram Shetty (VS)	Chairperson	(External)
2. Dr. Sayeegeetha (SH)	Layperson	(External)
3. Fr Teji Thomas (TT)	Theologian	(External)
4. Dr. Nagapathi Bhat (NB)	Pharmacologist	(Internal)
5. Dr. Ravi Vaswani (RV)	Clinician	(Internal)
6. Dr. Vijayalaxmi Mogasale (VM)	Clinician	(Internal)
7. Dr. Mohammed Guthigar (MG)	Social Scientist	(Internal)
8. Ms. Viji Prasad (VP)	Nurse	(Internal)
9. Dr. Kiran Kammar (KK)	Homeopath	(Internal)
10. Dr. Uma Kulkarni (UK)	Member-Secretary	(Internal)

The following members were granted leave of absence:


1. Ms. Mudasir Baba Rashid (MBR)	Physiotherapy	(Internal)
2. Mr. Saduddin Salihi (SS)	Legal expert	(External)
3. Dr. Grrishma B (GB)	Basic Scientist	(Internal)
4. Mr. Moideen Khurshid (MK)	Risk assessor	(Internal)
5. Dr. Lakshminarayan Sonde	Clinician	(Internal)

The following members attended the meeting as observers from the FERCAP resurvey team after signing the confidentiality agreement:

1. Dr. Prasad Ranatunga	Lead Surveyor
2. Dr. PHG Janaka Pushpakumara	International Surveyor
3. Dr. P Paul Kumaran	Survey Coordinator
4. Dr. Swarnalakshmi	Local Surveyor
5. Dr. Cynthia Arunachalam	Trainee Surveyor
6. Ms. Khadeejath Farseena TH	Trainee Surveyor
7. Dr. Lavanya R	Trainee Surveyor
8. Dr. Meera Jacob	Trainee Surveyor
9. Dr. Megha Rani	Trainee Surveyor
10. Dr. Navyashree	Trainee Surveyor
11. Dr. Pooja Shetty	Trainee Surveyor
12. Ms. Shridevi Kalkoti	Trainee Surveyor
13. Dr. Shreshtha Shetty	Trainee Surveyor
14. Dr. Vasudha Devi	Trainee Surveyor


Secretary

Yenepoya Ethics Committee-1

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Registrar
Yenepoya (Deemed to be University)
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Mangalore-575 018, Karnataka

16. Correspondence from regulatory authorities, university and other communications:

1

- a. DCGI approval letter – newly reconstituted YEC-1 - Noted

17. Any other matter with the permission of the chair:

a. Conduct an additional meeting in view of lawyer being abroad and three clinical trial protocols pending review. Resolved to request the Member-Secretary and Chairperson to fix date and communicate.

b. Resolved to recommend to the university to hire a full time translator for research studies (Malayalam and Kannada)

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date:10-06-2019
Place: Mangalore



Dr. Uma Kulkarni
Member Secretary

Secretary
Yenepoya Ethics Committee-1



Secretary
Yenepoya Ethics Committee-1

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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Core Minutes of the 90th Meeting of Yenepoya Ethics Committee- 1

The 90th meeting of the Yenepoya Ethics Committee- 1 was held on 02 May 2019 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

- | | |
|------------------------------|------------------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Dr. Sayeegeetha | Layperson |
| 5. Dr. Ravi Vaswani | Clinician |
| 6. Dr. Nagapati Bhat | Pharmacologist |
| 7. Dr. Laxminarayan Sonde | Basic Scientist |
| 8. Dr. Mohammed Guthigar | Social Scientist |
| 9. Ms Viji Prasad | Nurse |
| 10. Dr. Vijayalaxmi Mogasale | Clinician |
| 11. Dr. Mudasir Rashid Baba | Physiotherapy representative |

The following members were granted leave of absence:

- | | |
|--------------------|-----------------|
| 1. Dr. Grrishma | Basic Scientist |
| 2. Mr. Khurshid | Risk assessor |
| 3. Fr. Teji Thomas | Priest |
| 4. Kiran Kammar | Homeopath |

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified whether any member had conflict of interest.
 - Dr. Uma Kulkarni declared CoI for the following protocols
 - 2017/209 by Dr. Aditi Vidha listed under Agenda No. 5 Item no. 3 for which she is the Guide
 - 2019/117 by Dr. Aditi Vidha listed under Agenda No. 9 Item No. 20 for which she is the Guide
 - 2019/088 Dr. Aditi Vidha listed under Agenda No. 9 Item No. 22 because she is the Guide for the student

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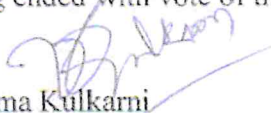
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deemed to be University
Mangalore-575 018, Karnataka


Secretary

Yenepoya Ethics Committee-1

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 02-05-2019
Place: Mangalore


Dr. Uma Kulkarni
Member Secretary
Secretary
Yenepoya Ethics Committee-1

CONFIDENTIAL


Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Core Minutes of the 89th Meeting of Yenepoya Ethics Committee – 1

The 89th meeting of the Yenepoya Ethics Committee – 1 was held on 04 April 2019 at 11.00 Am in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

- | | |
|-----------------------------|------------------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Ravi Vaswani | Clinician |
| 4. Dr. Nagapati Bhat | Pharmacologist |
| 5. Dr. Laxminarayan Sonde | Basic Scientist |
| 6. Dr. Vijayalaxmi Mogasale | Clinician |
| 7. Dr. Kiran S Kammar | Homeopathy Member |
| 8. Dr. Mudassir Rashid Baba | Physiotherapy representative |

The following members were granted leave of absence:

- | | |
|---------------------------|------------------|
| 1. Dr. Sayeegeetha | Layperson |
| 2. Mr. Saduddin Salihi | Lawyer |
| 3. Fr. Teji Thomas | Priest |
| 4. Dr. Mohammed Guthigar | Social Scientist |
| 5. Dr. Grrishma B | Basic Scientist |
| 6. Dr. Shubada VI | Ayurveda Member |
| 7. Mr. Y Moideen Khurshid | Risk Assessor |
| 8. Ms. Viji Prasad | Nursing faculty |

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified whether any member had conflict of interest.
 - Dr. Mudassir declared a CoI for her protocols No. 2019/011 & 2019/195 which were listed under agenda No. 7(1) and (2) as completed protocol for ratification
 - Dr. Vijayalakshmi declared CoI for her protocol No. 2019/094 which was listed under agenda No.6 (2) as Exemption from review approved for ratification
 - Rest of the members declared no CoI for any of the protocols
 - The Chairperson asked the two members to step out for the duration of the discussion of their respective protocols.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.


Secretary

Yenepoya Ethics Committee-1

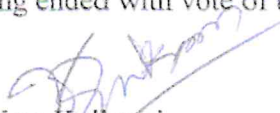
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 04-04-2019

Place: Mangalore


Dr. Uma Kulkarni

Member Secretary

Secretary

Yenepoya Ethics Committee-1

SECRET



Secretary

Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

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Core Minutes of the 88th Meeting of Yenepoya Ethics Committee - 1

The 88th meeting of the Yenepoya Ethics Committee - 1 was held on 13 March 2019 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

- | | |
|----------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Fr. Teji Thomas | Priest |
| 5. Dr. Sayeegeetha | Layperson |
| 6. Dr. Ravi Vaswani | Clinician |
| 7. Dr. Nagapati Bhat | Pharmacologist |
| 8. Dr. Mohd Guthigar | Social Scientist |
| 9. Dr. Laxminarayan Sonde | Basic Scientist |
| 10. Ms. Viji Prasad | Nursing faculty |
| 11. Mr. Y Moideen Khurshid | Risk Assessor |

The following members were granted leave of absence:
None

The following new members of ethics committee attended the meeting as guest/observers after signing the confidentiality agreement.

1. Dr. Vijayalaxmi Mogasale
2. Dr. Grrishma B
3. Dr. Kiran S Kammar
4. Dr. Mudasir Rashid Baba
5. Dr. Shubada VI

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified whether any member had conflict of interest. No conflict of interest was declared by any of the members.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:


Secretary
Yenepoya Ethics Committee-1

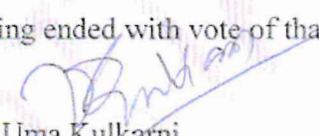
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Dr. Gangadhara Jayaraj K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

- Letter from Dr. Ravi P, Head of the institution, New Amrutha Medical & Research Centre, Raichur – Regarding MoU with ethics committee: The members approved the proposal of having an MoU with the concerned institution and also the suggestion of creating a local standing committee/SAE subcommittee at Raichur, which will look after the post-approval processes. This may be considered for a three year period - renewable. Amrutha Institute, Raichur to develop local capacity by then, by deputing 3-5 potential ethics committee members for training in the forthcoming I-SWEAR to be held in May 2019 at Centre for Ethics, Yenepoya deemed to be University.
- Letter from Soumya RP, Clinical Researcher, request for email IDs of EC members for conducting a questionnaire based study: Approved that instead of directly contacting the members, the applicant should provide the questionnaire to the Member secretary of YEC-1 who in turn will distribute and collect the questionnaire to the EC members and return them to the applicant, ensuring privacy of the YEC-1 members.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date:13-03-2019
Place: Mangalore


Dr. Uma Kulkarni
Member Secretary

Secretary
Yenepoya Ethics Committee-1


Secretary
Yenepoya Ethics Committee-1

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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575009, Karnataka
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Core Minutes of the 87th Meeting of Yenepoya Ethics Committee - 1

The 87th meeting of the Yenepoya Ethics Committee - 1 was held on 07 February 2019 from 11.00 AM to 1.30 PM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Sayeegeetha | Layperson |
| 4. Dr. Ravi Vaswani | Clinician |
| 5. Dr. Nagapati Bhat | Pharmacologist |
| 6. Dr. Mohd Guthigar | Social Scientist |
| 7. Dr. Laxminarayan Sonde | Basic Scientist |
| 8. Ms. Viji Prasad | Nursing faculty |
| 9. Mr. Y Moideen Khurshid | Risk Assessor |

The following members were granted leave of absence:

- | | |
|------------------------|--------|
| 1. Mr. Saduddin Salihi | Lawyer |
| 2. Fr. Teji Thomas | Priest |

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified whether any member had conflict of interest. No conflict of interest was declared by any of the members.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 87th YEC-1 meeting were read and approved by the members.
2. Full review protocols (new): 05

Sl. No	Protocol No	Title
1.	2019/003	Title: Evaluation of degree of staining and efficacy of two chlorhexidine (CHX) mouthrinses chlorhexidine 0.2% with an

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Dr. Gangadhara Somayaji K.S.
Registrar

Resolution: It was unanimously resolved to request the Member-Secretary to write to the Registrar to make arrangements for digitization of the ethical review process.

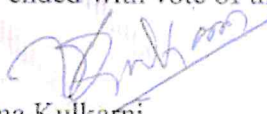
f. Increasing the strength of the YEC-1:

Discussion: In view of the increasing number of protocols being reviewed each year by YEC-1 (approximately 500-550 protocols each year) it was perceived that increasing the number of members in the YEC-1 would distribute the burden across the members and improve the quality of the ethical review process.

Resolution: It was unanimously resolved to request the Member-Secretary to write to the Registrar to increase the number of members in EC, with at least 2 more internal members.

Since there was no other matter for discussion, the meeting ended with vote of thanks.


Date: 07-02-2019
Place: Mangalore


Dr. Uma Kulkarni
Member Secretary

Secretary
Yenepoya Ethics Committee-1


Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Page 14 of 14
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore - 575 018, Karnataka

Core Minutes of the 86th Meeting of Yenepoya Ethics Committee - 1

The 86th meeting of the Yenepoya Ethics Committee - 1 was held on 03 January 2019 at 11.00 AM in the Forensic Demo Room-2, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Fr. Teji Thomas | Priest |
| 5. Dr. Mohd Guthigar | Social Scientist |
| 6. Dr. Laxminarayan Sonde | Basic Scientist |
| 7. Ms. Viji Prasad | Nursing faculty |

The following members were granted leave of absence:

- | | |
|-------------------------|----------------|
| 1. Dr. Ravi Vaswani | Clinician |
| 2. Dr. Sayeegeetha | Layperson |
| 3. Dr. Nagapati Bhat | Pharmacologist |
| 4. Mr. Moideen Khurshid | Risk Assessor |

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified whether any member had conflict of interest. Declared no conflict of interest
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 85th YEC-1 meeting were read and approved by the members.
2. Full review protocols (new):09 Old (01) = N (10)

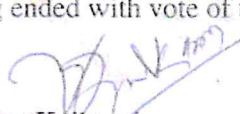
Sl. No	Protocol No	Title
1.	2018/244	Title: Oral Acetazolamide for antipsychotic induced weight gain-an open label study (PG Dissertation)

Resolution: the waiver of consent issued by Member Secretary YEC-1 was unanimously ratified

11. Monitoring reports – For review (1)
12. SAE Subcommittee Meeting for review - (1)
13. SAE/Safety reports – for review – (0)
14. Training Session: SOP subcommittee meeting minutes discussion
15. Correspondence from regulatory authorities, university and other communications: (Nil)
16. Individual department SRB approval
17. Any other matter with the permission of the chair:
 - Response letter from Dr. Prabha Adhikari – Protocol No. 2018/084
 - Electronic IORG-IRB Registration for Yenepoya Ethics Committee – I- For information

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 03-01-2019
Place: Mangalore


Dr. Uma Kulkarni
Member Secretary

Secretary
Yenepoya Ethics Committee-1


Secretary
Yenepoya Ethics Committee-1

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Page 13 of 13
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Core minutes of the 85th Meeting of Yenepoya Ethics Committee - 1

The 85th meeting of the Yenepoya Ethics Committee - 1 was held on 05December2018 at 11.00 Am in the Forensic Demo Room2, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. VikramShetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Dr. Ravi Vaswani | Clinician |
| 5. Dr. Nagapati Bhat | Pharmacologist |
| 6. Dr. Laxminarayan Sonde | Basic Scientist |
| 7. Ms. Viji Prasad | Nursing faculty |
| 8. Mr. Moideen Khurshid | Risk Assessor |

The following members were granted leave of absence:

- | | |
|----------------------|-------------------|
| 1. Fr. Teji Thomas | Priest/Theologian |
| 2. Dr. Sayeegeetha | Layperson |
| 3. Dr. Mohd Guthigar | Social Scientist |

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified whether any member had conflict of interest. Declared no conflict of interest
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 84th YEC-1 meeting were read and approved by the members.
2. Full review protocols (new):08

Sl. No	Protocol No	Title
1.	2018/233	<p>Title: Study on weight changes in patients receiving antipsychotic treatment: Monotherapy vs polypharmacy, in tertiary care hospital</p> <p>Name of the PI: Ms. Aneeta P Devasia& Others</p> <p>Lead discussant: Dr. Laxminarayan Sonde</p>

ATTESTED
(Signature)

(Signature)
Secretary

Yenepoya Ethics Committee-1

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 05-12-2018
Place: Mangalore



Dr. Uma Kulkarni
Member Secretary

Secretary
Yenepoya Ethics Committee-1



Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University
Mangalore - 575 018, Karnataka

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Core minutes of the 84th Meeting of Yenepoya Ethics Committee - 1

The 84th meeting of the Yenepoya Ethics Committee - 1 was held on 02 November 2018 at 11.00 AM in the Forensic Demo Room2, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. VikramShetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Ravi Vaswani | Clinician |
| 4. Dr. Nagapati Bhat | Pharmacologist |
| 5. Dr. Laxminarayan Sonde | Basic Scientist |
| 6. Dr. MohdGuthigar | Social Scientist |
| 7. Ms. Viji Prasad | Nursing faculty |

The following members were granted leave of absence:

- | | |
|------------------------|-------------------|
| 1. Fr. Teji Thomas | Priest/Theologian |
| 2. Mr. SaduddinSalihi | Lawyer |
| 3. Dr. Sayeegeetha | Layperson |
| 4. Dr. MoideenKhurshid | Risk Assessor |

The following members of YEC-2 attended the meeting as guest/observers after signing the conflict of interest declaration and confidentiality agreement.

1. Dr. Padmini
2. Dr. PrabhankarAdke

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 83rd YEC-1 meeting were read and approved by the members.
2. Full review protocols (new):03

Sl. No	Protocol No	Title
1.	2018/202	Title: Effectiveness of multicomponent home exercises on

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(Signature)

Dr. Gangadnara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be) University,
 University Road, Channarayana
 Mangalore - 575 018, Karnataka

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(Signature)
 Secretary


Yenepoya Ethics Committee-1

- To seek clarification from the Registrar, Yenepoya deemed to be University about investigator ship.


It was further unanimously resolved to keep this protocol pending till clarification sought from Registrar

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 02-11-2018
Place: Mangalore


Dr. Uma Kulkarni
Member Secretary

Secretary
Yenepoya Ethics Committee-1


Secretary
Yenepoya Ethics Committee-1
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Core minutes of the 83rd Meeting of Yenepoya Ethics Committee - 1

The 83rd meeting of the Yenepoya Ethics Committee - 1 was held on 04 October 2018 at 11.00 AM in the Forensic Demo Room I, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|---------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Sayeegeetha | Layperson |
| 4. Fr. Teji Thomas | Theologist / Priest |
| 5. Dr. Ravi Vaswani | Clinician |
| 6. Dr. Nagapati Bhat | Pharmacologist |
| 7. Dr. Laxminarayan Sonde | Basic Scientist |
| 8. Dr. Mohd Guthigar | Social Scientist |
| 9. Ms. Viji Prasad | Nurse |

The following members were granted leave of absence:


- | | |
|-------------------------|---------------|
| 1. Mr. Saduddin Salihi | Lawyer |
| 2. Dr. Moideen Khurshid | Risk Assessor |

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified whether any member had conflict of interest. Dr Uma Kulkarni declared conflict of interest in protocol no. 2018/188 and stepped out of the meeting during the deliberation and decision-making on this protocol.

The following items as per the agenda were discussed:

1. The minutes of the 82nd YEC meeting were read and approved by the members.
2. Full review protocols (new):08

Sl. No	Protocol No	Title
1.	2018/181	Title: Understanding the role and function of Non-coding-RNAs during myogenic differentiations and its impact on skeletal muscle diseases


Secretary

Yenepoya Ethics Committee-1

14. SAE/Safety reports – for review
Nil

15. Training Session: Auditing of the documents of active protocols

16. Correspondence from regulatory authorities, university and other communications: (Nil)

17. Any other matter with the permission of the chair:

- Waiver not approved. For discussion


SI No	Protocol No	Title of the study
1	2018/197	Point prevalence of Malnutrition in admitted patients at Yenepoya Medical College Hospital Discussion: Waiver of consent not approved. It was unanimously resolved that PI has to submit Informed consent form.

- Resubmission protocol no. 2018/084 – For approval
 - Site specific protocol is desirable without which risk benefit analysis cannot be assessed
- Protocol deviations(14) were informed to all members. It was decided to permit the students to consider the samples collected outside the EC validity period since most of the studies are with less than minimal risk. It was also decided to conduct monitoring / auditing of files on a regular basis. It was also resolved to make a report of the same and circulate among all department in order to make them aware of the ground realities of conduct of research by postgraduate students. The effort of the EC members in conducting the audit in short period of was appreciated.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 04-10-2018


Place: Mangalore


Member Secretary

Dr. Uma Kulkarni

Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Core minutes of the 82nd Meeting of Yenepoya Ethics Committee - 1

The 82nd meeting of the Yenepoya Ethics Committee - 1 was held on 06 September 2018 at 11.00 AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Dr. Sayeegeetha | Layperson |
| 5. Dr. Ravi Vaswani | Clinician |
| 6. Dr. Nagapati Bhat | Pharmacologist |
| 7. Dr. Laxminarayan Sonde | Basic Scientist |
| 8. Dr. Mohd Guthigar | Social Scientist |
| 9. Dr. Moideen Khurshid | Risk Assessor |
| 10. Ms. Viji Prasad | Nurse |

The following members were granted leave of absence:

- | | |
|--------------------|--------|
| 1. Fr. Teji Thomas | Priest |
|--------------------|--------|

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 81st YUEC meeting were read and approved by the members.
2. Full review protocols (new):04

Sl. No	Protocol No	Title
1.	2018/059	<p>Title:A study to prevalence of Internet addiction, associated psycho-social factors and health related quality of life in adolescents: A mixed method approach</p> <p align="right">ATTESTED</p> <p>Name of the PI:Ms. Poornima</p>


Secretary

Dr. Gangadhara Somayaji K.S.
Regd. Page 1 of 9
Yenepoya (Deemed to be University)
University Road, Doralakatte
Mangalore - 575 018, Karnataka

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 06-09-2018

Place: Mangalore



Member Secretary

Dr. Uma Kulkarni

Secretary

Yenepoya Ethics Committee-1



Secretary

Yenepoya Ethics Committee-1

ATTESTED



Dr. Gangadhara Somayaji K.S.

Registrar

Yenepoya (Deemed to be University)

University Road, Deralakatte

Mangalore - 575 018, Karnataka

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Core minutes of the 81st Meeting of Yenepoya Ethics Committee - 1

The 81st meeting of the Yenepoya Ethics Committee - 1 was held on 02 August 2018 at 11.00 AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. VikramShetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Sayeegeetha | Layperson |
| 4. Dr. Ravi Vaswani | Clinician |
| 5. Dr. Nagapati Bhat | Pharmacologist |
| 6. Dr. Laxminarayan Sonde | Basic Scientist |
| 7. Ms. Viji Prasad | Nurse |
| 8. Dr. Mohd Guthigar | Social Scientist |
| 9. Dr. Moideen Khurshid | Risk Assessor |
| 10. Fr. Teji Thomas | Priest |

The following members were granted leave of absence:

1. Mr. Saduddin Salihi Lawyer

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 80th YUEC meeting were read and approved by the members.
2. Full review protocols (new):07

Sl. No	Protocol No	Title
1.	2018/131	Title: Awareness and perceptions regarding prenatal sex determination, Pre-conception and Pre-natal diagnostics technique act and gender preferences among pregnant women attending a medical college hospital in Mangaluru

[Handwritten Signature]
Secretary

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya University
University Road, Kakatte
Mangalore - 575 018, Karnataka

4	2018/138	A study of varied clinical manifestations and correlation with antinuclear antibodies in connective tissue disorders in a tertiary care hospital
5	2018/127	A comparative study of ethylene oxide gas sterilization with plasma sterilization in central sterilization supply department of a teaching hospital
6	2018/130	Epidemiological profile and geographical distribution using QGIS of road traffic accidents reported to a tertiary care hospital, Mangaluru

11. Exemption from ethical review: (0)
12. Monitoring reports – For review (0)
13. SAE Subcommittee Meeting for review- 1
14. SAE/Safety reports – for review
Nil

15. Training Session: SOP03/v2 review – Reviewed by Dr. Uma Kulkarni awaiting approval by SOP subcommittee members.

16. Correspondence from regulatory authorities, university and other communications: (Nil)


17. Any other matter with the permission of the chair:

1. Participants rights document for approval – Minor changes suggested. The same will be incorporated.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 02-08-2018


Place: Mangalore


Member Secretary

Dr. Uma Kulkarni

Yenepoya Ethics Committee-1


Secretary
Yenepoya Ethics Committee-1

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
Institutional Road, Boratakatte
Mangalore - 575 018, Karnataka

Core Minutes of the 80th Meeting of Yenepeya Ethics Committee - 1

The 80th meeting of the Yenepeya Ethics Committee - 1 was held on 05 July 2018 at 11.00 AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|--------------------------|------------------|
| 1. Dr. VikramShetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. SaduddinSalihi | Lawyer |
| 4. Dr. Sayeegeetha | Layperson |
| 5. Dr. Ravi Vaswani | Clinician |
| 6. Dr. Nagapati Bhat | Pharmacologist |
| 7. Dr.Laxminarayan Sonde | Basic Scientist |
| 8. Dr. MohammedGuthigar | Social Scientist |
| 9. Ms. Viji Prasad | Nurse |

The following members were granted leave of absence:

1. Fr. Teji Thomas Theologian
2. Mr. Y Moideen Khurshid Risk Assessor

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified whether any member had conflict of interest. Dr Laxminarayan Sonde declared conflict of interest in protocol no. 2018/124 and stepped out of the meeting during the deliberation and decision-making on this protocol. Dr. Uma Kulkarni declared conflict of interest in protocol no. 2018/128 but since this protocol was an expedited review only for ratification, the committee unanimously voted to permit her to sit through the concerned agenda item.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 79thYUEC meeting were read and approved by the members.
2. Full review protocols (new):09


Secretary
Yenepeya Ethics Committee-1

Sl No	Protocol No	Title of the research study
1	2018/103	Clinical profile and geographical distribution of malaria patients attending a tertiary care centre in Mangaluru
2	2018/089	An in vitro evaluation of the sealing ability of Biodentine and Mineral trioxide aggregate as a root end filling material following the use of different irrigating solutions

11. Exemption from ethical review: (0)

12. Monitoring reports – For review (0)

13. SAE Subcommittee Meeting for review- 1

14. SAE/Safety reports – for review

Nil

15. Training Session: SOP02/v2 review

The modifications suggested in the SOP02/v2 were discussed and approved. Minutes of the SOP meeting are attached.

16. Correspondence from regulatory authorities, university and other communications: (Nil)

17. Any other matter with the permission of the chair:

1. Assessment of the members by the Chairperson was conducted. The assessment forms have been filled.
2. Approval for Declaration by the PI for using data from MRD files for the purpose of research with a waiver of informed consent: request letter. It was resolved that the EC should write to the Medical Superintendent to strengthen the MRD file security since retrospective MRD studies are being conducted without EC clearance and that MRD files on backbone are easily available to any faculty or PG even for research.
3. It was unanimously approved to request the Chairperson to write to the university seeking clarification on the delegation of responsibilities between YEC-1 and YEC-2

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 05-07-2018

Place: Mangalore

Member Secretary

Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-1

SECRET

Yenepoya Ethics Committee-1
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
Deralakatte
Mangalore - 575 013, Karnataka

Core Minutes of the 79th Meeting of Yenepoya Ethics Committee - 1

The 79th meeting of the Yenepoya Ethics Committee - 1 was held on 07 June 2018 at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Fr. Teji Thomas | Priest |
| 5. Dr. Sayeegeetha | Layperson |
| 6. Dr. Ravi Vaswani | Clinician |
| 7. Dr. Nagapati Bhat | Pharmacologist |
| 8. Dr. Laxminarayan Sonde | Basic Scientist |
| 9. Mr. Y Moideen Khurshid | Risk Assessor |

The following members were granted leave of absence:

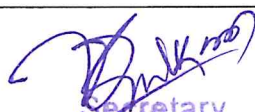
1. Dr. Mohd Guthigar Social Scientist


- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson clarified that no member had any conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 78th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 06

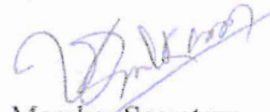
Sl. No	Protocol No	Title
1.	2018/083	<p>Title: Influence of lifestyle stressors, menstrual, obstetric pattern and cardiometabolic risk factors on young female patients with abnormal uterine bleeding</p> <p>Name of the PI: Dr. Manasvi Tyagi Lead discussant: Dr. Ravi Vaswani</p>


 Secretary
Yenepoya Ethics Committee-1
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 Page 1 of 12
 Dr. Gangadhara Somayaji Kulkarni
 Registrar
 Yenepoya (Deemed to be University)
 100, Jyoti Road, Gerelakatte
 Bangalore - 575 018, Karnataka

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 07 June 2018
Place: Mangalore




Member Secretary
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-1



Secretary
Yenepoya Ethics Committee-1

ATTESTED



Dr. Gangadhara Somayaji M.S.
Registrar
Yenepoya (Deemed to be University)
Mangalore Road, Yenepoya, Mangalore
Page 12 of 12
Mangalore 575 018, Karnataka

Core Minutes of the 78th Meeting of Yenepoya University Ethics Committee

The 78th meeting of the Yenepoya University Ethics Committee was held on 03 May 2018 at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|-----------------------------|------------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Dr. Ravi Vaswani | Clinician |
| 5. Mr. Moideen Khurshid | Risk Assessor |
| 6. Dr. Mohd Guthigar | Social Scientist |
| 7. Dr. Nagapati Bhat | New member as observer |
| 8. Dr. Lakshminarayan Sonde | New member as observer |

The following members were granted leave of absence:


- | | |
|--------------------|-----------|
| 1. Dr. Sayeegeetha | Layperson |
| 2. Fr. Teji Thomas | Priest |


- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 77th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 05

Sl. No	Protocol No	Title
1.	2018/070	<p>Title: Comparison of use of subglottic secretion drainage endotracheal tube with conventional endotracheal tube in prevention of ventilator associated pneumonia in patients admitted in the medical Intensive Care Unit</p> <p>Name of the PI: Dr. Sheena Marry Boban</p>


 Secretary
 Yenepoya Ethics Committee-1
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 Dr. Gangadhara Somayaji K. S.
 Registrar
 Yenepoya University
 Mangalore - 576 016, Karnataka
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- Dr. Nagapati Bhat in lieu of Dr. Shyamjith
- Dr. Laxminarayan Sonde in lieu of Dr. Sudeendra Prabhu

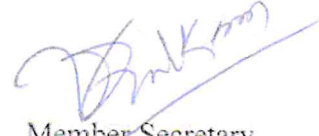
- Re-nomenclature

- It was resolved to request the registrar to consider the re-nomenclature of YUEC on a urgent basis, in view of the application process for NABH accreditation.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 03 May 2018

Place: Mangalore



Member Secretary

Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-



Secretary
Yenepoya Ethics Committee-1

ATTESTED



Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Mangalore
Mangalore - 575 016, Karnataka

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Core Minutes of the 77th Meeting of Yenepoya University Ethics Committee

The 77th meeting of the Yenepoya University Ethics Committee was held on 05 April 2018 at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

1. Dr. Vikram Shetty Chairperson
2. Dr. Uma Kulkarni Member Secretary
3. Dr. Sayeegeetha Layperson
4. Mr. Saduddin Salihi Lawyer
5. Fr. Teji Thomas Priest
6. Dr. Ravi Vaswani Clinician
7. Dr. Mohd Guthigar Social Scientist
8. Dr. Shyamjith M Pharmacologist

The following members were granted leave of absence:

1. Mr. Khurshid

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

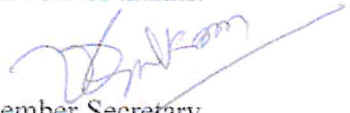
The following items as per the agenda were discussed:

1. The minutes of the 76th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 08

Sl. No	Protocol No	Title
1.	2018/044	Title: A study to assess the knowledge on reproductive health among adolescent girls in selected pre-university colleges of Mangaluru with the view to prepare an information booklet Name of the PI: Ms. Athira Surendran & Others Resolution: It was unanimously resolved to approve the study protocol no.


Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 05 April 2018
Place: Mangalore


Member Secretary
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Bengaluru
Mangalore 576 018, Karnataka
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Core Minutes of the 76th Meeting of Yenepoya University Ethics Committee

The 76th meeting of the Yenepoya University Ethics Committee was held on 01 March 2018 at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

1. Dr. Vikram Shetty Chairperson
2. Dr. Uma Kulkarni Member Secretary
3. Dr. Sayeegeetha Layperson
4. Dr. Ravi Vaswani Clinician
5. Fr. Teji Thomas Priest
6. Mr. Y Moideen Khurshid Risk Assessor
7. Dr. Sudeendra Prabhu Basic Scientist

The following members were granted leave of absence:

1. Mr. SaduddinSalihi Lawyer
2. Dr. Mohd Guthigar Social Scientist
3. Ms. Viji Prasad Nurse

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 75th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 08

Sl. No	Protocol No	Title
1.	2018/033	<p>Title: A study to assess the knowledge and practice regarding balanced diet among adolescents in selected schools at Mangaluru</p> <p>Name of the PI: Ms. Krupa Reji</p> <p>Lead discussant: Dr. Uma Kulkarni</p> <p>Resolution: It was unanimously resolved to approve the study protocol no. 2018/033 titled "A study to assess the knowledge and practice regarding balanced diet among adolescents in selected schools at Mangaluru" with modification as mentioned above in the</p>


Secretary
Yenepoya Ethics Committee-1
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Decided to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

protocol. It was further decided to request the registrar to notify the same.

- C. Plan for site monitoring for funded high risk protocols : Deferred to next meeting
- D. Decision about issue of separate approval letter for protocol no. 2016/376
- E. Approval for New Amendment request form: To be sent by email to all members of YUEC by email for approval.
- F. Protocol submitted by Dr. Anurag Bhargava: It was unanimously resolved not to accept this protocol as the participant recruitment, intervention and observation will be done in the state of Jharkhand and therefore not eligible for YUEC ethical clearance. It was further resolved to recommend to the PI to approach a local ethics committee in Jharkhand.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 01 March 2018
Place: Mangalore



Member Secretary
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee

ATTESTED



Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Serakkiate
Mangalore- 575 015, Karnataka



Secretary
Yenepoya Ethics Committee-1

Core Minutes of the 75th Meeting of Yenepoya University Ethics Committee

The 75th meeting of the Yenepoya University Ethics Committee was held on 08 February 2018 at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Sayeegeetha | Layperson |
| 4. Mr. Saduddin Salihi | Lawyer |
| 5. Dr. Ravi Vaswani | Clinician |
| 6. Dr. Mohd Guthigar | Social Scientist |
| 7. Mr. Y Moideen Khurshid | Risk Assessor |

The following members were granted leave of absence:

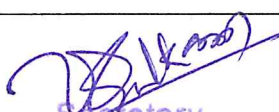
- Dr. Sudeendra Prabhu Basic Scientist
- Fr. Teji Thomas Priest

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 74th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 03

Sl. No	Protocol No	Title
	8/023	<p>Topic: Evaluation of inflammatory mediators and magnetic resonance imaging changes in temporomandibular joint disorders following arthrocentesis and sodium hyaluronate injection</p> <p>Name of the PI: Dr. Joyce Sequiera</p> <p>Resolution: Submission for full review</p>
	8/020	<p>Topic: Patient positioning and variations in respiratory mechanics during robotic surgeries</p>


 Secretary
 Yenepoya Ethics Committee-1
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 Dr. Gangadhar K. Somayaji K.S.
 Registrar
 Yenepoya (Doanmed) University
 University Road, Derlakatte
 Mangalore- 575 018, Karnataka

11. Other Letters related to projects – for information
Nil

12. Monitoring reports – For review

13. SAE Subcommittee Meeting for review- 1

13. SAE/Safety reports – for review

Nil

14. Training Session: “Risk Benefit Assessment” By Dr. Ravi Vaswani

15. Correspondence from regulatory authorities, university and other communications.


16. Any other matter with the permission of the chair:

Application process for NABH Accreditation informed to all the members.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 08 February 2018

Place: Mangalore


Member Secretary

Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee -


Secretary
Yenepoya Ethics Committee-1

ATTESTED


Page 7 of 7
Dr. Gangadhar Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Core Minutes of the 74th Meeting of Yenepeya University Ethics Committee

The 74th meeting of the Yenepeya University Ethics Committee was held on 11 January 2018 at 11.AMin the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Sayeegeetha | Layperson |
| 4. Mr. Saduddin Salihi | Lawyer |
| 5. Dr. Sudeendra Prabhu | Basic Scientist |
| 6. Dr. Shyamjith | Pharmacologist |
| 7. Mr. Y Moideen Khurshid | Risk Assessor |

The following members were granted leave of absence:

- Dr. Ravi Vaswani Clinician
- Dr. Mohd Guthigar Member
- Fr. Teji Thomas Priest

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 73rd YUEC meeting were read and approved by the members.
2. Full review protocols (new): 04

Sl. No	Protocol No	Title
1.	2017/347	<p>Title: Impact and implementation challenges of tuberculosis treatment with daily regimen and ICT enabled adherence support among HIV-infected TB patients in selected districts of Karnataka, India: A mixed methods study</p> <p>Name of the PI: Dr. Abhay Nirgude</p>

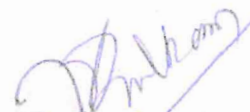
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Secretary
Yenepeya Ethics Committee-1
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Page 1 of 7
Dr. Gangappa Soodayaji K.S.
Yenepeya (Deemed to be University)
University Road, Bengalakatto
Mangalore- 575 018, Karnataka


Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 11 January 2018
Place: Mangalore


Member Secretary
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee


Secretary
Yenepoya Ethics Committee-1

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Page 7 of 7
Dr. Gangadhar Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 016, Karnataka

Core minutes of the 73rd Meeting of Yenepoya University Ethics Committee

The 73rd meeting of the Yenepoya University Ethics Committee was held on **21 December 2017** at 11.AMin the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|-------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Sayeegeetha | Layperson |
| 4. Mr. Saduddin Salihi | Lawyer |
| 5. Dr. Sudeendra Prabhu | Basic Scientist |
| 6. Dr. Mohd Guthigar | Social Scientist |
| 7. Fr. Teji Thomas | Priest |

The following members were granted leave of absence:

- Dr. Ravi Vaswani Clinician
- Dr. Shyamjith Pharmacologist
- Mr. Y Moideen Khurshid Risk Assessor

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

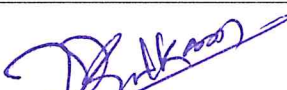
The following items as per the agenda were discussed:

1. The minutes of the 72nd YUEC meeting were read and approved by the members.
2. Full review protocols (new): 02

Sl. No	Protocol No	Title
1.	2017/329	Title: Effect of scientific exercises approach to scoliosis (SEAS) on idiopathic scoliosis in pre pubertal girls - A prospective clinical study Name of the PI: Ms. Mudasir Rashid Baba Lead discussant: Dr. Vikram Shetty Resolution: Approved
2	2017/343	Title: Horizontal ridge augmentation using a biphasic calcium

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Dr. Gangaiah G. Ganeshaiah K.S.
 Yenepoya (Deemed to be) University
 University Road, Yerakalatte
 Mangalore- 575 018, Karnataka


 Secretary

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 21 December 2017
Place: Mangalore


Member Secretary
Dr. Uma Kulkarni
Secretary
Yenepoya Ethics Committee-


Secretary
Yenepoya Ethics Committee-1 -

ATTESTED

Dr. Chandhara Semayaji K.S.
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Core minutes of the 72nd Meeting of Yenepoya University Ethics Committee

The 72nd meeting of the Yenepoya University Ethics Committee was held on 30 November 2017 at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Dr. Sayeegeetha | Layperson |
| 4. Fr. Teji Thomas | Priest |
| 5. Dr. SudeendraPrabhu | Basic Scientist |
| 6. Dr. Shyamjith | Pharmacologist |

The following members were granted leave of absence:

- Dr. Ravi Vaswani Clinician
- Mr. Saduddinsalihi Lawyer
- Dr. Mohd Guthigar Social Scientist
- Mr. Y Moideen Khurshid Risk Assessor

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 71st YUEC meeting were read and approved by the members.
2. Full review protocols (new): 05

Sl. No	Protocol No	Title
1.	2017/297	<p>Title:Early screening for autism in children in high risk newborn clinic</p> <p>Name of the PI:Ms. JagratiKarkera</p> <p>Lead discussant:Dr.</p>

ATTESTED



Dr. Ganeshram Ganeshrao K.S.
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 013, Karnataka



Secretary

11. Other Letters related to projects – for information

Nil

12. Monitoring reports – For review

Nil

13. SAE Subcommittee Meeting for review- 0

13. SAE/Safety reports – for review

Nil

14. Training Session: Review forms for full review and expedited review discussed

15. Correspondence from regulatory authorities, university and other communications.

16. Any other matter with the permission of the chair:

1. To expand the existing checklist for protocol submission
2. To explore the possibility of software for protocol review management with possible cost of 1.5 to 2 lakhs

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 30-November 2017

Place: Mangalore



Member Secretary

Dr. Uma Kulkarni

Secretary

Yenepoya Ethics Committee

ATTESTED



Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoyat (Deemed to be University)
University Road, Derahakatte
Mangalore- 575 013, Karnataka



Secretary

Yenepoya Ethics Committee-1

Core minutes of the 71st Meeting of Yenepeya University Ethics Committee

The 71st meeting of the Yenepeya University Ethics Committee was held on 02 November 2017 at 11.AMin the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|-------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. SaduddinSalihi | Lawyer |
| 4. Fr. Teji Thomas | Priest |
| 5. Dr. Sayeegeetha | Layperson |
| 6. Dr. Ravi Vaswani | Clinician |
| 7. Dr. Mohd Guthigar | Social Scientists |
| 8. Dr. Sudeendra Prabhu | Basic Scientist |
| 9. Mr. Y Moideen Khurshid | Risk Assessor |
| 10. Ms. Viji Prasad | Nurse |

The following members were granted leave of absence:

1. Dr. Shyamjith

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Dr. Ravi Vaswani declared conflict of interest for one protocol 2017/246and steeped out during discussion of that protocol. Other members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 70th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 07

Sl. No	Protocol No	Title
1.	2017/245	Title: Study of depression among children in a tertiary care hospital - Outpatient and inpatient cases Name of the PI: Dr. Keerthy Kurian Lead discussant: Dr. Uma Kulkarni / Ms. Viji Prasad

ATTESTED
ly

Uma Kulkarni
Secretary

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepeya University
University Road, Kagalakatta
Mangalore- 575 016, Karnataka

			admitted at a medical college hospital		
42.	Dr. Akbar Ali (2017/244)	Radiology	Evaluation of articular cartilage of knee joint with routine magnetic resonance sequences and T2-cartilage mapping (cartigram) using 3tesla MRI in tertiary care teaching hospital	Dissertation	30-10-17
43.	Dr. Shifa Junaidi (2017/229)	OBG	Prevalence & Pregnancy outcome in cases of asymptomatic bacteriuria during pregnancy	Dissertation	30-10-17

The above forty-three protocols for expedited review were unanimously ratified as approved.

10. Other Letters related to projects – for information

Nil

11. Monitoring reports – For review

Nil

12. SAE Subcommittee Meeting for review- 0

13. SAE/Safety reports – for review

Nil

14. Training Session: **Serious Adverse Event**

15. Correspondence from regulatory authorities, university and other communications.

- SAE subcommittee reconstitution notification informed to all

16. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 02-November 2017

Place: Mangalore



Member Secretary

Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 013, Karnataka

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Secretary

Yenepoya Ethics Committee-1

Core minutes of the 70th Meeting of Yenepoya University Ethics Committee

The 70th meeting of the Yenepoya University Ethics Committee was held on 12 October 2017 at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|---------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Dr. Teji Thomas | Priest |
| 5. Dr. Sayeegeetha | Layperson |
| 6. Dr. Ravi Vaswani | Clinician |
| 7. Mr. Y Moideen Khurshid | Risk Assessor |

The following members were granted leave of absence:

1. Dr. Mohd Guthigar
2. Ms. Viji Prasad
3. Dr. Shyamjith
4. Dr. Sudeendra Prabhu

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Members declared 'No' conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 69th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 26

Sl. No	Protocol No	Title
1.	2017/196	Title: Prevalence of chlamydia trachomatis infection among pregnant women attending the antenatal clinic at tertiary care hospital and its maternal and fetal outcome Name of the PI: Dr. Swetha S

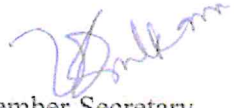
16. Any other matter with the permission of the chair:

- DCGI Re-Registration informed to all the members.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 12 October 2017

Place: Mangalore


Member Secretary

Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 010, Karnataka

Core minutes of the 69th Meeting of Yenepoya University Ethics Committee

The 69th meeting of the Yenepoya University Ethics Committee was held on **21 September 2017** at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|------------------------|------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Uma Kulkarni | Member Secretary |
| 3. Mr.SaduddinSalihi | Lawyer |
| 4. Dr. Sayeegeetha | Layperson |
| 5. Dr. SudeendraParbhu | Basic Scientist |
| 6. Dr. Ravi Vaswani | Clinician |
| 7. Dr. Shyamjith | Pharmacologist |
| 8. Ms. Viji Prasad | Nurse |

The following members were granted leave of absence:

1. Dr. Mohd Guthigar
2. Fr. Teji Thomas

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No member declared a conflict of interest.
- The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 68th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 8

Sl. No	Protocol No	Title
1.	2017/158	Title: Fabrication of hybrid-biocompositenanofibrous scaffolds for loading dental stem cells and their evaluation in pre-clinical

ATTESTED
[Signature]

*Dr. Gangadhara Ganayaji K.S.
Member Secretary
Yenepoya University
Karakatta
Karnataka*

[Signature]
Secretary

15. Correspondence from regulatory authorities, university and other communications.

Nil

16. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 21 Sep 2017

Place: Mangalore

Member Secretary

Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee

Secretary

Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 013, Karnataka

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Core minutes of the 68th Meeting of Yenepeya University Ethics Committee

The 68th meeting of the Yenepeya University Ethics Committee was held on **17 August 2017** at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|-------------------------|---------------------------------|
| 1. Dr. Vikram Shetty | Chairperson |
| 2. Dr. Sayeegeetha | Layperson |
| 3. Dr. Ravi Vaswani | Clinician (In-charge Secretary) |
| 4. Dr. Sudeendra Prabhu | Basic Scientist |
| 5. Dr. Mohd Guthigar | Social Scientist |
| 6. Ms Viji Prasad | Nurse |

The following members were granted leave of absence:

- | | |
|---------------------------|----------------|
| 1. Dr. Uma Kulkarni | Secretary |
| 2. Fr. Teji Thomas | Priest |
| 3. Mr. Saduddin Salihi | Lawyer |
| 4. Dr. Shyamjith | Pharmacologist |
| 5. Mr. Y Moideen Khurshid | Risk assessor |

- The In-charge Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No member declared a conflict of interest. The Chairperson called upon the In-charge Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 67th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 2

Sl. No	Protocol No	Title
1.	2017/152	Title: Efficacy of caudal needle placement using stimulator in pediatric caudal anaesthesia


Secretary

Yenepeya Ethics Committee-1

			mosquitoborne at selected community area, Mangaluru		
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The above fifteen protocols for expedited review were unanimously ratified as approved.

10. Other Letters related to projects – for information

Nil

11. Monitoring reports – For review

Nil

12. SAE Subcommittee Meeting for review- 0

13. SAE/Safety reports – for review

14. Training Session: Discussed “Protocol review process” for new members

15. Correspondence from regulatory authorities, university and other communications.

Nil

16. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 17 Aug 17

Place: Mangalore


Jt. Secretary

Dr. Ravi Vaswani

Secretary

Yenepoya Ethics Committee


Secretary

Yenepoya Ethics Committee-1

ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka
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Core minutes of the 67th Meeting of Yenepoya University Ethics Committee

The 67th meeting of the Yenepoya University Ethics Committee was held on 20 July 2017 at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|-------------------------|-------------|
| 1. Dr. Sayeegeetha | Chairperson |
| 2. Dr. Uma Kulkarni | Secretary |
| 3. Mr. SadudinSalihi | Lawyer |
| 4. Dr. Ravi Vaswani | Clinician |
| 5. Dr. Manjunath Shenoy | Clinician |
| 6. Dr. Vidya | Clinician |
| 7. Mrs.Vineetha Jacob | Clinician |

The following members were granted leave of absence:

1. Dr. Vina Vaswani
2. Dr. Shyamjith

Following guests were invited to the attend the meeting after signing the confidentiality agreements:

1. Dr. Vikram Shetty
2. Mr.MoideenKhurshid
3. Ms. Viji Prasad

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No member declared a conflict of interest. The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 66th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 3


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Formerly to be University)
University Road, Talakatte
Mangalore- 575 015, Karnataka

12. SAE Subcommittee Meeting for review- 01

13. SAE/Safety reports – for review

Sl No	Protocol No	Title of the study
1	2016/376	Phase 1 Multicenter, double blind, placebo-controlled, randomized (intra-group) clinical trial to evaluate two doses of three sequentially escalating cohort of Zika virus vaccine inactivated adsorbed (BBV121) in healthy adult dengue sero-negative and dengue sero-positive volunteers

14. Training Session: “**Informed Consent**” conducted by Dr. Ravi Vaswani.

15. Correspondence from regulatory authorities, university and other communications.
Nil

16. Any other matter with the permission of the chair:

- Change of title: No objection certificate to be issued to the PI acknowledging the change in title from..... Toas there is no amendment in the methodology.
- To inform the YU regarding the number of PIs who have not collected the EC clearance/extension letters from the YUEC over the last 3-4 months.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 20-July-2017

Place: Mangalore


Secretary

Dr. Uma Kulkarni

Secretary

Yenepoya Ethics Committee


Secretary

Yenepoya Ethics Committee-1

ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 019 Karnataka

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Core minutes of the 66th Meeting of Yenepoya University Ethics Committee

The 66th meeting of the Yenepoya University Ethics Committee was held on **15 June 2017** at 11.AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|-------------------------|--------------------------------|
| 1. Dr. Sayeegeetha | Chairperson |
| 2. Dr. Vina Vaswani | Member-Secretary (Bioethicist) |
| 3. Mr. Sadudin Salihi | Lawyer |
| 4. Dr. Ravi Vaswani | Clinician |
| 5. Dr. Manjunath Shenoy | Clinician |
| 6. Dr. Vidya | Clinician |
| 7. Mrs. Vineetha Jacob | Clinician |

The following members were granted leave of absence:

- | | |
|----------------------|------------------|
| 1. Dr. Uma Kulkarni | Jt Secretary |
| 2. Dr. Mohd Guthigar | Social Scientist |
| 3. Dr. Shyamjith | Pharmacologist |

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No member declared a conflict of interest. The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 65th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 5

Sl. No	Protocol No	Title
1.	2017/105	<p>Title: Feasibility study to implement select components of RNTCP nutritional guidance document for patients with Tuberculosis at Dakshina Kannada districts, India</p> <p>Name of the PI: Dr. Madhavi Bhargava</p>

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Secretary

Yenepoya Ethics Committee-1

13. Training Session: "Post Trial Access" conducted by Dr. Vina Vaswani. The session included a role play by Dr. Ravi Vaswani and Dr. Vina Vaswani.

14. Correspondence from regulatory authorities, university and other communications.

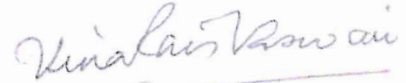
Nil

15. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 15-June-2017

Place: Mangalore



Secretary

Dr. Vina Vaswani


Secretary

Yenepoya Ethics Committee.



Secretary
Yenepoya Ethics Committee-1

ATTESTED



Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 016, Karnataka

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Core minutes of the 65th Meeting of Yenepoya University Ethics Committee

The 65th meeting of the Yenepoya University Ethics Committee was held on **22 May 2017** at 2 PM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|-----------------------|--------------------------------|
| 1. Dr. Sayeegeetha | Chairperson |
| 2. Dr. Vina Vaswani | Member-Secretary (Bioethicist) |
| 3. Dr. Uma Kulkarni | Jt Secretary |
| 4. Mr. Sadudin Salihi | Lawyer |
| 5. Dr. Ravi Vaswani | Clinician-Bioethicist |
| 6. Dr. Shyamjith | Pharmacologist |
| 7. Dr. Vidya | Microbiologist |

The following members were granted leave of absence:

- | | |
|-------------------------|------------------|
| 1. Dr. Mohd Guthigar | Social Scientist |
| 2. Fr Wilfred Prakash | Priest |
| 3. Dr. Manjunath Shenoy | Dermatologist |
| 4. Ms. Prema Amin | Layperson |

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No member declared a conflict of interest. The Chairperson called upon the Member-Secretary to start the business on the agenda.

The following items as per the agenda were discussed:

1. The minutes of the 64th YUEC meeting were read and approved by the members.
2. Full review protocols (new): 4

Sl. No	Protocol No	Title
1.	2017/084	<p>Title: A clinical study to assess the efficacy of dexamethasone on swelling, pain and trismus following surgical extraction of third molar</p> <p>Name of the PI: Dr. Shifa</p>

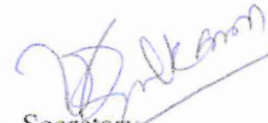

Secretary

Yenepoya Ethics Committee-1

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 22-May-2017

Place: Mangalore



Secretary

Dr. Uma Kulkarni

Secretary

Yenepoya Ethics Committee



Secretary

Yenepoya Ethics Committee-1

ATTESTED



Page 10 of 10
Dr. Ardhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore- 575 018, Karnataka

Core minutes of the 64th Meeting of Yenepoya University Ethics Committee

The 64th meeting of the Yenepoya University Ethics Committee was held on 20th April 2017 at 11 AM in the Forensic Demo Room, Academic Block, YMC.

The following members were present:

- | | |
|-------------------------|--------------|
| 1. Dr. Sayeegetha | Chairperson |
| 2. Dr. Uma Kulkarni | Jt Secretary |
| 3. Dr. Ravi Vaswani | Member |
| 4. Fr. Wilfred Prakash | Member |
| 5. Dr. Manjunath Shenoy | Member |
| 6. Mrs. Vinitha Jacob | Member |

The following members were granted leave of absence:

- | | |
|------------------------|------------------|
| 1. Dr. Vina Vaswani | Member secretary |
| 2. Mr. Saduddin Salihi | External Member |
| 3. Dr. Mohd Guthigar | External Member |
| 4. Dr. Shyamjith | Member |
| 5. Dr. Vidya | Member |

- The Jt Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- Mrs. Vinitha Jacob declared CoI for two projects (2017/076 and 2017/077)

The following items as per the agenda were discussed:

1. The minutes of the 63rd YUEC meeting were read and approved by the members.
2. Full review proposals: 6

Sl. No	Protocol No	Title
1.	2017/059	<p>Title: Psychiatric morbidity in wives of patients with alcohol dependence syndrome</p> <p>Name of the PI: Dr. Rajashekar YR</p> <p>Lead discussant: Dr. Ravi Vaswani</p> <p>Resolution:</p> <ul style="list-style-type: none"> • Approved with modification

ATTESTED
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[Signature]
Secretary

Yenepoya Ethics Committee-1
Page 108

Dr. Gangadhara Srinivasaji K.S.
Registrar
Yenepoya University (to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka


9. Other Letters related to projects – for information: Nil
10. Monitoring reports – For review: Nil
11. SAE Subcommittee Meeting minutes for review- Nil
12. SAE/Safety reports – for review: Nil
13. Correspondence from regulatory authorities, university and other communications: Nil
14. Training sessions: Training session of members was conducted by Dr. Ravi Vaswani on the topic “Risk-Benefit Assessment”.
15. Any other matter with the permission of the chair:

The following points were suggested and approved by all members

- a. When there is a temporal disparity in the EC approval of a project and the date of starting of the project, the EC clearance may include in the EC validity, the starting as well as completion date.
- b. To prepare a template for declarations
 - a. Declaration by PI about destruction of samples
 - b. Declaration by the department issues samples about delinking the identifying data from the samples before issuing it to the PIs.
- c. Separate EC clearance to be issued for all pilot studies and fresh EC clearance to be issued after the PI submit the pilot study report.
- d. To insist on writing month and year in the time line.


Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 20-April-2017
Place: Mangalore


Jt. Secretary
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka
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Core minutes of the 63rd Meeting of Yenepoya University Ethics Committee

The 63rd meeting of the Yenepoya University Ethics Committee was held on 16th March 2017 at 11 AM in the Forensic Demo Room, Academic Block, YMC.

The following members were present:

- | | |
|-------------------------|-----------------|
| 1. Dr. Sayegetha | Chairperson |
| 2. Dr. Uma Kulkarni | Jt Secretary |
| 3. Mr. Saduddin Salihi | External Member |
| 4. Dr. Manjunath Shenoy | Member |
| 5. Dr. Ravi Vaswani | Member |
| 6. Dr. Vidya | Member |
| 7. Dr. Mohd Guthigar | Member |
| 8. Mrs. Vineetha Jacob | Member |

The following members were granted leave of absence:


- | | |
|-------------------------|-----------------|
| 1. Dr. Vina Vaswani | Secretary |
| 2. Dr. Shamjith | Member |
| 3. Fr. Wilfred Prakash | External Member |
| 4. Mr. Farhaad Yenepoya | Member |
| 5. Dr. Maji Jose | Member |
| 6. Dr. Mohd Sherif | Member |
| 7. Ms. Prema Amin | External Member |


- The Jt Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No conflict of interest was declared.

The following items as per the agenda were discussed:

1. The minutes of the 62nd YUEC meeting were read and approved the members.
2. Full review proposals:

Sl. No	Protocol No	Title
1.	2016/380	Title: Development of Polymerase chain reaction (PCR) based assay for Scrub Typhus at Yenepoya Medical College Hospital


Secretary
Yenepoya Ethics Committee-1
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ATTESTED

Dr. Gangadhara Somayaji K.S.
Reg. Secy (Yenepoya University)
Yenepoya Medical College Hospital
University Road, Deralasa
Bijaluru- 575 010, Karnataka
Page 1 of 8

			care hospital		
20	Mr. Enrichson Suting (2017/029)	Public Health	Prevalence of hypertension and stress among anganwadi workers in Mangalore taluk Karnataka	Short Study	13-03-17
21	Ms. Aime Mol Antony & Others (2017/032)	Community Health Nursing	Attitude towards E learning among nursing students of selected nursing colleges of Mangaluru	UG Group study	13-03-17

The above twenty one protocols for expedited review were unanimously ratified as approved.

9. Other Letters related to projects – for information

Nil

10. Monitoring reports – For review

Nil

11. SAE Subcommittee Meeting for review- Nil

12. SAE/Safety reports – for review

Nil

13. Correspondence from regulatory authorities, university and other communications.

Nil

14. Training sessions: Training session of members was conducted by Dr. Uma Kulkarni on the topic “**Compensation Issues**”.

15. SOP amendment suggested.

Approved by all that the SOP sub-committee should work on this.

16. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 16-March-2017

Place: Mangalore



Jt. Secretary

Dr. Uma Kulkarni

Secretary

Yenepoya Ethics Committee

ATTESTED



Secretary

Yenepoya Ethics Committee-1

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Yeravathur, Mangalore - 575 016, Karnataka

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Core minutes of the 62nd Meeting of Yenepoya University Ethics Committee

The 62nd meeting of the Yenepoya University Ethics Committee was held on 21st February 2017 at 11 AM in the Forensic Demo Room, Academic Block, YMC.

The following members were present:

1. Dr. Vina Vaswani - Secretary
2. Dr. Uma Kulkarni - Jt. Secretary
3. Mr. Saduddin Salihi - External Member
4. Dr. Ravi Vaswani - Member
5. Dr. Shyamjith - Member
6. Mr. Farhaad Yenepoya - Member
7. Dr. Vinitha Jacob - Member

The following members were granted leave of absence:

1. Dr. Sayeegeetha - Chairperson
2. Dr. Vidya - Member
3. Dr. Mohd Guthigar - Member
4. Dr. Manjunath Shenoy - Member
5. Dr. Maji Jose - Member
6. Dr. Mohd Sherif - Member
7. Ms. Prema Amin - Member
8. Fr. Wifred Prakash - Member

- The Secretary welcomed the members and handed over the proceedings to the Chairperson.
- Since the Chairperson Dr. Sayeegeetha was granted leave of absence, Mr. Saduddin Salihi was designated as the Chairperson for the meeting and the meeting was conducted.
- The quorum was declared to be sufficient to conduct a full committee meeting
- The Chairperson asked the members if there was any Conflict of interest among members.
- No conflict of interest was declared by any members

The following items as per the agenda were discussed:

1. The minutes of the 61st YUEC meeting were read and approved the members.
2. Full review proposals:

Sl. No	Protocol No	Title


Secretary

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 21-Feb-2017
Place: Mangalore

Jt. Secretary
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-

Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Page 8 of 8

Core minutes of the 61st Meeting of Yenepoya University Ethics Committee

The 61st meeting of the Yenepoya University Ethics Committee was held on 31st January 2017 at 11 AM in the Forensic Demo Room, Academic Block, YMC.

The following members were present:

- | | |
|-------------------------|-------------------|
| 1. Dr. Sayeegeetha | - Chairperson |
| 2. Dr. Vina Vaswani | - Secretary |
| 3. Dr. Uma Kulkarni | - Jt. Secretary |
| 4. Mr. Saduddin Salihi | - External Member |
| 5. Dr. Manjunath Shenoy | - Member |
| 6. Dr. Ravi Vaswani | - Member |
| 7. Dr. Vidya | - Member |
| 8. Dr. Mohd Guthigar | - Member |
| 9. Mrs. Vineetha Jacob | - Member |
| 10. Dr. Shyamjith | - Member |

- The Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No conflict of interest was declared.

The following items as per the agenda were discussed:

1. The minutes of the 60th YUEC meeting were approved and passed by all the members.
2. Full review proposals:

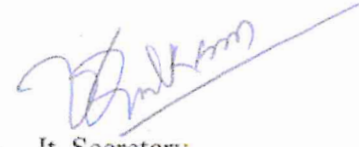
Sl. No	Protocol No	Title
1.	2016/360	<p>Title: Ultrasound guided saline infusion of a pathological shoulder joint and its correlation with magnetic resonance imaging</p> <p>Name of the PI: Dr. Eknath Jayapalan</p> <p>Lead discussant: Dr. Uma Kulkarni / Dr. Mohd Guthigar</p> <p>Resolution:</p> <ul style="list-style-type: none"> • Resubmission • Resubmission to be reviewed in an expedited review meeting

			University colleges in Mangaluru Taluk		
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9. Other Letters related to projects – for information
Nil
10. Monitoring reports – For review
Nil
11. SAE Subcommittee Meeting for review- Nil
12. SAE/Safety reports – for review
Nil
13. Correspondence from regulatory authorities, university and other communications.
Nil
14. Training sessions: **Ethical issues in Genomics** conducted by Dr. Uma Kulkarni.
15. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 31-Jan-2017
Place: Mangalore



Jt. Secretary
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-



Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Core minutes of the 60th Meeting of Yenepoya University Ethics Committee

The 60th meeting of the Yenepoya University Ethics Committee was held on 15th December 2016 at 11 AM in the Summer Sand Resort, Ullal, Mangalore.

The following members were present:

- | | |
|-------------------------|--------------------------|
| 1. Dr. Sayeegeetha | - Chairperson |
| 2. Dr. Vina Vaswani | - Secretary |
| 3. Dr. Uma Kulkarni | - Jt. Secretary |
| 4. Mr. Saduddin Salihi | - External Member Lawyer |
| 5. Dr. Mohd. Guthigar | - Member |
| 6. Dr. Ravi Vaswani | - Member |
| 7. Dr. Manjunath Shenoy | - Member |
| 8. Mrs. Vineetha Jacob | - Member |
| 9. Dr. Shyamjith | - Member |

- The Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No conflict of interest was declared.

The following items as per the agenda were discussed:

1. The minutes of the 59th YUEC meeting were approved and passed by all the members.
2. Full review proposals:

Sl. No	Protocol No	Title
1.	2016/327	Title: Role of alfa adrenergic blockers (silodosin) in the management of distal ureteric calculus Name of the PI: Dr. Karthik R Aithal Lead discussant: Dr. Uma Kulkarni / Dr. Manjunath Shenoy Resolution: Approved with Modification
2	2016/342	Title: Safety and efficacy of paracetamol infusion in comparison with tramadol on labour analgesia and foetal outcome Name of the PI: Dr. Anamika Singh Lead discussant: Dr. Shyamjith / Mrs. Vineetha Jacob


Secretary

Yenepoya Ethics Committee-1

15. Any other matter with the permission of the chair:

It was decided that for every communication with PI, be copied to guide, so that guide can be on the same page as PI.

The Secretary and Jt Secretary express thanks to ethics committee members and those who held with FERCAP accreditation. And the meeting was followed by lunch at Summer Sand Beach Resort, Ullal. The entire meeting include the travel time was between 11.00 AM to 2.00 PM.

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 15-Dec-2016
Place: Mangalore

Jt. Secretary
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee

Secretary
Yenepoya Ethics Committee-1

ATTTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Core minutes of the 59th Meeting of Yenepoya University Ethics Committee

The 59th meeting of the Yenepoya University Ethics Committee was held on 10th November 2016 at 11 AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

1. Dr. Sayeegeetha- Chairperson
2. Dr. Uma Kulkarni - Jt. Secretary
3. Mr. Saduddin Salihi - External Member Lawyer
4. Fr. Wilfred Prakash D'Souza - External Member Priest
5. Dr. Mohd. Guthigar - Member
6. Dr. Ravi Vaswani - Member
7. Mrs. Vineetha Jacob - Member
8. Dr. Shyamjith - Member
9. Dr. Vidya - Member

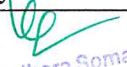
- The Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum was present and declared the meeting open.
- The Chairperson asked the members if there was any Conflict of interest among members.
- No conflict of interest was declared.

The following items as per the agenda were discussed:

1. The minutes of the 58th YUEC meeting were approved and passed by all the members
2. Full review proposals:

Sl. No	Protocol No	Title
1.	2016/242	<p>Title: Comparative study of two point versus three point fixation in the management of zygomatic complex fractures</p> <p>Name of the PI: Dr. Harisankar</p> <p>Lead discussant: Dr. Uma Kulkarni / Dr. Ravi Vaswani</p> <p>Resolution:</p> <ul style="list-style-type: none"> • Resubmission • Resubmission to be reviewed in an expedited review meeting
2	2016/243	<p>Title: Comparative study on efficacy of polyvinyl siloxane and</p>


 Secretary
 Yenepoya Ethics Committee-1


 Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Derol, Mangalore
 Mangalore - 575 018, Karnataka

25	Dr. Shahana P Sulaiman (2016/190)	Oral Medicine & Radiology	Age determination by Demirjian's method in Mangalore population - Radiographic study	Short study	15-10-16
26	Dr. Uma M (2016/173)	PGDFA Student	Cephalometric evaluation to determine sexual dimorphism in South Indians and Malaysian population	Short study	15-10-16
27	Mr. Enrichson Suiting (2016/209)	Public Health	Rapid Appraisal of road-safety environment around educational institutions of Mangalore and Deralakatte	Short study	15-10-16
28	Dr. Vaishnavi Gopal (2016/194)	Dermatology	Nail changes in autoimmune blistering disorders	Short study	15-10-16
29	Dr. Jaquilin George G (2016/193)	Oral Medicine & Radiology	Age determination by schour and massler method- A Radiographic study	Short study	15-10-16

8. Other Letters related to projects – for information

Nil

9. Monitoring reports – For review

Nil

10. SAE Subcommittee Meeting for review-3rd SAE meeting minutes read and passed.

11. SAE/Safety reports – for review

Nil

12. Correspondence from regulatory authorities, university and other communications.

Nil

13. Training sessions: Nil

14. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Jt. Secretary

Date: 20-Oct-2016

Place: Mangalore

Dr. Uma Kulkarni

Secretary

Yenepoya Ethics Committee-1
ATTESTED

Secretary
Yenepoya Ethics Committee-1

Dr. G. Parashara Somayaji K.S.
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Core minutes of the 58th Meeting of Yenepoya University Ethics Committee

The 58th meeting of the Yenepoya University Ethics Committee was held on 20th October 2016 at 11 AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

1. Dr. Sayeegeetha - Chairperson
2. Dr. Vina Vaswani - Secretary
3. Dr. Uma Kulkarni - Jt. Secretary
4. Mr. Saduddin Salihi - External Member Lawyer
5. Fr. Wilfred Prakash D'Souza - External Member Priest
6. Dr. Mohd. Guthigar - Member
7. Dr. Ravi Vaswani - Member
8. Dr. Manjunath Shenoy - Member
9. Mrs. Vineetha Jacob - Member
10. Dr. Shyamjith - Member
11. Dr. Vidya - Member

The Secretary welcomed the members and handed over the proceedings to the Chairperson. The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson asked the members if there was any conflict of interest to declare. Dr. Vidya declared conflict of interest for the research proposal 2016/200 and stepped out during the discussion, decision-making and voting for that proposal.

The following items as per the agenda were discussed:

1. The minutes of the 57th YUEC meeting were approved and passed by all the members.
2. Full review proposals:

Sl. No	Protocol No	Title
1.	2016/200	<p>Title: Detection and Genotyping of Human Papillomavirus and Its Role in Cervical Cancer in Sexually Active Women Attending Tertiary Care Hospital</p> <p>Name of the PI: Ms. Varsha Saxena</p> <p>Lead discussant: Dr. Uma Kulkarni / Mrs. Vineetha Jacob</p> <p>Resolution: Approved with modification</p>
2	2016/210	<p>Title: A study on prevalence of Internet Addiction and Mental Health among Medical College Students of Mangalore, Dakshina Kannada District</p>

15	Dr. ViegasMrinali Maria (2016/233)	Prosthodontics	Effect of mechanical and chemical surface treatment on bond strength of acrylic denture teeth to heat-cure acrylic resin - An Invitro study	Dissertation	02-11-16
16	Dr. NaseehaPaduppungar (2016/253)	Paedodontics	Evaluation of the effect of bioactive glass and alumina air abrasion on enamel surfaces of primary teeth-an invitro study	Dissertation	02-11-16
17	Dr. Kishor Kumar (2016/293)	Forensic Medicine & Toxicology	Research and Innovations: Challenges among different stakeholders of a private Health University	Short study	05-11-16
18	Ms.SachithaNandagopal (2016/296)	Centre for Ethics	Developing curriculum for academic programme in medical humanities	Short study	07-11-16

9. Other Letters related to projects – for information

Nil

10. Monitoring reports – For review

Nil

11. SAE Subcommittee Meeting for review-3rd SAE meeting minutes read and passed.

12. SAE/Safety reports – for review

Nil

13. Correspondence from regulatory authorities, university and other communications.

Nil

14. Training sessions: Nil

15. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 20-Oct-2016

Place: Mangalore

Jt. Secretary, YUEC

Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-

ATTESTED

Dr. G. S. Gomayji
Page 13 of 13
Yenepoya (Deemed to be University)
Mangalore - 575 016, Karnataka

Secretary
Yenepoya Ethics Committee-1

Core minutes of the 57th Meeting of Yenepeya University Ethics Committee

The 57th meeting of the Yenepeya University Ethics Committee was held on 15th September 2016 at 11 AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | | |
|--------------------------------|-------------------|--------|
| 1. Dr. Sayeegeetha | - Chairperson | |
| 2. Dr. Uma Kulkarni | - Jt Secretary | |
| 3. Mr. Saduddin Salihi | - External Member | Lawyer |
| 4. Fr. Wilfred Prakash D'Souza | - External Member | Priest |
| 5. Dr. Mohd. Guthigar | - Member | |
| 6. Dr. Manjunath Shenoy | - Member | |
| 7. Mrs. Vineetha Jacob | - Member | |

The following members were granted leave of absence:

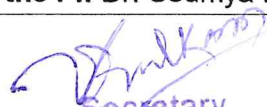
- | | |
|---------------------|-------------|
| 1. Dr. Vina Vaswani | - Secretary |
| 2. Dr. Ravi Vaswani | - Member |
| 3. Dr. Vidya Pai | - Member |


Since the Chairperson Dr. Sayeegeetha informed about her late arrival, Mr. Saduddin Salihi was designated as the Chairperson for the meeting and the meeting was conducted. The Jt. Secretary welcomed the members and handed over the proceedings to the Chairperson. The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson asked the members if there was any Conflict of interest among members. No conflict of interest was declared.

The following items as per the agenda were discussed:

1. The minutes of the 56th YUEC meeting were approved and passed by the members.
2. Full review proposals:

Sl. No	Protocol No	Title
1.	2016/179	<p>Title: Assessment of knowledge, attitude and practice of ethical principles when prescribing Cone Beam Computed Tomography (CBCT) scan in orthodontics among Orthodontists and Orthodontic residents</p> <p>Name of the PI: Dr. Shahistha Parveen</p> <p>Lead discussant: Dr. Vidya Pai</p> <p>Resolution: APPROVED</p>
2	2016/180	<p>Title: Correlation of CD4 count with cariogenic oral flora indicators and dental caries in HIV-positive children in Dakshina Kannada district</p> <p>Name of the PI: Dr. Soumya Muraleedharan</p>


Secretary
Yenepeya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepeya (Deemed to be University)
University Road, De. A. K. P. S.
Mangalore - 575 018, Karnataka

4	Dr. Ahrsia VF (2016/167)	Physiology	A comparative study of hand grip strength among sedentary males and non sedentary males and non sedentary constructive site workers	Short study	03-09-16
5	Mr. Diwan Mahmood Khan (2016/172)	General Surgery	Antimicrobial susceptibility and virulence factors of multi drug resistance (MDR) Acinetobacter species from diabetic foot ulcer patients	PhD proposal	03-09-16
6	Dr. B Kalpana (2016/169)	Physiology	A study on the assessment of academic stress and the perception of Yoga among medical and dental students	Short study	03-09-16
7	Mr. Diwan Mahmood Khan (2016/174)	General Surgery	Diabetic foot ulcer infections associated with Gram negative bacteria with special reference of drug resistant isolates	Short study	10-09-16
8	Dr. Sunil Kumar (2016/163)	Director, STDC-Kerala	Evaluation of the social support framework for people affected with MDR Tuberculosis through food kit provision in Kasaragod District	Short study	10-09-16

8. Other Letters related to projects – for information

Nil

9. Monitoring reports – For review

Nil

10. SAE Subcommittee Meeting for review-2nd SAE meeting minutes read and passed.

11. SAE/Safety reports – for review

Nil

12. Correspondence from regulatory authorities, university and other communications.


Nil

13. Training sessions: “**Serious Adverse Event Reporting**” by Dr. Uma Kulkarni

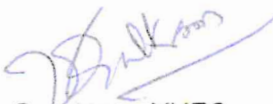
14. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, H. S. Road,
Mangalore - 575 016, Karnataka

Date: 15-Sep-2016
Place: Mangalore


Jt. Secretary, YUEC
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Core minutes of the 56th Meeting of Yenepoya University Ethics Committee

The 56th meeting of the Yenepoya University Ethics Committee was held on 17 August 2016 at 11 AM in the Forensic Demo Room II, Academic Block, YMC.

The following members were present:

- | | |
|--------------------------------|--------------------------|
| 1. Dr. Sayeegeetha | - Chairperson |
| 2. Dr. Vina Vaswani | - Secretary |
| 3. Dr. Uma Kulkarni | - Jt Secretary |
| 4. Mr. Saduddin Salihi | - External Member Lawyer |
| 5. Fr. Wilfred Prakash D'Souza | - External Member Priest |
| 6. Dr. Ravi Vaswani | - Member |
| 7. Dr. Shyamjith M | - Member |
| 8. Dr. Mohd. Guthigar | - Member |
| 9. Dr. VidyaPai | - Member |
| 10. Dr. Manjunath Shenoy | - Member |

The following members were granted leave of absence:

1. Mr. Farhaad Yenepoya

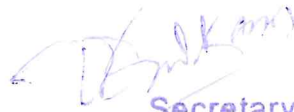
Following guests were invited to attend the meeting signing the confidentiality agreements:

1. Dr. Vasantha Muthuswamy (as FERCAP representative for compliance assessment)

The Secretary welcomed the members and handed over the proceedings to the Chairperson. The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson asked the members if there was any Conflict of interest among members. No conflict of interest was declared.

The following items as per the agenda were discussed:

1. The minutes of the 55th YUEC meeting were approved and passed by the members.
2. Full review proposals:


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Mangalore
Mangalore - 575 015, Karnataka

9. Other letters

- a. DCGI: Regarding addition of site for a clinical trial: Ethics committee can decide, additional PI's responsibility to inform DCGI
- b. Site requirements for clinical trials: Minimum 50 beds not a necessary requirement. Ethics committee can assess and decide based on number of beds and provisions for appropriate emergency care.
- c. Restriction of number of clinical trials per investigators: Previous restriction of 3 trials per investigator removed. Ethics committee can decide.

10. YUEC SOP version 2 – for information and necessary action

All members confirmed that they have received soft copies of the YUEC SOP version 2.

11. Any other matter with the permission of the chair:

Since there was no other matter for discussion, the meeting ended with vote of thanks.


Date: 17-Aug-2016

Place: Mangalore


Jt. Secretary, YUEC

Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore - 575 018, Karnataka

Core minutes of the 55th Meeting of Yenepoya University Ethics Committee

The 55th meeting of the Yenepoya University Ethics Committee was held on **21 July 2016** at 11 AM in the Forensic Demo Room II, 3rd floor, A Wing, Academic block, YMC.

The following members were present:

1. Dr. Sayeegeetha
2. Dr. Vina Vaswani
3. Dr. Ravi Vaswani
4. Dr. Uma Kulkarni
5. Dr. Shyamjith
6. Fr. Wilfred Prakash D Souza
7. Dr. Vidya Pai
8. Mrs. Vineetha Jacob

The following members were granted leave of absence:

1. Dr. Manjunath Shenoy
2. Mr. Farhaad Yenepoya
3. Mr. Saduddin Salihi
4. Ms. Prema Amin
5. Dr. Mohammed Guthigar
6. Dr. Mohammed Sheriff

The Secretary welcomed the members.

The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson asked the members if there was any Conflict of interest among members. No conflict of interest was declared.

The following items as per the agenda were discussed:

1. The minutes of the 54th YUEC meeting were approved and passed by the members.
2. Full review proposals:

Sl. No	Protocol No	Title
1.	2016/129	<p>Title: 3-dimensional (3D) assessment of effect of various orthopaedic treatment modalities in nonsyndromic unilateral cleft lip and palate (NSUCLP) patients</p> <p>Name of the PI: Dr. Shahistha Parveen</p> <p>Resolution:</p> <ol style="list-style-type: none"> 1. Approve after an appropriate response from the PI, corrections in Informed consent and declaration of conflict of interest 2. Ethics committee authorizes the primary reviewer to recommend approval of ethical clearance based of satisfaction of the reviewer. 3. Ethics committee authorizes the member secretary to

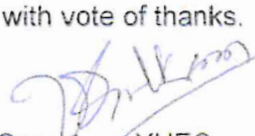
Instead of training program on Informed consent, Dr. Ravi Vaswani and Dr. Uma Kulkarni addressed the EC members on the new YUEC SOP's No 1to 5 based on FERCI templates.

2. Any other matter with the permission of the chair:

- a. **Informed consent Clinic for PGs of Yenepoya University;** Since every Post graduate does one research and a dissertation, it was decided to train the PGs on how to Informed Consent, Participant Information Sheet after research methodology workshop for PGs. It is also Open for guides

Since there was no other matter for discussion, the meeting ended with vote of thanks.

Date: 21 July 2016
Place: Mangalore


Jt. Secretary, YUEC
Dr. Uma Kulkarni

Secretary
Yenepoya Ethics Committee-


Secretary
Yenepoya Ethics Committee-1

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Duralakube
Mangalore - 575 016, Karnataka



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Meeting Details and Minutes of Yenepoya Ethics Committee- 2

Sl. No.	Year	No. of Meetings
1.	2020-21	11
2.	2019-20	07
3.	2018-19	04
4.	2017-18	03

NO Sign noted

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Daralakatte
Mangalore - 575 018, Karnataka



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Yenepeya Ethics Committee 2

Yenepeya (Deemed to be University)

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration)No.: EC/NEW/INST/2020/1216

Meeting Summary	
Meeting Number	25
Date	12.06.2021
Day	Saturday
Timing	10.00 am
Members Present	, Dr. Kumuda Rao, Dr.Prasanna , Dr.H.Hari Kishore Bhat ,Dr. Leena Pramod, Dr. Padmini, Mr.Jayaram, Dr. Prabhakar Adake, Mrs.Jameela, Dr. Suphala Kotian, Dr. Rashmi Jain, Dr. Thippeswamy H G, Mrs. Smitha D
Members not present	Ms.Jaklin mary
Members not present with prior intimation	Dr. Vijaya Hegde,
Quorum	Present
Full Board Review	----
Protocol for Amendment	YEC2/826, YEC2/710, YEC2/430, YEC2/393, YEC2/105, YEC2/214
Completed Protocol	-----
Protocol for Continuing review	YEC2/ 413, YEC2/239, YEC2/ 214

The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.

The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson clarified whether any member had conflict of interest.

The Chairperson called upon the Member-Secretary to start the meeting on the agenda.

20. June 2021


Member Secretary
Yenepeya Ethics Committee 2
Yenepeya (Deemed to be University)
Mangalore


ATTESTED

Dr.Gangadhara Somayaji
Registrar
Yenepeya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 010, Karnataka

The following as per the agenda were discussed:

1. Discussion protocol for amendment
2. Discussion on Continuing review protocols
3. Discussion on Full review board protocols
4. Discussion on Continuing review annual report corrections
5. Any other matter with the permission of the chair.


Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED

Dr. Sahagadham Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Yenepoya
Mangalore- 575 013, Karnataka

Yenepoya Ethics Committee 2

Yenepoya (Deemed to be University)

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration)No.: EC/NEW/INST/2020/1216

Dr.Suphala Kotian :

Thank you sir,

Mrs.Smitha D: Thank you

Ujjwal

Signature of the member secretary

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Ujjwal
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
Ujjwal
Dr.Cangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka



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Yenepoya Ethics Committee 2

Yenepoya (Deemed to be University)

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration) No.: EC/NEW/INST/2020/1216

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Meeting Summary	
Meeting Number	24
Date	29. May.2021
Day	Saturday
Timing	10.00 am
Members Present	Dr. Vijaya Hegde, Dr. Kumuda Rao, Dr. Prasanna, Dr. H. Hari Kishore Bhat, Dr. Leena Pramod, Dr. Padmini, Mr. Jayaram, Dr. Prabhakar Adake, Mrs. Jameela Dr. Suphala Kotian, Dr. Rashmi Jain, Dr. Thippeswamy H G,
Members not present	Mrs. Smitha D
Members not present with prior intimation	Ms. Jaklin Mary
Quorum	Present
Full Board Review	YEC2/811
Protocol for Amendment	YEC/621, YEC2/681
Completed Protocol	YEC2/510, YEC2/449
Protocol for Continuing review	YEC2/213, YEC2/229, YEC2/228, YEC2/286, YEC2/379, YEC2/185, YEC2/184

The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.

The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson clarified whether any member had conflict of interest.

The Chairperson called upon the Member-Secretary to start the meeting on the agenda.

W. S. H. S.
**Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore**

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TESTED
**Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore- 575 018, Karnataka**

The following as per the agenda were discussed:

1. Discussion protocol for amendment
2. Discussion on Study completion report protocols
4. Discussion on Continuing review protocols
5. Discussion on Full review board protocols
6. Discussion on Continuing review annual report corrections
7. Any other matter with the permission of the chair.

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Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
[Signature]
Dr. Gangadhar Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore- 575 018, Karnataka

Yenepoya Ethics Committee 2

Yenepoya (Deemed to be University)

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration)No.: EC/NEW/INST/2020/1216

Dr. H.Hari Kishore Bhat: Thank you madam, Thank you all

Dr. Vijaya Hegde: Thank you

Signature of the member secretary

Ujjwal

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Ujjwal

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
Ujjwal

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 016, Karnataka



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DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration) No.: EC/NEW/INST/2020/1216

Meeting Summary	
Meeting Number	23
Date	26 th April 2021
Day	Monday
Timing	10.00 am
Members Present	Dr. Vijaya Hegde, Dr. Kumuda Rao, Dr. Prasanna, Dr. H. Hari Kishore Bhat, Dr. Leena Pramod, Dr. Padmini, Mr. Jayaram, Dr. Prabhakar Adake, Mrs. Jameela Dr. Suphala Kotian, Dr. Rashmi Jain, Dr. Thippeswamy H G,
Members not present	Mrs. Smitha D
Members not present with prior intimation	Ms. Jaklin Mary
Quorum	Present
Full Board Review	YEC2/ 789, YEC2/792
Protocol for Amendment	YEC2/284, YEC2/401, YEC2/647, YEC2/285, YEC2/241, YEC2/495, YEC2/ 630
Completed Protocol	YEC2/34, YEC2/119, YEC2/254, YEC2/249, YEC2/348, YEC2/292, YEC2/272, YEC2/161 YEC2/78
Protocol for Continuing review	YEC2/ 303, YEC2/304, YEC2/364, YEC2/251, YEC2/297, YEC2/241, YEC2/266, YEC2/227, YEC2/ 357, YEC2/226, YEC2/330, YEC2/324, YEC2/177, YEC2/243, YEC2/335, YEC2/273, YEC2/203, YEC2/ 182, YEC2/200, YEC2/284 YEC2/219 YEC2/217 YEC2/201, YEC2/ 218 YEC2/208, YEC2/ 225

The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.

The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson clarified whether any member had conflict of interest.

The Chairperson called upon the Member-Secretary to start the meeting on the agenda.

Uthol
Member Secretary
YenePOYA Ethics Committee 2
(Deemed to be University)
Mangalore

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Dr. Gangadhara Somayaji K.S.
Registrar
YenePOYA (Deemed to be University)
University Road, Derlakatte
Mangalore-575 015, Karnataka

The following as per the agenda were discussed:

1. Discussion protocol for amendment
2. Discussion on Study completion report protocols
4. Discussion on Continuing review protocols
5. Discussion on Full review board protocols
6. Discussion on Continuing review annual report corrections
7. Any other matter with the permission of the chair.

Ukkal
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
ls
Dr. Gangadhar Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore - 575 013, Karnataka

Yenepoya Ethics Committee 2

Yenepoya (Deemed to be University)

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration) No.: EC/NEW/INST/2020/1216

Ushant

Signature of the member secretary

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Ushant
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
[Signature]
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Mangalore
Mangalore - 575 016, Karnataka



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Yenepeya (Deemed to be University)

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration) No.: EC/NEW/INST/2020/1216

Meeting Summary	
Meeting Number	22
Date	18 th February 2021
Day	Saturday
Timing	10.00 am
Members Present	Dr. Vijaya Hegde, Dr. Kumuda Rao, Dr. Prasanna , Dr.H.Hari Kishore Bhat ,Dr. Leena Pramod, Dr. Padmini, Mr.Jayaram, Dr. Prabhakar Adake, Mrs.Jameela Dr. Suphala Kotian, Dr. Rashmi Jain, Dr.Smitha D,Ms.Jaklin Mary
Members not present	Dr. Thippeswamy H G,
Members not present with prior intimation	-----
Quorum	Present
Full Board Review	YEC2/701, YEC2/707, YEC2/554, YEC2/699, YEC2/ 762, YEC2/742
Protocol for Amendment	YEC2/176, YEC2/298, YEC2/427
Completed Protocol	YEC2/537 ,YEC2/525, YEC2/53 YEC2/156 YEC2/61 YEC2/74 YEC2/167 YEC2/144 YEC2/172 YEC2/36 , YEC2/ 07, YEC2/141
Protocol for Continuing review	YEC2/176, YEC2/197

The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.

The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson clarified whether any member had conflict of interest.

The Chairperson called upon the Member-Secretary to start the meeting on the agenda

Ujjwal
Member Secretary
Yenepeya Ethics Committee 2
Yenepeya (Deemed to be University)
Mangalore

ATTESTED
[Signature]
Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepeya (Deemed to be University)
 University Road, Deralakki, 575
 Mangalore - 575 016, Karnataka

The following as per the agenda were discussed:

1. Discussion protocol for amendment
2. Discussion on Study completion report protocols
4. Discussion on Continuing review protocols
5. Discussion on Full review board protocols
6. Discussion on Continuing review annual report corrections
7. Any other matter with the permission of the chair.

Ullas
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka



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DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration) No.: EC/NEW/INST/2020/1216

Dr .H.Hari Kishore Bhat: We done with full board review ma'am

Dr.Vijaya Hegde: Hari, What shall we do, Anything else to be discuss members

Dr .Leena pramod: Nothing maam

Dr.Vijaya Hegde: That's it hari. Shall we end the meeting, Thanks a lot

Dr .Padmini Thalanjeri: Thank you all

Ullas

Signature of the member secretary

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Ullas

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED

Ullas
Dr. Gangadhara Jayaji K.S.
Registration
Yenepoya (Deemed to be University)
University Road, Deralakatte,
Mangalore - 575 018, Karnataka



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Yenepeya (Deemed to be University)

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration) No.: EC/NEW/INST/2020/1216

Meeting Summary	
Meeting Number	21
Date	9 th January 2021
Day	Saturday
Timing	10.00 am
Members Present	Dr. Vijaya Hegde, Dr. Kumuda Rao, Dr. Prasanna, Dr. H. Hari Kishore Bhat, Dr. Leena Pramod, Dr. Padmini, Mr. Jayaram, Dr. Prabhakar Adake, Dr. Thippeswamy H G, Mrs. Jameela, Dr. Suphala Kotian, Dr. Rashmi Jain, Dr. Smitha D
Members not present	Ms. Jaklin Mary
Members not present with prior intimation	
Quorum	Present
Full Board Review	YEC2/553, YEC2/546
Protocol for Amendment	YEC2/388, YEC2/291
Completed Protocol	YEC2/505, YEC2/89, YEC2/500
Protocol for Continuing review	YEC2/202, YEC2/259

The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.

The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson clarified whether any member had conflict of interest.

The Chairperson called upon the Member-Secretary to start the meeting on the agenda.

The following as per the agenda were discussed:

1. Discussion protocol for amendment
2. Discussion on Study completion report protocols
4. Discussion on Continuing review protocols
5. Discussion on Full review board protocols
6. Discussion on Continuing review annual report corrections

Uthkar
Member Secretary
Yenepeya Ethics Committee 2
(Deemed to be University)
Mangalore

ATTESTED
[Signature]
Dr. Gangadhara Somayaji K S.
Registrar
Yenepeya (Deemed to be University)
University Road, Dorasikote
Mangalore - 575 018, Karnataka

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Yenepoya (Deemed to be University)

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration) No.: EC/NEW/INST/2020/1216

7. Decision on Continuation of the protocol number YEC2/263
8. Discussion on post trial assessment
9. Discussion on Protocol number YEC2/608
10. Discussion on email sending to the guides
11. Any other matter with the permission of the chair.

1. The members discussed about the following Protocol for amendment. The decision taken by full board review are as follows:

Protocol Number : YEC2/388

Name of the PI: Ms. Aysha CM

Title: Causes of, and potential responses to research misconduct

Nature of amendment: There will not be any changes to the conduct of the study, but I wish to get 2 documents approved- participant invitation flyer and google form version of informed consent for collecting data online.

Reason for requesting amendment:

1. Google form format of Informed Consent Document- as some of the participants prefer conducting in depth interviews online.
2. Participation Invitation Flyer- to brief the study details while approaching participants.

Lead Discussants: Dr .Thippeswamy H G

Dr. Prasanna Keshava B

Decision taken by the reviewer

1.Approved by the reviewer

Ushak
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
lb
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore - 575 018, Karnataka

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DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR (Provisional Registration) No.: EC/NEW/INST/2020/1216

reflect for UG protocols ,The same was discussed in the animal ethics committee. Because id principal investigator is the main responsible, no need to email the PG guide Since we are addressing to the PI ethical clearance we are addressing to the PI that how it is done

Dr.H.Hari Kishore Bhat: Then how it is done but what the registrar sir is requesting what the request was made is at least what we need to send the comments to them but at least given which we are sending for 15 days to remind these are the things copy can be mailed he has requested not the comments

Dr.Leena Pramod: Sir ,but PI they are the responsible

Dr.H.Hari Kishore Bhat: I agree all the comment everything will go on to the PI the PI is discussed with this what is telling is sequence of events ,now we send a reminder ,we send every 15 days reminder in master chart we drag everything is drag we don't have online system

Dr.H.Hari Kishore Bhat: Anything else ma'am

Mrs. Smitha d : Nothing sir

Dr.H.Hari Kishore Bhat: Shall we wind up

Dr.Leena Pramod: Yes sir

Dr.H.Hari Kishore Bhat: Thank you so much for everyone for attending ,and one more thing Once again happy new year to all this first our meeting of this year

Mr.Jayaram Padakannayya :Thank you same to you

Dr.Leena Pramod:Thank you

Dr.H.Hari Kishore Bhat:Hope everything goes well in 2021 an we are out of this pandemic ,Shall we wind up then

Mrs. Smitha d : Ok Sir,Thank you

Dr.Leena Pramod:Thank you Sir

Dr.Kumuda Rao:Thank you Hari

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Signature of the member Secretary

Member Secretary
YenePOYA Ethics Committee 2
YenePOYA (Deemed to be University)
Mangalore

ATTESTED
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Dr.Gangadhar Somayaji K.S.
Registrar
YenePOYA (Deemed to be University)
1st Floor, 2nd, Derlakatto
Mangalore - 575 018, Karnataka



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Yenepoya (Deemed to be University)

DCGI RegistrationNo.:ECR/1337/Inst/KA/2020

DHR Registration (Provisional certificate)No.:EC/NEW/INST/2020/1216

Meeting Summary	
Meeting Number	20
Date	12 th December 2020
Day	Saturday
Timing	10.00 am to 11.30 am
Members Present	Dr. Vijaya Hegde, Dr. Kumuda Rao, Dr.Prasanna ,Dr .H.Hari Kishore Bhat ,Dr. Leena Pramod Dr. Padmini, Mr. Jayaram, Dr. Prabhakar Adake, Ms.Jaklin Mary ,Mrs.Jameela Dr. Suphala Kotian, Dr.Rashmi Jain
Members not present	Ms.Jaklin Mary, Dr.Kumuda Rao, Dr.Thippeswamy H G
Members not present with prior intimation	-
Quorum	Present
Full Board Review	YEC2/629, YEC2/554, YEC2/624, YEC2/631, YEC2/634, YEC2/641, YEC2/623
Protocol for Amendment	YEC2/347, YEC2/445, YEC2/298, YEC2/439, YEC2/239
Completed Protocol	YEC2/22, YEC2/143, YEC2/57, YEC2/09, YEC2/446, YEC2/15, YEC2/18, YEC2/38, YEC2/20, YEC2/41, YEC2/35, YEC2/37, YEC2/95, YEC2/94, YEC2/16, YEC2/116, YEC2/106, YEC2/115, YEC2/98, YEC2/104
Protocol for Continuing review	YEC2/210, YEC2/239, YEC2/285
Minutes of the Meeting Approved by	Dr. H.Hari Kishore Bhat ,Dr. Vijay Hegde, Dr. Suphala S. Kotian, Dr. Leena Pramod ,Dr. Prasanna Keshava B

The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.

The Chairperson confirmed that the quorum was present and declared the meeting open.

The Chairperson clarified whether any member had conflict of interest.

The Chairperson called upon the Member-Secretary to start the meeting on the agenda.

The following as per the agenda were discussed

W. S. S.
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
W. S. S.

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
Mangalore, Karnataka
1 | Page

1. Discussion on Protocol for amendment
2. Discussion on Study completion report protocols
3. Discussion on Full board review protocols
4. Discussion on continuing review of protocols

Any other matter with the permission of the chair.

The members discussed about the following Protocol for amendment. The decisions taken by full board review are as follows:

Protocol Number : YEC2/347
 Name of the PI: Dr. Naziya RB
 Title: "A prospective study of role of bacteria in gall stone disease"
Nature of amendment: Reduction in sample size
Reason for requesting amendment: In view of reduction in case load of elective laproscopic cholecystectomy surgeries.

Lead Discussants: Dr. H.Hari Kishore Bhat

Decision taken by the meeting:
 1. Approved

Protocol Number : YEC2445
 Name of the PI: Dr. Mhaskar Zeeshan Munir
 Title: Evaluation of the role of dexamethasone in decreasing recurrence of in tussusception
Nature of amendment: Prospective study is changed to Hospital based retrospective study
Reason for requesting amendment: Not enough patients in COVID pandemic for prospective study

Lead Discussants: Dr. Rashmi Jain , Dr. Prabhakar Adake

Decision taken by the meeting:
 1. Approved

Protocol Number : YEC2/298
 Name of the PI: Dr. Najiya Nasrin
 Title: „Correlation of serum magnesium levels and severity of childhood asthma in a tertiary care teaching hospital.“
Nature of amendment: To reduce the sample size and extend the time period for the study
Reason for requesting amendment: Drastic reduction in asthma cases(3 in last 6 months) due to covid 19 pandemic

Lead Discussants: Dr.H.Hari Kishore Bhat, Dr. Prabhakar Adake

Decision taken by the meeting:
 1. Approved

(Signature)
 Member Secretary
 Yenepoya Ethics Committee 2
 Yenepoya (Deemed to be University)
 Mangalore

ATTESTED
(Signature)

Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Derlakatte
 Mangalore- 575 016, Karnataka

Ushat

Signature of the member secretary

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr. H.Hari Kishore Bhat
Ms. Pramitha

Yenepoya Ethics Committee 2, Yenepoya (Deemed to be University)
Floor -2(Basement), Yenepoya Dental College, Mangalore-575018
(0824)2206000- Extension Number

Ushat
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
[Signature]

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 16th November at 2 pm am. through google meet

Meeting No: 19

Members Present

Dr. Vijaya Hegde,
Dr. Kumuda Rao,
Dr. Prasanna ,
Dr .H.Hari Kishore Bhat ,
Dr. Leena Pramod
Dr. Padmini,
Mr. Jayaram,
Dr. Prabhakar Adake,
Dr. Thippeswamy H G,
Ms. Jaklin Mary
Mrs. Jameela
Dr. Suphala Kotian,

The following members were granted leave of absence:

Dr. Rashmi Jain,
Dr. Smitha D


The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.

The Chairperson confirmed that the quorum was present and declared the meeting open. The Chairperson clarified whether any member had conflict of interest.

The Chairperson called upon the Member-Secretary to start the meeting on the agenda.

The following as per the agenda were discussed

1. Discussion on Protocol for amendment
2. Discussion on Study completion report protocols
3. Discussion on Full board review protocols
4. Discussion on continuing review of protocols


Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Title: Oral health status and salivary parameters among smokers and non-smokers aged between 30-60 years – a cross sectional study.

Name of the PI: Dr.Soundarya S P

Protocol Number:YEC2/61

Title: "Comparative assessment of microbial adherence on two suture materials in periodontal flap procedures."

Name of the PI: Dr.Gudimetla Sruthi

Protocol Number:YEC2/51

3.Regarding SOP Committee meeting, members were decided reconstitute the SOP committee in that including the external members in SOP committee, existing sop will be sent to each members of the committee, and also decided that draft SOP will be complete within 7 to 8 weeks.

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Member Secretary
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Yenepoya (Deemed to be University)
Mangalore

Ushat

Dr.H.Hari Kishore Bhat
Member Secretary
Yenepoya ethics committee 2

Ushat
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Ushat
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 18.06.2020 at 2.00pm. through google meet

Meeting No: 14

Members Present

Dr. Vijaya Hegde
Dr. H.Hari Kishore Bhat
Dr. Padmini Thalanjeri
Dr. Prabhakar Adake
Dr. H.G.Thippeswamy
Dr. Rashmi Jain
Dr. Kumuda Rao
Dr. Prasanna Keshava B
Dr. Suphala S Kotian
Dr. Smitha. D
Mr. Jayaram Padakanayya
Mrs. Jameela

Agenda:

1. Discussion on amendment request protocol.
2. Discussion on extension of the study protocols.
3. Discussion Full board review protocols.
4. Discussion on Standard Operating Procedure of Yenepoya Ethics Committee 2
5. Discussion on DHR Registration
6. Discussion on regarding membership
7. General instruction mail to the principal investigator
8. Any other matter

5. The Quorum was established by Dr.Vijaya Hegde (Chairperson).

6. Previous minutes of meeting briefed out by Chairperson.

7. Agenda of the meeting presented by Member Secretary

Dr. H.Hari Kishore Bhat presented the progress report of the YEC2. YEC2 has reviewed 123 protocols in 2018 out of which 115 protocols have been given ethical clearance.

Remaining 8 protocols were asked to be submitted to Yenepoya ethics committee , since it involved high risk possibility of clinical trial registration and monitoring by SAE Committee of a DCGI registered ethics committee. 213 protocols were reviewed in 2019 of which 208 proposals

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Dr. Gangadhara Somayaji K.S.
Secretary
Yenepoya (Deemed to be University)
Mangalore-575 018, Karnataka

8. Dr.Padmini Thalanjeri discussed SOP 7B on expedite review and emphasised on the line for expedite review process
9. It was also discussed as per the notification by register date 30.08.2019.YEC2 will be handling
 - a. Post graduate dissertation/thesis (including super speciality)
 - b. Post graduate short studies
 - c. Undergraduate studies(Including ICMR-STs)

Ushat

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr.H.Hari Kishore Bhat
Member Secretary
Yenepoya ethics committee 2

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Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED
[Signature]
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Derlakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 10.08.2019 at 9.00 am in the Yenepoya Ethics committee 2 basement (-2 floor) Yenepoya Dental College

Meeting no: 8

1. Dr. Vijaya Hegde
2. Dr. H.Hari Kishore Bhat
3. Dr. Padmini Thalanjeri
4. Dr. Prabhakar Adake
6. Mr. Jayaram Padakanayya
7. Mrs. Jameela
8. Dr.Irene Veigas
9. Dr.Rashmi Jain

Agenda:

- 1.Discussion on Standard Operating Procedure of Yenepoya Ethics Committee 2

SOP NO	Title of the Standard Operating Procedures (SOP s)	Lead Discussants
SOP07A/v1	Initial Full Review of Research Study Protocols	Dr.Vijaya Hegde
SOP07B/v1	Expedited Review of Research Study Protocols	Dr.Padmini Thalanjeri
SOP7C/v1	Exemption from ethics review of Research Study Protocols	Dr.H. G.Thippeswamy
SOP08/v1	Agenda preparation, meeting procedures and recording of minutes	Dr.Smitha.D
SOP09/v1	Review of Resubmitted and Amended Protocols and Protocol-related Documents	Dr. Rashmi Jain
SOP10/v1	Continuing Review of Study Protocols	Dr.H.Hari Kishore Bhat

1. The Quorum was established by Dr.Vijaya Hegde (Chairperson).
2. Previous minutes of the briefed out by Chairperson.
3. Agenda of the meeting presented by Member Secretary.

Minutes of the meeting YEC-2 2018-2020

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*Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore*

ATTESTED
[Signature]
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore-575 018, Karnataka

4. Mrs.Smitha.D. detailed explained about the agenda of the meeting, and in the discussion members of the ethics committee decide to fix the monthly meeting of the Yenepoya Ethics Committee 2 for every second Saturday of the month.
5. Dr.Vijaya Hegde presented SOP about the initial full review of research study protocols.
6. Dr.H.Hari Kishore Bhat presented the onsite monitoring visit report.
7. Dr.H.Hari Kishore Bhat spoke about the NABH inspection.

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Dr.H.Hari Kishore Bhat
Member Secretary
Yenepoya ethics committee 2

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Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 22.06.2019 at 9.00 am in the Yenepoya Ethics committee 2
basement (-2 floor) Yenepoya Dental College

Meeting no: 7

1. Dr. Vijaya Hegde
2. Dr. H.Hari Kishore Bhat
3. Dr. Padmini Thalanjeri
4. Dr. Prabhakar Adake
5. Dr. Thippeswamy H G
7. Mr. Jayaram Padakanayya
8. Mrs. Jameela
9. Dr.Irene Veigas
10. Rashmi Jain

Agenda: Discussion on Standard operating procedure of Yenepoya Ethics Committee 2.

1. The Quorum was established by Dr.Vijaya Hegde (Chairperson).
2. Previous minutes of the briefed out by Chairperson.
3. Agenda of the meeting presented by Member Secretary.
4. Dr.Vijaya Hegde Chairperson of the YEC2 presented the SOP about Management of submission research study related documents
 - a)The Chairperson explain the duties and responsibilities of the member secretary, Joint member secretary, Members and Secretariat of the YEC2.
 - b) Discussed about the initial review of the protocol resubmission and Submission of protocol
- 5.Dr.H.Hari Kishore Bhat Presented the SOP about the preparation of Standard operating procedure of YEC2 and Categorization of new research protocols for initial review
- 6.Dr.Padmini Thalanjeri Spoke about the Selection, Roles and Responsibility of Members of YEC2
7. Dr.H.G.Thippeswamy detailed explained about the Conflict of interest and Types of Conflict Interest
8. Dr.Rashmi Jain presented SOP about the Procedure for allowing guest observer to Visit YEC2 or attend YEC2 meeting.

Ushant

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr.H. Hari Kishore Bhat
Member Secretary,
Yenepoya ethics committee 2

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Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Ushant
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 23.05.2019 at 9.00 am in the Yenepoya Ethics committee 2 basement (-2 floor) Yenepoya Dental College

Meeting no: 6

1. Dr. Vijaya Hegde
2. Dr. H.Hari Kishore Bhat
3. Dr. Padmini Thalanjeri
4. Dr. Prabhakar Adake
5. Dr. Thippeswamy H G
6. Dr. Smitha.D
7. Mr. Jayaram Padakanayya
8. Jameela
9. Dr.Irene Veigas

Agenda

1. Note on clinical trial
2. Full board review of 5 nursing protocols

1. The Quorum was established by Dr.Vijaya Hegde (Chairperson).
2. Previous minutes of the briefed out by Chairperson
3. Agenda of the meeting presented by Member Secretary

Sl. no	Protocol number	Title	Lead Discussants
1.	YEC2/140	"A study to assess the academic burn out and its contributing factors among undergraduate nursing students in selected college Mangalore	Dr. Irene Veigas
2.	YEC2/141	"Effectiveness of intradialytic stretching exercise on leg muscle cramps among patients undergoing hemodialysis in selected hospitals, Mangaluru"	Dr. Irene Veigas
3.	YEC2/142	" Effectiveness of planned early ambulation on selected post-operative outcome among caesarean mothers in Yenepoya Medical College Hospital at Mangaluru "	Dr. Padmini Thalanjeri
4.	YEC2/143	Effectiveness of ambulation during first stage of labor on maternal parameters among primigravida in a tertiary care hospital at Dakshina Kannada.	Dr. Smitha.D
5.	YEC2/144	"A study to assess the effectiveness of non nutritive sucking on weight and oral feeding attainment among preterm neonates admitted in Yenepoya Medical College Hospital, Mangaluru".	Dr. Padmini Thalanjeri

Ushata
Member Secretary
Yenepoya Ethics Committee
Yenepoya (to be University)
Mangalore

ATL
Dr. Somayaji K.S.
Registrar
(to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

The members discussed about the full board review protocols. The decision taken by full board review are as follows:

Minutes of the meeting YEC-2 2018-2020

1. [REDACTED] attainment among preterm neonates admitted in a private medical college Hospital ,Mangaluru” – a pilot study
2. The participation information sheet should [REDACTED]. Kindly attach a fresh PIS & IC stating clearly procedure for study groups.
3. [REDACTED] methodology. [REDACTED] among preterm neonates in control group.

Ushant

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr.H.Hari Kishore Bhat
Member secretary
Yenepoya ethics committee 2

Ushant
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Ushant
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 13th April 2019 at 9.30 am in the Yenepoya Ethics committee 2 basement (-2 floor) Yenepoya Dental College

Meeting no: 5

1. Dr.Vijaya Hegde
2. Dr. H.Hari Kishore Bhat
3. Dr. Padmini Thalanjeri
4. Dr.Prabhakar Adake
5. Dr.Thippeswamy H G
6. Dr.Smitha.D
7. Dr.Rashmi Jain
8. Mr.Jayaram Padakanayya
9. Jameela

Agenda

- 1.Introduction of new members
- 2.Briefing of last year activities
- 3.Discussion on further training of members
- 4.Note on ICMR guidelines

1. The Quorum was established by Dr.Vijaya Hegde (Chairperson).
2. Previous minutes of the briefed out by Chairperson
3. Agenda of the meeting presented by Member Secretary.
4. The chairperson introduce the new members

- Jayaram Padakannyya -Advocate (External member)
- Dr. Rashmi Jain –Associate Professor ,M.B.B.S, MS (Internal Member)
- Mrs.Jameela- Lay person (External member)

5.The chairperson announce the Padmini Thalanjeri being the Joint member secretary of the Yenepoya Ethics Committee 2

6.Dr.H.Hari Kishore Bhat present the last academic year activities

In last year Yenepoya Ethics Committee 2 received the 123 protocols from dental and medical college postgraduates student out of 123 protocols 115 Clearance have been given ethical clearance. Remaining 8 protocols were asked to be submitted to Yenepoya ethics committee,

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Yenepoya Ethics Committee 2
Member Secretary
Yenepoya (Deemed to be University)
Mangalore

since it involved high risk possibility of clinical trial registration and monitoring by SAE Committee of a DCGI registered ethics committee.

6. Dr.H.Hari Kishore Bhat spoke about ICMR Guidelines

7. Dr.Padmini Thalanjeri Presented article about ICMR

Title: The new Indian ethical guidelines for biomedical and health research delving new vistas

Author: Raj GM, Priyadrshini R

8. Regarding training of the ethics committee members, 5 members are nominated for 1 swear training programme.

Sl.no	Name	Organisational title
1.	Dr.Prabhakar Adake	Member
2.	Dr.Thippeswamy H G	Member
3.	Mr.Jayaram Padakanayya	External Member
4.	Mrs. Jameela	External Member
5.	Ms.Pramitha	YEC2 Secretariat

Witness

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr.H.Hari Kishore Bhat
Member secretary
Yenepoya ethics committee 2

Witness
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Witness
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 16th January 2019 at 10.30 am in the Yenepoya Ethics committee 2 basement (-2 floor) Yenepoya Dental College

Meeting No: 04

Members Present

1. Dr.Vijaya Hegde
2. Dr. H.Hari Kishore Bhat
3. Dr. Padmini Thalanjeri
4. Dr.Prabhakar Adake
5. Dr.Thippeswamy H G
6. Dr.Smitha.D

Agenda :

1. Report on the review of the 125 protocols
2. Discussion on new members
3. Streamlining the archiving protocols
4. Formation of SAE committee
5. Uploading document for DCGI approval
6. Discussion on ICMR Guidelines

1. The Quorum was established by Dr.Vijaya Hegde (Chairperson).
2. Previous minutes of the briefed out by Chairperson
3. Agenda of the meeting presented by Member Secretary.
4. Dr.H.Hari Kishore Bhat presented the Report of 123 protocols
YEC2 has reviewed 123 protocols in 2018 out of which 115 protocols have been given ethical clearance. Remaining 8 protocols were asked to be submitted to Yenepoya ethics committee, since it involved high risk possibility of clinical trial registration and monitoring by SAE Committee of a DCGI registered ethics committee.
5. Regarding new members, External subject expert in all the special department was planned and the names have to be finalised after intimating the person and taking his permission

6. ICMR guidelines for the recent changes in the consent form was discussed and reviewed the members.

7. SAE Committee was formed with following members

1. Dr.Vijaya Hegde
2. Dr. H.Hari Kishore Bhat
3. Dr. Padmini Thalanjeri
4. Dr.Prabhakar Adake
5. Dr.Thippeswamy H G

Minutes of the meeting YEC-2 2018-2020

Uthahat
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Page 159

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Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
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8. Uploading document for DCGI approval is pending and will be initiated shortly.

Ushat

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Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr.H.Hari Kishore Bhat
Member secretary
Yenepoya ethics committee 2

Ushat
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Ushat
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Minutes of the meeting held on 20th June 2018 at 11.00 am Clinical demonstration room, Post operative unit, Wing B, dept of Anaesthesia(Recovery room-opposite to OT Complex) 6 th floor, Yenepoya Medical college Hospital,

Meeting No:03

Members Present

Dr. Vijaya Hegde
 Dr.Thippeswamy H G
 Dr.Prabhakar Adake
 Dr.Smitha.D
 Dr.Irene Veigas
 Dr. H,Hari Kishore Bhat

Agenda:

1. Presentation of SOP final approval
2. Presentation of NABH accreditation procedure-Workshops attended by Member secretary
3. Formation of SAE committee for YEC2

1. The Quorum was established by Dr.Vijaya Hegde (Chairperson).
2. Previous minutes of the briefed out by Chairperson
3. Agenda of the meeting presented by Member Secretary.
4. SOP team members presented the Final SOP approval

Yenepoya Ethics Committee 2 final SOP as follows:

SI. No	SOP NO	Title of the Standard Operating Procedures (SOP s)
1	SOP01/v1	Preparation of Standard Operating Procedures for Yenepoya Ethics Committee 2
2	SOP02/v1	Constitution of Yenepoya Ethics Committee (YEC2), Selection, Roles and Responsibilities of Members of the Yenepoya Ethics Committee 2
3	SOP03/v1	Handling Conflict of Interest among Ethics Committee Members in Yenepoya Ethics Committee 2
4	SOP04/v1	Selection and Responsibilities of Independent Consultants in Yenepoya Ethics Committee 2

Handwritten signature and stamp:
 Member Secretary
 Yenepoya Ethics Committee 2
 Yenepoya (Deemed to be University)
 Mangalore

Stamp and signature:
ATTESTED
 Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya Medical College
 University Road, Deralakatte
 Mangalore - 575 018, Karnataka

5	SOP05/v1	Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee 2 or attend Yenepoya Ethics Committee 2 meeting
6	SOP06/v1	Management of Submission of Research Study Related Documents
7	SOP07/v1	Categorisation of new research protocols for initial review in Yenepoya Ethics Committee 2
8	SOP7A/v1	Initial Full Review Research study Protocols in Yenepoya Ethics Committee 2
9	SOP7B/v1	Expedited Review of Research Study Protocols Yenepoya Ethics Committee 2
10	SOP7C/v1	Exemption from Ethics Review of Research Study Protocols in Yenepoya Ethics Committee 2
11	SOP08/v1	Agenda Preparation, Meeting Procedures and Recording of Minutes
12	SOP09/v1	Review of resubmitted and Amended Protocols and Protocol-related Documents in Yenepoya Ethics Committee 2
13	SOP10/v1	Continuing Review of Study Protocols in Yenepoya Ethics Committee 2
14	SOP11/v1	Review of Protocol Deviations/Violations in Yenepoya Ethics Committee 2
15	SOP12/v1	Review of Serious Adverse Events(SAE) Reports in Yenepoya Ethics Committee 2
16	SOP13/v1	Review of Study Completion Reports in Yenepoya Ethics Committee 2
17	SOP14/v1	Management of Premature Termination /Suspension/Discontinuation of the Study in Yenepoya Ethics Committee 2
18	SOP15/v1	Waiver of Written/Verbal Informed Consent in Yenepoya Ethics Committee 2
19	SOP16/v1	Site Monitoring and Post Monitoring Activities in Yenepoya Ethics Committee 2
20	SOP17/v1	Dealing with Participants 'Request and/or Complaints in Yenepoya Ethics Committee 2
21	SOP18/v1	Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of closed Files and Retrieval of Documents in Yenepoya Ethics Committee 2
22	SOP19/v1	Reviewing Proposals involving Vulnerable Populations in Yenepoya Ethics Committee 2
23	SOP20/v1	Preparing for Yenepoya Ethics Committee 2 Audit/Inspection
24	SOP21/v1	Training and Assessment of Ethics Committee Members in Yenepoya Ethics Committee 2
25	SOP22/v1	Special consideration for Clinical trials in Ayurveda, Siddha, Unani, Yoga and Naturopathy protocol submission in Yenepoya Ethics Committee 2

Member Secretary
Yenepoya Ethics Committee 2
(Deemed to be University)
Mangalore

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

2. Dr .H.Hari Kishore Bhat presented about the importance of NABH accreditation procedure.
3. SAE committee was formed with following members:

1. Dr.Vijaya Hegde
2. Dr.H.Hari Kishore Bhat
3. Dr.Prabhakar Adake
4. Dr.Padmini Thalanjeri
5. Dr. H.G.Thippeswamy

Ushat

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr.H.Hari Kishore Bhat
Member secretary
Yenepoya ethics committee 2

Ushat
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Ushat
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 9th March 2018 at 10.30 am Clinical demonstration room, Post operative unit, Wing B, dept of Anaesthesia(Recovery room-opposite to OT Complex) 6 th floor, Yenepoya Medical college Hospital,

Meeting No:02

Members Present

Dr. Vijaya Hegde
Dr.H.Hari Kishore Bhat
Dr. H.G.Thippeswamy
Dr. Smitha. D
Dr.Irene Veigas

Agenda:

1. Discussion on YEC2 SOP's
2. Place for YEC2 office decided
3. Progress review of SOP's

1. The Quorum was established by Dr.Vijaya Hegde (Chairperson).
2. Previous minutes of the briefed out by Chairperson
3. Agenda of the meeting presented by Member Secretary.
4. Members discussed regarding SOP preparation and decided format the SOP team members. In this regard 5 members are nominated for SOP preparation team.
 - a. Dr.Vijaya Hegde
 - b. Dr.H.Hari Kishore Bhat
 - c. Dr.Prabhakar Adake
 - d. Dr.H.G.Thippeswamy
 - e. Dr.Smitha.D
5. YEC2 members discussed about place for YEC2 office. Finally members decided that YEC2 office functioned at (-2 floor Basement) Yenepoya Dental college, Deralakatte.
6. Dr. H.Hari Kishore Bhat presented the progress report of the YEC2.


Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

W. Kishore

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr.H.Hari Kishore Bhat
Member secretary
Yenepoya ethics committee 2

W. Kishore
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED

Gy
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting held on 1st February 2018 at 10.30 am Clinical demonstration room, Post operative unit, Wing B, dept of Anaesthesia(Recovery room-opposite to OT Complex) 6 th floor, Yenepoya Medical college Hospital,

Meeting No:01

Members Present

Dr. Vijaya Hegde
Dr.H.Hari Kishore Bhat
Dr. Balakrishna Sharma N
Dr. Padmini Thalanjeri
Dr. Prabhakar Adake
Dr. H.G.Thippeswamy
Dr. Smitha. D

Guest /Guest Speakers

1. Ravi Vaswani (Faculty in Centre for ethics)
2. Uma Kulkarni (Member secretary of Yenepoya Ethics Committee 1)

Agenda:

1. Introduction of the new members
2. Debriefing by the faculty of Centre for ethics
Dr. Ravi Vaswani and Dr.Uma Kulakarni
3. Formation of SOP members /any other matter to be discussed

1. The Quorum was established by Dr.Vijaya Hegde (Chairperson).
2. Agenda of the meeting presented by Member Secretary.
3. The chairperson introduce the new members.
4. Members discussed regarding SOP document preparation.

SOP committee was formed with following members

1. . Dr.Vijaya Hegde
- b. Dr.H.Hari Kishore Bhat
- c. Dr.Prabhakar Adake
- d. Dr.H.G.Thippeswamy
- e. Dr.Smitha.D

Uthayak
Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

ATTESTED

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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting YEC-2 2018-2020

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Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

Dr.H.Hari Kishore Bhat
Member secretary
Yenepoya ethics committee 2

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Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)
Mangalore

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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



YENEPOYA

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Recognized under Sec 3(A) of the UGC Act 1956

Accredited by NAAC with 'A' Grade

Meeting Details and Minutes of Institutional Animal Ethics Committee (IAEC)

Sl. No.	Year	No. of Meetings
1.	2020-21	02
2.	2019-20	02
3.	2018-19	03
4.	2017-18	02
5.	2016-17	03

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Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

YENEPOYA (DEEMED TO BE UNIVERSITY)
INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]
347/PO/ReBi-S/Rc-L/01/CPCSEA

MINUTES:

The minutes of the 27th meeting of YU-IAEC held on 25th January 2021 at 09.30 am-1:00pm via online video conferencing app-Google meet is as follows, Meeting was recorded.

Chairman welcomed the members of the YU-IAEC for the meeting.

Snapshot of members attending the online meeting was taken as proof of conduct of online meeting.

The following members attended the meeting:

1. Dr. Roopa P Nayak [Chairman]
2. Dr. Hemanth Gowda [Main Nominee CPCSEA]
3. Dr. Megha Rani N [Member Secretary]
4. Dr. Murali B [Socially Aware Nominee]
5. Dr. K.L. Krishna [Scientist from outside the Institute]
6. Dr. Bindu S [Member]
7. Dr. Vidya Pai [Member]
8. Dr. Suprith Surya [Member]

Member secretary thanked all the members for acknowledging the agenda circulated through mail and she read out the minutes of 26th IAEC meeting held on 3rd July 2020 with action taken.

The following proposals were discussed and concluded.

Sl No	Project Title and Principal Investigator	Remarks
NEW PROJECTS		
1	Silk fibroin- anastrazole in situ injectable: A novel targeted treatment cancer by Ms. Arfa Nasrine Under the guidance of Dr. Mohammed Gulzar Ahmed	Approved 36 Sprague Dawley rats on submission of invitro data (In situ gel formulations, skin irritation test etc). IAEC certificate no: YU/IAEC/1/2021.
2	Design and evaluation of in situ gels of bevacizumab for ophthalmic delivery by Ms.	Approved 24 wistar albino rats on submission of


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	Soumya under the guidance of Dr. Mohammed Gulzar Ahmed	invitro data (in situ gel formulations, skin irritation test etc) IAEC certificate no: YU/IAEC/2/2021.
3	Role of PAI-1 in Regulating Basement Membrane Proteins and Matrix-Metaloproteinases by Ms. Fathimath Muneesa M under guidance of Dr. Yashodhar P Bhandary	Revised form B and protocol to be submitted with additional references on duration of study and dose of drug. Approved 30 C57BL/6 mice IAEC certificate no: YU/IAEC/3/2021.
4	Modulation of Quorum Sensing in Selected Gram-Negative Pathogenic Bacteria Using Novel Molecules by Ms. Saptami U Kanekar under the guidance of Dr. Rekha P D	Revised form B and protocol with scientific justification of grouping, In vitro study data and IBSC certificate to be submitted. Approved 24 swiss albino mice on submission of above documents IAEC certificate no: YU/IAEC/4/2021.
5	Evaluation of in vivo neuroprotective activity of bergenin against cerebral ischemia reperfusion injury in rats by Mrs. Sindhu Priya E S	Revised form B and protocol to be submitted. Approved 36 wistar albino rats after submission of in vitro study data. IAEC certificate no: YU/IAEC/5/2021.
6	Evaluation of in vivo antiulcer activity of Callicarpa tomentosa plant extract by Mrs. Sindhu Priya E S	Revised form B and protocol to be submitted. Approved 56 wistar albino rats after submission of in vitro data and phytochemical characterization details IAEC certificate no:

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Mangalore-575 018, Karnataka

		YU/IAEC/6/2021.
7	Evaluation of antiparkinsonian and memory enhancer activity of Cinnamomum tamala in mice by Mrs. Sindhu Priya E S	Approved 30 swiss albino mice. IAEC certificate no: YU/IAEC/7/2021.
8	Evaluation of cardio protective activity of Triphala against Isoproterenol induced Myocardial Infarction by Mrs. Tahreen Taj	Approved 24 wistar albino against 36 wistar albino rats requested. IAEC certificate no: YU/IAEC/8/2021.
9	Evaluation of in vivo wound healing activity of Callicarpa tomentosa plant extract by Mrs. Tahreen Taj	Revised form B and protocol to be submitted. Approved 18 rats against 36wistar albino rats requested. IAEC certificate no: YU/IAEC/9/2021.
10	Development and Evaluation of Cubosomes Containing Tacrolimus and Dexamethasone for the Treatment of Vitiligo by Ms. Sanjana A	Revised form B and protocol to be submitted. Approved 36 C57BL/6 mice after scientific justification for sacrifice of animals. IAEC certificate no: YU/IAEC/10/2021.
12	Deciphering the possible osteogenesis of mammalian mesenchymal stem cells using various dilutions (potencies) of homeopathic medicine Ferula asafoetida in vitro by Dr. Bipasha Bose	Approved 32 Balb/c mice/year IAEC certificate no: YU/IAEC/11/2021.
EXTENSION		
1	Evaluation of cardioprotective and antihyperlipidemic activities of Syzygium campanulatum and Callicarpa tomentosa leaf extracts in wistar albino rats by Ms. Nadira Noushida under guidance of Dr. Roopa P Nayak YU/IAEC/8/2020-25/01/2020	Approval for use of remaining 42 Wistar albino rats for the first year of the study extended for one year. IAEC certificate no: YU/IAEC/8/2020. ATTESTED 

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2	Role of Thymoquinone in regulation of Pro inflammatory cytokines and Pro fibrotic components during Sepsis induced Acute Kidney Injury by Mr. Anwar A.S under guidance of Dr. Ramadas Naik YU/IAEC/20/2019- 14/09/2020	Approval for use of remaining 12Balb/c Mice extended for one year. IAEC certificate no: YU/IAEC/20/2019
3	Assessment of cellular and molecular changes with response to thoron inhalation in mice by Dr. Bipasha Bose - IAEC NO.: 9/9.06.2016	Approval for use of remaining 90 Balb/c mice IAEC certificate no: 9/9.06.2016
RENEWAL- In view of Covid pandemic one year extension was approved to the below projects and same IAEC clearance number is retained.		
1	Development of a wound healing material from the biopolymers produced by two novel bacterial strains isolated from West Coast of India by Dr. Rekha P D- YU/ IAEC/6/2020 – 25/01/2020	Approved 60wistar albino rats. IAEC certificate no: YU/IAEC/6/2020.
2	Development of an exopolysaccharide-based bio ink and the pre-clinical evaluation of its action on wound healing by Ms. Athmika under guidance of Dr. Rekha P D - YU/ IAEC/19/2020 – 14/09/2019	Approved 54 wistar albino rats. IAEC certificate no: YU/IAEC/19/2019
3	Enhancing the efficiency of growth factor release from platelets using natural sulfated polysaccharide nanoparticles for treating chronic wounds by Ms. Sneha S Rao under the guidance of Dr. Rekha P D YU/IAEC/19/2020 – 25/01/2020	Approved 60 C57BL/6 mice as requested for the study. IAEC certificate no: YU/IAEC/19/2020.
4	A Study On The Role Of Steridiogenesis Activating Transcription Factor 3 In The Development Of Hypospadias On Male Mice Induced By Finasteride - A Randomized Controlled Trial by Dr Bindhu S YU/IAEC/18/2020 – 25/01/2020	Approved 10 female and 5 male swiss albino mice for the study. IAEC certificate no: YU/IAEC/18/2020.
5	Evaluation of antidepressant properties of ethanolic extract of root of rubia cordifolia in swiss albino mice by Dr Karri Ramesh Kumar Under the guidance of Dr Roopa P Nayak- YU/ IAEC/17/2019 – 14/09/2019	Approved 24 swiss albino mice. IAEC certificate no: YU/IAEC/17/2019

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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

6	Evaluation of Anxiolytic Properties of Hydro-Alcoholic Extract of <i>Aegle marmelos</i> Fruit (<i>Bael Fruit</i>) in Swiss Albino Mice by Dr. Shefeek S N Under guidance of Dr. Nagapati P Bhat YU/ IAEC/18/2019 – 14/09/2019	Approved 30 swiss albino mice IAEC certificate no: YU/IAEC/18/2019
7	Development of thermoresponsive polymer nanogels for sustained release of Bevacizumab towards efficient treatment of diabetic macular edema by Dr. Renjith P Johnson YU/IAEC/15/2020- 25/01/2020	Approved 24 rabbits as requested for the study. IAEC certificate no: YU/IAEC/15/2020.
8	Application of Calendula officinalis in promoting granulation tissue growth in wound healing by Dr. A. Vincer George. YU/IAEC/7/2020 -25/01/2020	Approved 42wistar albino rats for the first phase of the study. IAEC certificate no: YU/IAEC/7/2020
9	Developing liver transplant skills in Surgeons using Swine model by Dr. Rohan Shetty- YU/ IAEC/1/2020 – 25/01/2020	Recommended for CPCSEA approval. YU/ IAEC/1/2020
10	To develop renal transplant skills in Surgeons using Swine model by Dr. Mujeeburahiman M- YU/ IAEC/2/2020 – 25/01/2020	Recommended for CPCSEA approval YU/ IAEC/2/2020
Other matters		
1	In view of COVID pandemic related lockdown and following request from PI, the below mentioned projects were given 3 months of extension A. Chitosan and silk fibroin topical hydrogel for blood clotting and wound healing by Ms.Soumya. (YU/ IAEC/15/2019) – 14/09/2019 B. Design and evaluation of a neem (<i>Azadirachta Indica</i>) loaded silk fibroin formulation for wound healing effect by Ms. Arfa Nasrine(YU/ IAEC/16/2019) -14/09/2019 C. Role of Thymoquinone in regulation of Pro inflammatory cytokines and Pro fibrotic components during Sepsis Induced Acute Kidney Injury by Mr.Anwar.AS.(YU/ IAEC/20/2019) - 14/09/2019	
2	Project title amendment ratification YU/IAEC/24/2020 (meeting date – July 3rd 2020) – Title amended to “Microspheres containing nanostructured transition metal dichalcogenides for bone tissue repair and regeneration” by Mr. Pandurang Appana Dalavi under the guidance of Dr. J Venkatesan.	

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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

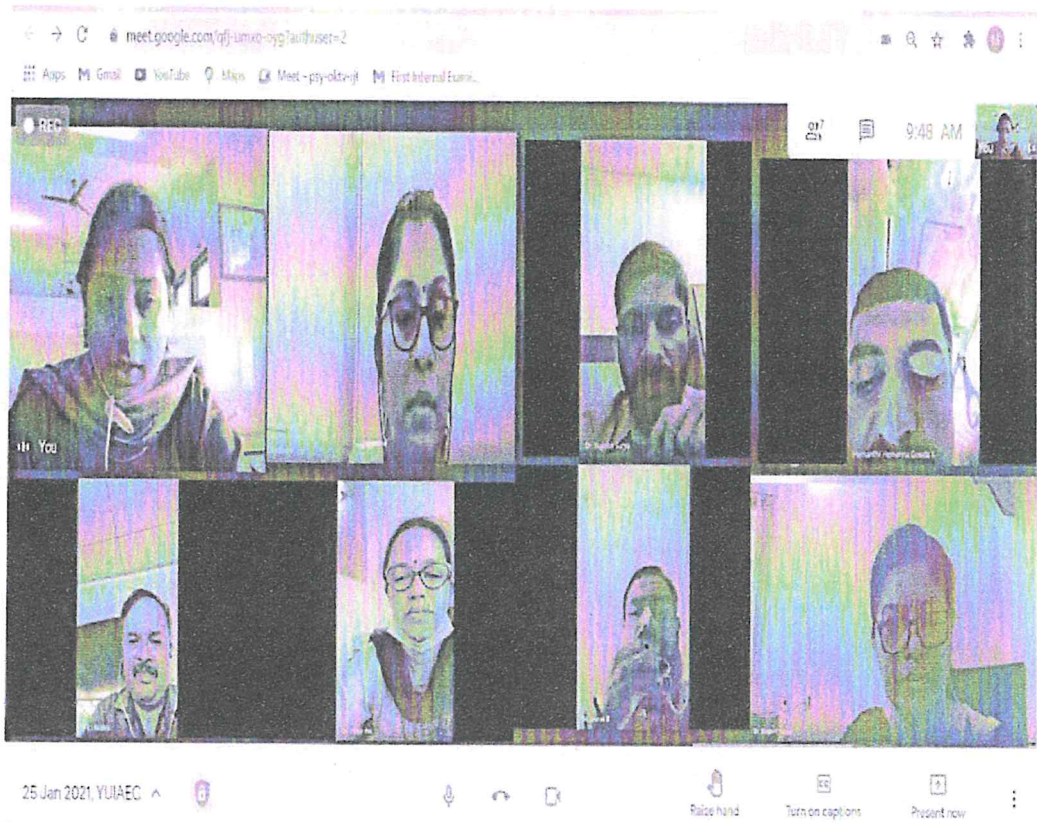
3	<p>Breeding approval and amendment in Registration No</p> <p>The YU animal house inspection for the purpose of breeding was conducted on 28/08/2020 by Dr. Ravikumar C and the CPCSEA permission was received 09/11/2020. The registration No is amended to 347/PO/ReBi-S/Rc-L/01/CPCSEA</p>
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After detailed discussion, the IAEC members approved 12 revised Form Bs of new projects and approved the use of total number of 152 mice and 194 rats. Member secretary proposed the vote of thanks to the members for attending the meeting.

Roopa Kuni A. 27/11/2021
~~Chairman / Member Secretary~~
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 Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Deralakatte
 Mangalore-575 018, Karnataka



Roopa Kuni.A.
25/1/2021
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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

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INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]
347/PO/Re-S/Rc-L/01/CPCSEA

MINUTES:

The minutes of the 26th meeting of YU-IAEC held on 3rd July 2020 at 10.30 am-12:30pm via online video conferencing app- Google meet is as follows, Meeting was recorded.

Chairman welcomed the members of the YU-IAEC for the meeting.

Snapshot of members attending the online meeting was taken as proof of conduct of online meeting.

Member secretary thanked all the members for acknowledging the agenda circulated through mail and she read out the minutes of 25th IAEC meeting held on 25th January 2020 with action taken.

The following proposals were discussed and concluded.

Sl No	Project title and Principal Investigator	Remarks
1.	Molecular changes/damages, in the ocular surface associated stem cell populations, in response to, acute exposures to ultraviolet radiation (UVR) dose ranges and amelioration using novel Epigallocatechin gallate (EGCG) analogs from marine sources: an in vitro study by Dr. Bipasha Bose	Revised form B and protocol to be submitted. She has Applied for 36 mice for a period of 3 years but Approved 12 Swiss albino mice for one year. Further extension to be applied. IAEC certificate no: YU/IAEC/22/2020.
2.	Inducing reversal of skeletal muscle atrophy in Type 2 diabetes by intrinsic stem cell mobilization using bioactive lipids by Dr. Sudheer Shenoy P	Approved 30 C57BL/6 mice for one year subject to funding approval. IAEC certificate no: YU/IAEC/23/2020.
3.	Polymeric scaffolding system containing nanostructured transition metal dichalcogenides for bone tissue repair and regeneration by Dr. J. Venkatesan	Revised form B and protocol to be submitted. Approved 12 New Zealand white rabbits. IAEC certificate no: YU/IAEC/24/2020.
4.	Evaluation of antiparkinsonian and memory enhancer activity of	Resubmission in the next meeting with changes in the

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	<i>Cinnamomum tamala</i> in mice by Dr. Manodeep Chakraborty	form B. B-Pharm (UG) students are not eligible to conduct animal experiments as per CPCSEA guidelines mentioned in CPCSEA compendium 2018.
5.	Evaluation of cardio protective activity of Triphala against Isoproteronol induced Myocardial Infarction by Dr. Manodeep Chakraborty	Resubmission in the next meeting with changes in the form B. B-Pharm (UG) students are not eligible to conduct animal experiments as per CPCSEA guidelines mentioned in CPCSEA compendium 2018.
6.	Evaluation of <i>in vivo</i> antiulcer activity of <i>Callicarpa tomentosa</i> plant extract by Mrs. Sindhu Priya E S	Resubmission in the next meeting with changes in the form B. B-Pharm (UG) students are not eligible to conduct animal experiments as per CPCSEA guidelines mentioned in CPCSEA compendium 2018.
7.	Evaluation of <i>in vivo</i> wound healing activity of <i>Callicarpa tomentosa</i> plant extract by Mrs. Sindhu Priya E S	Resubmission in the next meeting with changes in the form B. B-Pharm (UG) students are not eligible to conduct animal experiments as per CPCSEA guidelines mentioned in CPCSEA compendium 2018.
8.	Neuroprotective role of <i>Phyllanthus amarus</i> on Adenine induced Chronic Kidney Disease experimental model of Rats Mr. Kevin Joakim Pinto	Resubmit corrected Form-B. Approved 36 Wistar albino rats. IAEC certificate no: YU/IAEC/25/2020.
9.	Possibility of urinary tract colonization by a recently described <i>Kalamiella piersonii</i> strain YU-22 by Dr. Rekha P D	Approved 12 Swiss albino female mice IAEC certificate no: YU/IAEC/26/2020.

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Yenepoya (Deemed to be University)
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10.	Developing innovative acute respiratory distress (ARDS) ventilatory strategies and skills in Intensivists & Anesthesiologists in Swine model by Dr. Thippeswamy H G	Recommended for approval from CPCSEA with the request for validity of 2 years. 30 Sus scrofa, White Yorkshire pigs Either sex IAEC No: YU/IAEC/27/2020.
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After detailed discussion, the IAEC members approved 6 revised Form B and approved the use of total number of 54 mice, 36 rats and 12 rabbits.

Member secretary informed all the members that the minutes will be mailed to all and requested to send the approval for the same.

Chairman proposed the vote of thanks to the members for attending the online meeting.

Roopa Kuni A
3/7/2020
Chairman / Member Secretary
YU, IAEC

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Chairman / Member Secretary
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[Signature]
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

YENEPOYA (DEEMED TO BE UNIVERSITY)
INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]

347/PO/Re-S/Rc-L/01/CPCSEA

MINUTES:

The minutes of the 25th meeting of YU-IAEC held on January 25th, 2020 at 9.00 am-12.30 pm is as follows,

Chairman welcomed the members of the YU-IAEC for the meeting.

Member secretary read out the minutes of 24th IAEC meeting held on 14th September 2019 with action taken.

The following proposals were discussed and concluded.

Sl. No	Project title and Principal Investigator	Remarks
1.	Developing liver transplant skills in surgeons using swine model by Dr. Rohan Shetty	Recommended for approval from CPCSEA with the request for validity of 2 years. IAEC NO: YU/IAEC/1/2020
2.	Developing renal transplant skills in surgeons using swine model by Dr. Mujeeburahiman	Recommended for approval from CPCSEA with the request for validity of 2 years. IAEC NO:YU/IAEC/2/2020
3.	Evaluation of Antidepressant Properties of Hydro-Alcoholic Extract of <i>Aegle marmelos</i> Fruit (Bael Fruit) In Swiss Albino Mice by Dr. Shefeek S N	Approved 30 rehabilitated swiss albino Mice (YU/IAEC/18/2019). IAEC certificate no: YU/IAEC/3/2020.
4.	Development of antifungal hydrogels against dermatophytes by Dr. Rajesh P Shastry	Revised form B and protocol to be submitted. Approved 54 female wistar albino rats for the study subject to submission of IBSC approval. IAEC certificate no: YU/IAEC/4/2020.
5.	To evaluate the cardioprotective effect of Crataeva Magna against Isoproterenol induced myocardial injury by Dr. Manodeep Chakraborty	Revised form B and protocol to be submitted. Approved 24 wistar albino rats. IAEC certificate no: YU/IAEC/5/2020.

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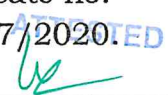
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Registrar
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6.	Development of a wound healing material from the biopolymers produced by two novel bacterial strains isolated from the west coast of India by Dr. Rekha P D	Revised form B and protocol to be submitted. Approved 60 wistar albino rats. IAEC certificate no: YU/IAEC/6/2020.
7.	Application of <i>Calendula officinalis</i> in promoting granulation tissue growth in wound healing by Dr. A. Vincer George	Revised form B and protocol to be submitted. Approved 42 wistar albino rats for the first phase of the study. IAEC certificate no: YU/IAEC/7/2020.
Resubmission		
8.	To evaluate cardioprotective and antihyperlipidemic activities of <i>Syzygium campanulatum</i> and <i>Callicarpa tomentosa</i> leaf extracts in rats by Ms.Nadira Noushida	Revised form B and protocol to be submitted. Approved 84 Wistar albino rats for the first year of the study. IAEC certificate no: YU/IAEC/8/2020.
Extension		
9.	Effect of valeric acid on alzheimer's disease induced rats: a behavioral and biochemical study. (YU/IAEC/4/2018) – 03/02/2018 by Ms. D. Blessina Sugandhi	Revised form B and protocol to be submitted. Approved 42 wistar albino rats as requested for the study. IAEC certificate no: YU/IAEC/9/2020.
10.	Effect of Quercetin on Cardio-Protective effect of Resveratrol against Isoproterenol induced myocardial injury. (YU/IAEC/1/2019) – 28/01/2019 by Dr. Mohammed Gulzar Ahmed	Revised form B and protocol to be submitted. FTIR data to be submitted before start of the study. Approved 36 wistar albino rats for Pharmacokinetic study, same animals can be used for pharmacodynamic study after a wash out period of 10 days. IAEC certificate no: YU/IAEC/10/2020.
11.	Formulation and study the effect of resveratrol phytosomes alone and in combination with piperine to treat	Revised form B and protocol to be submitted. FTIR data to be submitted before start of the

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Registrar
Yenepoya(Deemed to be University)
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	myocardial infarction (YU/IAEC/2/2019) – 28/01/2019 by Ms. Thriveni M	study. Approved 30 wistar albino rats for Pharmacokinetic study and same animals can be used for pharmacodynamic study after a wash out period of 10 days. IAEC certificate no: YU/IAEC/11/2020.
12.	Role of Inflammatory cytokines and fibrinolytic system in pulmonary fibrosis. (YU/IAEC/9/2019) – 28/01/2019 by Ms Fathimath Muneesa	Revised form B and Protocol to be submitted. Approved 42 C57BL/6 mice as requested for the study. IAEC certificate no: YU/IAEC/12/2020.
13.	Developing innovative laparoscopic surgical skills in surgeons - swine model. (YU/IAEC/13/2019) – 23/03/2019 by Dr. Rohan Shetty	Recommended for approval from CPCSEA with the request for extension of validity of 2 years. IAEC NO: YU/IAEC/13/2020
14.	Developing innovative Robotic surgery skills in surgeons using swine models. (YU/IAEC/1/2018) – 03/02/2018 by Dr. Rohan Shetty	Recommended for approval from CPCSEA with the request for extension of validity of 2 years. IAEC NO: YU/IAEC/14/2020
Renewal		
15.	Development of thermoresponsive polymer nanogels for sustained release of Bevacizumab towards efficient treatment of diabetic macular edema (YU/IAEC/12/2019) – 23/03/2019 by Dr. Renjith P Johnson	Approved 24 rabbits as requested for the study. IAEC certificate no: YU/IAEC/15/2020.
16.	Cdk mediated Epigenetic Modifications in Mouse tissues and Head and Neck Cancer (HNC) Cell lines. (YU/IAEC/5/2019) – 28/01/2019 by Dr. Ratnacaram Chandrahas Koumar	Approved 20 mice as requested for the study. IAEC certificate no: YU/IAEC/16/2020.
17.	Targeting of breast and colon cancer stem cells using Vitamin C- in vivo validation using cell-line derived tumor xenograft models and derivation of primary cells from human patient samples (colon and breast	Approved 53 Athymic mice as requested for the study. IAEC certificate no: YU/IAEC/17/2020 

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Dr. Gangadhara Somayaji K.S.
Registrar
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	cancer). (YU/IAEC/8/2019) – 28/01/2019 by Dr. Bipasha Bose	
18.	A Study On The Role Of Steroidogenesis Activating Transcription Factor 3 In The Development Of Hypospadias On Male Mice Induced By Finasteride - A Randomized Controlled Trial. (YU/IAEC/11/2019) – 23/03/2019 by Dr. Bindhu S	Approved 10 female and 5 male swiss albino mice for the study. IAEC certificate no: YU/IAEC/18/2020.
19.	Enhancing the efficiency of growth factor release from platelets using natural sulfated polysaccharide nanoparticles for treating chronic wounds (YU/IAEC/6/2019) – 23/01/2019 by Ms Sneha S Rao	Approved 60 C57BL/6 mice as requested for the study. IAEC certificate no: YU/IAEC/19/2020.
20.	A study on radio sensitization properties of natural compound against cancer cells. (YU/IAEC/10/2019) – 23/01/2019 by Dr. Divya Lakshmanan	Approved 108 swiss albino mice as requested for the study. IAEC certificate no: YU/IAEC/20/2020.
21.	Skeletal muscle fluorosis: effects of Fluoride on skeletal muscle cells and its associated mechanisms in vitro and in vivo studies - YU/IAEC/9/2018 – 04/08/2018 by Dr. Sudheer Shenoy P	Approved 24 swiss albino mice as requested for the study. IAEC certificate no: YU/IAEC/21/2020.
	For projects mentioned from serial no 15-20, the committee agreed to give extension for period of one year. The investigators are instructed to complete the study within a period of one year and further extensions will not be given.	

22. Any other matter with the permission of chair.

- a) Presentation by Dr. Suprith Surya on – Training Programs in ASSEND and Training Undergone by him.
- b) Member Secretary mentioned that the animal handling workshop will be conducted in the month of February 2020, for which permission for use of 5 rats and 5 mice was taken in the YU-IAEC meeting held on 29/09/2019.
- c) Ratification of number of animals mentioned in 24th YU-IAEC meeting – There was error in noticing final number of mice and rats. So it was

Meghala
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YU, IAEC

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[Signature]
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University Road, Derlakatte
Mangalore-575 018, Karnataka

brought to notice of the committee. Following changes were made as follows- The animal sanctioned for use in 24th YU-IAEC meeting was 170 mice and 90 rats.

- d) In view of protocols requiring breeding facility, Application for registration of 347/PO/Re-S/Rc-L/01/CPCSEA for breeding of small animals for in-house use will be forwarded to CPCSEA after the infrastructural changes in the central animal facility.

After detailed discussion, the IAEC members approved 21 revised Form B and approved the use of total number of 322 mice and 372 rats.

Member secretary proposed the vote of thanks to the members for attending the meeting.

The meeting was followed by lunch.

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

YENEPOYA (DEEMED TO BE UNIVERSITY)
INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]
347/PO/Re-S/Rc-L/01/CPCSEA

MINUTES:

The minutes of the meeting of YU-IAEC is as follows,

Chairman welcomed the members of the YU-IAEC for the meeting.

Member secretary read out the minutes of 23rd IAEC meeting held on 23rd March 2019 with action taken.

The following proposals were discussed and concluded.

Sl. No	Project title and Principal Investigator	Remarks
1	Evaluation for the muscle regeneration potential of mouse liver derived CD34+/45- adult stem cells in mouse models of muscular dystrophy by Mr. Saketh Kapoor.	Revised form B to be submitted. Approved 24 BALB/c Mice as requested for the study. IAEC certificate no: YU/IAEC/14/2019.
2	Neuroprotective effect of <i>Rose alba</i> in Alzheimer's induced rats: a behavioral and biochemical study by Ms Blessina S.	Retracted the protocol
3	Chitosan and silk fibroin topical hydrogel for blood clotting and wound healing by Ms.Soumya.	Advised to perform the invitro study. 18 wistar albino rats sanctioned subject to submission of invitro study data- FTR study, drug interactions, invitro wound healing and blood coagulation activities, characterization of

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Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

		hydrogel, physico- chemical properties and formulation studies IAEC certificate no: YU/IAEC/15/2019.
4	Design and evaluation of a neem (<i>Azadirachta Indica</i>) loaded silk fibroin formulation for wound healing effect by Ms. Arfa Nasrine	Advised to perform the invitro study. 18 Wistar albino rats sanctioned subject to submission of invitro study data- FTR study, drug interactions, invitro wound healing and blood coagulation activities, characterization of hydrogel, physico- chemical properties and formulation studies IAEC certificate no: YU/IAEC/16/2019.
5	Evaluation of Antidepressant Properties of Ethanolic Extract of Root of <i>Rubia Cordifolia</i> In Swiss Albino Mice by Dr. Karri Ramesh Kumar.	Revised form B and protocol to be submitted. Approved 24 swiss albino mice against 60 animals requested for the study IAEC certificate no: YU/IAEC/17/2019
6	Evaluation of Anxiolytic Properties of Hydro-Alcoholic Extract of <i>Aegle marmelos</i> Fruit (Bael Fruit) in Swiss Albino Mice by Dr. Shefeek S N.	Revised form B and protocol to be submitted. Approved 30 swiss albino mice against 42 animals requested for the study

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Registrar
Yenepoya (Deemed to be University)
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		subject to the submission of relevant literatures. IAEC certificate no: YU/IAEC/18/2019
7	To evaluate cardioprotective and antihyperlipidemic activities of <i>Syzygium campanulatum</i> and <i>Callicarpa tomentosa</i> leaf extracts in rats by Ms.Nadira Noushida	Animals not sanctioned. Advised to resubmit in the next meeting
8	Development of an exopolysaccharide-based bio ink and the pre-clinical evaluation of its action on wound healing by Ms. Athmika.	Approved 54 wistar albino rats as requested for the study subject to submission of invitro study data. IAEC certificate no: YU/IAEC/19/2019
9	Role of Thymoquinone in regulation of Pro inflammatory cytokines and Pro fibrotic components during Sepsis Induced Acute Kidney Injury by Mr.Anwar.AS.	Revised form B and protocol to be submitted. Approved 32 BALB/c Mice against 40 animals as requested for the study. IAEC certificate no: YU/IAEC/20/2019
Extension projects		
10	Effect of Valeric acid on Alzheimer's disease induced rats: a behavioral and biochemical study Ms Blessina S.	No animals approved. Advised Resubmission in the next meeting.
11	Studies On Inflammatory Cytokines Mediated Epithelial Mesenchymal Transition (EMT) During Lung Injury And Fibrosis by Ms. Sadiya Bi Shaikh.	Revised form B to be submitted. Approved 60C57BL mice as requested for the study IAEC certificate no: YU/ IAEC/21/2019

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Title amended for ratification	
12	Stimuli-responsive, tannic acid releasing biodegradable polymer hydrogels for chronic wound healing by Ms. Namitha K
	Title amended ratified YU/ IAEC/2/2018

13. Demonstration of animal handling technique by experts – Member Secretary requested for approval of 5 rats for demonstration of animal handling technique by experts to the in-house research scholar. The program tentatively scheduled in the month of January 2020.

14. Any other matter with the permission of chair.

- a) Link nominee relocated to Dehradun – Link Nominee Dr. Himanshu Joshi conveyed his unavailability for attending the meeting as he has relocated to Dehradun and he has conveyed the same to CPCSEA.
- b) Dr. Melanta expressed his inability to continue as member of YU-IAEC. Members of YU-IAEC suggested chairman to nominate a new veterinarian for the committee.

After detailed discussion, the IAEC members approved 8 revised Form B and approved the use of total number of 224 mice and 36 rats.

Member secretary proposed the vote of thanks to the members for attending the meeting.

Roopa-kuni A.
Chairman / Member Secretary
YU, IAEC
4/9/19
4/9/19

Megharaj
Chairman / Member Secretary
YU, IAEC

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
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Mangalore-575 018, Karnataka

YENEPOYA (DEEMED TO BE UNIVERSITY)
INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]
347/PO/Re-S/Rc-L/01/CPCSEA

23rd meeting of Yenepoya Institutional Animal Ethics Committee

Date & Time: 23 March 2019, 8.30 am.

Venue: Seminar room, Yenepoya research centre.

Members present:

1. Dr. Roopa P Nayak [Chairman]
2. Dr. Hemanth Gowda [Main Nominee CPCSEA]
3. Dr. Megha Rani N [Member Secretary]
4. Dr. Murali B [Socially Aware Nominee]
5. Dr. K.L. Krishna [Scientist from outside the Institute]
6. Dr. Bindu S [Member]
7. Dr. Vidya Pai [Member]
8. Dr. K B Melanta [Member]

AGENDA:

1. A study on the role of Steroidogenesis activating transcription factor 3 in the development of hypospadias on male mice induced by finasteride-A randomized controlled trial.
2. Development of thermoresponsive polymer nanogels for sustained release of Bevacizumab towards efficient treatment of diabetic macular edema.
3. Developing Innovate laparoscopic surgical skills in surgeons -swine models
4. Submission of application for registration of 347/PO/Re-S/Rc-L/01/CPCSEA for breeding of small animals for the purpose of trade (Bt).
5. Any other matter with the permission of chair.

Megha Rani N
Chairman / Member Secretary
YU, IAEC

ATTESTED
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

MINUTES:

The minutes of the 23rd meeting of YU-IAEC is as follows,

Chairman welcomed the members of the YU-IAEC for the meeting.

Member secretary read out the minutes of 22nd IAEC meeting held on 28th January 2019 with action taken.

The following proposals were discussed and concluded.

Sl. No	Project title and Principal Investigator	Remarks
1	A study on the role of Steridiogenesis activating transcription factor 3 in the development of hypospadias on male mice induced by finasteride-A randomized controlled trial.	Revised form B and protocol to be submitted. Approved 15 against 24 mice requested for the study. IAEC certificate no: YU/IAEC/11/2019.
2	Development of thermoresponsive polymer nanogels for sustained release of Bevacizumab towards efficient treatment of diabetic macular edema.	The justification for different group to be added and revised form B to be submitted. Approved 24 rabbits for the study. IAEC certificate no: YU/IAEC/12/2019.
3	Developing Innovate laparoscopic surgical skills in surgeons -swine models.	Recommended for approval from CPCSEA. Protocol No: YU/IAEC/13/2019.
4	Submission of application for registration of 347/PO/Re-S/Rc-L/01/CPCSEA for breeding of small animals for the purpose of trade (Bt).	Application for registration of 347/PO/Re-S/Rc - L/01/CPCSEA for breeding of small animals for the purpose of trade (Bt) (YU-IAEC recommendation was taken in 3 February 2018 meeting).

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		Submission of application now, as the breeding area is ready and hence applying for permission from CPCSEA. (Advised to follow standardized procedures as per CPCSEA guidelines).
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After detailed discussion, the IAEC members approved 3 Form B and approved the use of total number of 15 mice and 24 rabbits.

Member secretary proposed the vote of thanks to the members for attending the meeting.

Meghala
 Chairman / Member Secretary
YU, IAEC

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 Registrar
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 University Road, Deralakatte
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YENEPOYA (DEEMED TO BE UNIVERSITY)
INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]
347/PO/Re-S/Rc-L/01/CPCSEA

22nd Yenepoya Institutional Animal Ethics Committee

Date & Time: 28 January 2019, 10.00 am.

Venue: Pharmacology department, Yenepoya Medical College.


Members present:

1. Dr. Roopa P Nayak [Chairman]
2. Dr. Hemanth Gowda [Main Nominee CPCSEA]
3. Dr. Megha Rani N [Member Secretary]
4. Dr. Murali B [Socially Aware Nominee]
5. Dr. K.L. Krishna [Scientist from outside the Institute]
6. Dr. Bindu S [Member]
7. Dr. Vidya Pai [Member]
8. Dr. K B Melanta [Member]

AGENDA:

1. Effect of Quercetin on Cardio-Protective effect of Resveratrol against Isoproterenol induced myocardial injury by Dr. Mohammed Gulzar Ahmed.
2. Formulation and study the effect of resveratrol phytosomes alone and in combination with piperine to treat myocardial infarction by Ms. Thriveni M.
3. A Comparative urine metagenomic study of native cow breeds of Karnataka: microbiome approach by Dr.Sudeep D. Ghate.
4. Effect of Nigella sativa Seed Extract on Contrast dye Induced Acute Kidney Injury in Wistar Albino Rats by Mr.Anwar A.S.
5. Evaluation of antianxiety property of thiocolchicoside in swiss albino mice by Dr. Kumar Gourav
6. Evaluation of antidepressant properties of thiocolchicoside in swiss albino mice by Dr. Kumar Gourav

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7. Cdk mediated Epigenetic Modifications in Mouse tissues and Head and Neck Cancer (HNC) Cell lines by Ratnacaram Chandrahas Koumar.
8. Enhancing the efficiency of growth factor release from platelets using natural sulfated polysaccharide nanoparticles for treating chronic wounds by Sneha S Rao,
9. Distribution, pharmacokinetics and *in vivo* safety evaluation of donepezil niosomes in rat brain by Dr. Prashant Kumar Modi.
10. Targeting of breast and colon cancer stem cells using Vitamin C- *in vivo* validation using cell-line derived tumor xenograft models and derivation of primary cells from human patient samples (colon and breast cancer) by Dr Bipasha Bose.
11. Role of Inflammatory cytokines and fibrinolytic system in pulmonary fibrosis by Ms. Fathimath Muneesa M.
12. Re-submission proposal titled: A study on radio sensitization properties of natural compound against cancer cells by Dr. Divya Lakshmanan (3rd February 2018).
13. The confirmation of Dr. Megha Rani N as Member Secretary of YU-IAEC by CPCSEA will be conveyed to the YU-IAEC members.

MINUTES:

The minutes of the 22nd IAEC meeting of YU-IAEC is as follows,
Chairman welcomed the members of the YU-IAEC and read out the minutes of 22nd IAEC meeting held on 28th January 2019.

The following proposals were discussed and concluded.

Sl. No	Project title and Principal Investigator	Remarks
1	Effect of Quercetin on Cardio-Protective effect of Resveratrol against Isoproterenol induced myocardial injury by Dr. Mohammed Gulzar Ahmed.	Approved 36 rats against 65 albino rats requested for this study. Justification for use of animals and references to be

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University Road, Deralakatte
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		added, form B to be resubmitted. Reapply for next group of animals in the next IAEC. IAEC Certificate Number: YU/IAEC/1/2019
2	Formulation and study the effect of resveratrol phytosomes alone and in combination with piperine to treat myocardial infarction by Ms. Thriveni M.	Approved 30 rats against 65 albino rats requested for this study. Justification for use of animals and references to be added, Form B to be resubmitted. Reapply for next group of animals in the next IAEC. IAEC Certificate Number: YU/IAEC/2/2019
3	A Comparative urine metagenomic study of native cow breeds of Karnataka: microbiome approach by Dr. Sudeep D Ghate	No invasive procedure involved and hence study approved. IAEC Certificate Number: YU/IAEC/3/2019
4	Effect of <i>Nigella sativa</i> Seed Extract on Contrast dye Induced Acute Kidney Injury in Wistar Albino Rats by Mr. Anwar A.S.	Revise the form B with suitable justification and reference and reapply.
5	Evaluation of antianxiety property of thiolcolchicoside in swiss albino mice by Dr. Kumar Gourav	Submit the Revised form B Approved 24 swiss albino mice against 60 swiss albino mice requested for this study IAEC Certificate Number: YU/IAEC/4/2019

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6	Evaluation of antidepressant properties of thiocolchicoside in swiss albino mice by Dr. Kumar Gourav	Revise the protocol and resubmit in the next meeting.
7	Cdk mediated Epigenetic Modifications in Mouse tissues and Head and Neck Cancer (HNC) Cell lines by Ratnacaram Chandrahas Koumar	Approved 20 mice for the first one year of the study IAEC Certificate Number: YU/IAEC/5/2019
8	Enhancing the efficiency of growth factor release from platelets using natural sulfated polysaccharide nanoparticles for treating chronic wounds by Sneha S Rao	Resubmit the revise form B with scientific justification. 60 Mice; C57BL IAEC Certificate Number: YU/IAEC/6/2019
9	Distribution, pharmacokinetics and <i>in vivo</i> safety evaluation of donepezil niosomes in rat brain by Dr. Prashant Kumar Modi.	39 animals approved against 45 male Sprague dawley rats requested. Revised form B and protocol to be submitted. IAEC Certificate Number: YU/IAEC/7/2019
10	Targeting of breast and colon cancer stem cells using Vitamin C- in vivo validation using cell-line derived tumor xenograft models and derivation of primary cells from human patient samples (colon and breast cancer) by Dr Bipasha Bose.	53 Athymic Nude mice permitted against 55 animals requested. Animals are to be housed upon establishment of suitable facilities for placing nude mice colony and IBSC approval certificate. IAEC Certificate Number: YU/IAEC/8/2019
11	Role of Inflammatory cytokines and fibrinolytic system in pulmonary fibrosis by Fathimath Muneesa M.	Revised form B and protocol with scientific justification to be submitted. TESTED

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YU, IAEC

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		72 male C57BL/6 mice IAEC Certificate Number: YU/IAEC/9/2019
12	A study on radio sensitization properties of natural compound against cancer cells by Dr. Divya Lakshmanan	108 swiss albino mice has been resanctioned. Previous IAEC Certificate Number: YU/IAEC/2/2018 New IAEC Certificate Number: YU/IAEC/10/2019

13. The confirmation of Dr. Megha Rani N as Member Secretary of YU-IAEC by CPCSEA was conveyed to the YU-IAEC members.

After detailed discussion, the IAEC members approved 10 Form B and approved the use of total number of 237 mice and 105 rats.

Chairman proposed the vote of thanks to the members.

Megharani
Chairman Member Secretary
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Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

YENEPOYA (DEEMED TO BE UNIVERSITY)
INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]

21st Yenepoya Institutional Animal Ethics Committee

Date & Time: 4 August 2018, 1.30 pm

Venue: Pharmacology department, Yenepoya Medical College.

Members present:

1. Dr. Roopa P Nayak [Chairman]
2. Dr. Hemanth Gowda [Main Nominee CPCSEA]
3. Dr. Murali B [Socially Aware Nominee]
4. Dr. Bindu S [Member]
5. Dr. Vidya Pai [Member]
6. Dr. K B Melanta [Member]

Member absent:

1. Dr. K.L. Krishna [Scientist from outside the Institute]
2. Dr. Shyamjith M [Resigned & relieved in April 2018]

AGENDA:

1. Assessment of molecular changes upon the administration of Iron supplement in anaemic rats by Dr. Rekha P D.
2. Delineating the signaling mechanism involved in the neuroprotective effects of Yashtimadhu (*Glycyrrhiza glabra*) in Parkinson's disease model using quantitative phosphoproteomics approach by Dr. Prashant Kumar Modi.
3. Evaluation of Analgesic Activity of *Toxicodendron radicans* in Wistar Albino Rats by Dr. Marzana.
4. Evaluation of Aqueous Extract of *Tinospora cordifolia* - Aspirin Combination for Analgesic Activity in Wistar Albino Rats by Ms. Sunaina.

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5. Skeletal muscle fluorosis: effects of Fluoride on skeletal muscle cells and its associated mechanisms in vitro and in vivo studies by Dr. Sudheer Shenoy P.
6. Studies on Inflammatory Cytokines Mediated Epithelial Mesenchymal Transition (EMT) During Lung Injury And Fibrosis by Ms. Sadiya Bi Shaikh.
7. To nominate the Member Secretary, YU-IAEC.
8. Any other matter with the permission of chair.

MINUTES:

The minutes of the 21st IAEC meeting of YU-IAEC is as follows,
Chairman welcomed the members of the YU-IAEC and read out the minutes of 20th IAEC meeting held on 3rd February 2018.

The following proposals were discussed and concluded.

Sl. No	Project title and Principal Investigator	Remarks
1	Assessment of molecular changes upon the administration of Iron supplement in anaemic rats. PI: Dr. Rekha P D	Approved 78 rats for the study Revised Form B to be submitted IAEC Certificate Number: YU/IAEC/5/2018
2	Delineating the signaling mechanism involved in the neuroprotective effects of Yashtimadhu (Glycyrrhiza glabra) in Parkinson's disease model using quantitative phosphoproteomics approach. PI: Dr. Prashant Kumar Modi	Approved 65 mice for the study IAEC Certificate Number: YU/IAEC/6/2018 ATTESTED 

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Registrar
Yenepoya (Deemed to be University)
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3	Evaluation of Analgesic Activity of <i>Toxicodendron radicans</i> in Wistar Albino Rats. PI: Dr. Marzana	Approved 42 rats for the study IAEC Certificate Number: YU/IAEC/7/2018 Out of the Rehabilitated animals, a total number of 24 rats will be given to the IAEC Certificate Number YU/IAEC/8/2018
4	Evaluation of Aqueous Extract of <i>Tinospora cordifolia</i> - Aspirin Combination for Analgesic Activity in Wistar Albino Rats. PI: Ms. Sunaina	24 Rehabilitated rats will be given IAEC Certificate Number: YU/IAEC/8/2018
5	Skeletal muscle fluorosis: effects of Fluoride on skeletal muscle cells and its associated mechanisms in vitro and in vivo studies. PI: Dr. Sudheer Shenoy P	Approved 48 mice for the study IAEC Certificate Number: YU/IAEC/9/2018
6	Studies On Inflammatory Cytokines Mediated Epithelial Mesenchymal Transition (EMT) During Lung Injury And Fibrosis. PI: Ms. Sadiya Bi Shaikh	Approved 60 mice for the study IAEC Certificate Number: YU/IAEC/10/2018

7. The members were informed about Member Secretary, Dr. Shyamjith's resignation & relieved from Yenepoya (Deemed to be University) in the month of April 2018. Dr. Megha Rani N, Asst. Professor, Dept. of Pharmacology, Yenepoya Medical College has been nominated by Yenepoya (Deemed to be University) as Member Secretary, YU-IAEC. It was approved by all the members and the procedure for reconstitution may be carried out through CPCSEA website.

Megha Rani N
Chairman / Member Secretary
YU, IAEC

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
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After detailed discussion, the IAEC members approved 6 Form B and approved the use of total number of 173 mice and 120 rats.

Chairman proposed the vote of thanks to the members for attending the meeting.

1. Dr. Roopa P Nayak [Chairman] *Roopa Kuni. A 4/8/18*
2. Dr. Hemanth Gowda [Main Nominee CPCSEA] *H 4/8/18*
3. Dr. Murali B [Socially Aware Nominee] *M 4/8/18*
4. Dr. Bindu S [Member] *B 4/8/18*
5. Dr. Vidya Pai [Member] *V 4/8/18*
6. Dr. K B Melanta [Member] *M 4/8/18*

Megharai
Chairman / Member Secretary
YU, IAEC

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

YENEPOYA (DEEMED TO BE UNIVERSITY)

INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]

20th Yenepoya Institutional Animal Ethics Committee

Date: 3rd February 2018.

Venue: Department Seminar room, Pharmacology, Yenepoya Medical College.

Members present:

1. Dr. Roopa P Nayak [Chairman] *Roopa. Kuni. A. 3/2/18.*
2. Dr. Hemanna Gowda [Main Nominee CPCSEA] *H*
3. Dr. Shyamjith Manikkoth [Member Secretary]
4. Dr. Murali B [Socially Aware Nominee]
5. Dr. Bindu S [Member] *Bindu*
6. Dr. Vidya Pai [Member]
7. Dr. K B Melanta [Member]

Member absent:

1. Dr. K.L. Krishna [Scientist from outside the Institute]

AGENDA:

1. Developing Innovate robotic surgery skills in surgeons using swine models by Dr. Rohan Shetty.
2. Investigation on the wound healing efficiencies of tannic acid loaded dual stimuli responsive hydrogel by Dr. Renjith P. Johnson.
3. A study on radio sensitization properties of natural compound against cancer cells by Dr. Divya Lakshmanan.

Megharaj
Chairman / Member Secretary
YU, IAEC

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[Signature]
Dr. Gangadhara Somayaji K.S.
Registrar
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Mangalore-575 018, Karnataka

4. Morphological, Histological changes and estimation of A β -42 biomarker in the brain of Alzheimer's disease rats; Modification by Valeric acid by Dr. Bindhu S & Ms. D. Blessina Sugandhi.
5. Application for registration of 347/PO/Re-S/Rc-L/01/CPCSEA for breeding of small animals for the purpose of trade (Bt).
6. Any other matter with the permission of chair.

MINUTES:

Minutes of the 20th IAEC meeting of YU-IAEC was held on 3rd February 2018, Saturday at 1.00 pm at Pharmacology department seminar room, Yenepoya Medical College.

The following members attended the meeting.

1. Dr. Roopa P Nayak [Chairman]
2. Dr. Hemanna Gowda [Main Nominee CPCSEA]
3. Dr. Shyamjith Manikkoth [Member Secretary]
4. Dr. Murali B [Socially Aware Nominee]
5. Dr. Bindu S [Member]
6. Dr. Vidya Pai [Member]
7. Dr. K B Melanta [Member]

Member absent:

1. Dr. K.L. Krishna [Scientist from outside the Institute]

Chairman welcomed members of the IAEC for the meeting.

The minutes of the 19th IAEC meeting of YU-IAEC held on 7th August 2017 was read out by Member Secretary.

Megharaj
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
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Mangalore-575 018, Karnataka

The following proposals were discussed and concluded.

Sl. No	Project title and Principal Investigator	Remarks
1	Developing Innovate robotic surgery skills in surgeons using swine models. PI: Dr. Rohan Shetty	Recommended for the approval from CPCSEA. Protocol Number: YU/IAEC/1/2018 With reference to 347/PO/Re-S/Rc-L/01/CPCSEA
2	Investigation on the wound healing efficiencies of tannic acid loaded dual stimuli responsive hydrogel. PI: Dr. Renjith P. Johnson	Approved 36 rats for this study Protocol Number: YU/IAEC/2/2018
3	A study on radio sensitization properties of natural compound against cancer cells. PI: Dr. Divya Lakshmanan.	1. Advised to get permission from IBSC. 2. Approved 108 mice against 210 requested for this study, for a period of 6 months. Protocol Number: YU/IAEC/3/2018
4	Morphological, Histological changes and estimation of A β -42 biomarker in the brain of Alzheimer's disease rats; Modification by Valeric acid. PI: Dr. Bindhu S & Ms. D. Blessina Sugandhi.	Approved 42 rats against 53 requested for this study Protocol Number: YU/IAEC/4/2018
5	Application for registration of 347/PO/Re-S/Rc-L/01/CPCSEA for breeding of small	Advised to follow standardized procedures

Megharaj
Chairman/ Member Secretary
YU, IAEC

Dr. Gangadhara Somayaji M.S.
Registrar
Yenepoya University
University Road, Derafakatte
Mangalore-575 018, Karnataka

animals for the purpose of trade (Bt).	as per CPCSEA guidelines.
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After detailed discussion, the IAEC members approved Three Form B and approved the use of total number of 108 mice and 78 rats. Member Secretary proposed the vote of thanks for the members for attending the meeting.

1. Dr. Roopa P Nayak [Chairman] Roopa. Kuni. A
3/2/18
2. Dr. Hemanna Gowda [Main Nominee CPCSEA] H
3/2/18
3. Dr. Shyamjith Manikkoth [Member Secretary] S
3/2/18
4. Dr. Murali B [Socially Aware Nominee] M
3/2/18
5. Dr. Bindu S [Member] B
3/2/18
6. Dr. Vidya Pai [Member] V
3/2/18
7. Dr. K B Melanta [Member] M
3/2/18

Megharaj
Chairman / Member Secretary
YU, IAEC

ATTESTED
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Institutional Animal Ethics Committee

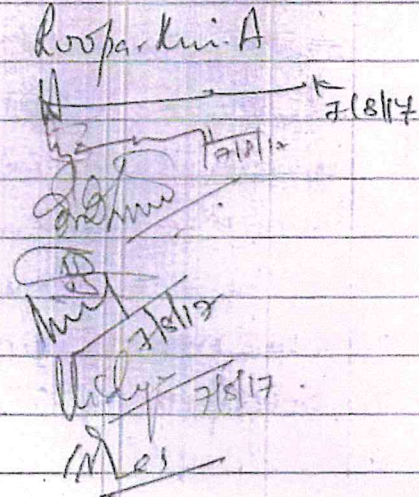
19th IAEC meeting

Date: 7th August 2017

Venue: Department Seminar Room, Pharmacology, YMC

Members Present:


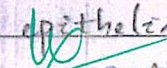
1. Dr. Roopa P. Nayak
2. Dr. Hemanna Gowda K
3. Dr. Shyamjith. Manikkoth
4. Dr. K.L. Krishna
5. Dr. Murali. B
6. Dr. Bendu. S
7. Dr. Vedya. Pai
8. Dr. K.B. Melanta

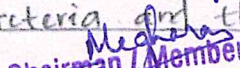


 Roopa P. Nayak
 Hemanna Gowda K
 Shyamjith. Manikkoth
 K.L. Krishna
 Murali. B
 Bendu. S
 Vedya. Pai
 K.B. Melanta

AGENDA:-

1. Skeletal muscle fluorosis: effects of Fluoride on skeletal muscle cells and its associated mechanisms *in vitro* and *in vivo* studies by Dr. Sudheer Shenoy P
2. Epigenetic changes in skeletal muscle stem cells during ageing (Sarcopenia) [BT/PR21306/MED/131/1357/2016] by Dr. Sudheer Shenoy. P.
3. Development and investigation of adjuvant therapeutic strategies for treating malignant glioma by gamma radiation based therapy in combination with angiogenesis inhibition by Dr. Ashwini. Prabhu.
4. Studies on Inflammatory cytokines mediated epithelial mesenchymal transition (EMT) during lung injury and pulmonary fibrosis by Ms. Sadiga Bi Shaikh.
5. Development of mixed type urinary stones in Wistar rats using ethylene glycol for the evaluation of the association between the bacteria and the urothelial cells by Ms. Sajeda Abdul Kadar.



 Registrar
 Yenepoya (Deemed to be University)
 University Road, Derlakatte
 Mangalore-575 018, Karnataka


 Chairman / Member Secretary
YU, IAEC

6. Assessing the effect of metformin treatment on healthy gut microbiota recovery by Dr. Rekha P.D.

7. Colonization sustainability and gut ecological co-occurrence network stability analysis of *Lactobacillus* sp by Dr. Rekha P.D

8. Any other matter with the permission of chair.

MINUTES :-

Minutes of the 19th IAEC meeting of YU-IAEC was held on 7th August 2017, Monday at 1:30 pm at Pharmacology department seminar room, YMC.

The following members attended the meeting: Dr. Roopa P. Nys
• Dr. Hemanna Gowda K ; Dr. Shyamjith Manikkoth,
Dr. K.L. Krishna, Dr. Murali B, Dr. Bindu S, Dr. Vidya Pai
and Dr. K.B. Melanta.

* Chairman welcomed members of the IAEC for the meeting.

* The minutes of the 18th IAEC meeting of YU-IAEC held on 28th February 2017 was read out by Member Secretary.

* The following proposals were discussed and concluded.

Sl. No	Project Title and Principal Investigator	Remarks
1	Skeletal muscle fibrosis fluorosis: effects of fluoride on skeletal muscle cells and its associated mechanism in vitro and in vivo studies PI: Dr. Sudheer Shenoy	Since no animals are required in the first year, Dr. Sudheer was advised to resubmit the protocol along with corrected Form B in the next year based on the results obtained from in vitro studies. • No any animals have been sanctioned for this study.
2	Development and investigation of adjuvant therapeutic strategies for treating malignant glioma by gamma radiation based therapy or combination of angiogenesis inhibition Dr. Achweni Prabhu	Since no animals are required in the first year, Dr. Achweni was advised to resubmit the protocol when the animals are required in the third year. Animal facility will be provided at the 3 rd year of the project. • No any animals have been sanctioned for this study.

ATTESTED

Dr. Gaanur Somanth
Registrar
University of Veterinary and Animal Sciences
Mangalore-575 018, Karnataka

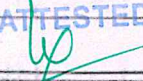
Megha
Chairman / Member Secretary
YU, IAEC

3. Epigenetic changes in skeletal muscle stem cells during ageing (Sarcopenia) [BT/PR 21306/MED/31/357/2016]
 PI: Dr. Sudbeer Shenoy
 YU/IAEC/6/2017
 Advised Dr. Sudbeer Shenoy to include procedural details (Carcase disposal and euthanasia procedure)
 Advised to carry out experiments using 15 animals. If the project requires more animals, PI can submit the protocol for next ethical committee
 * Approved 15 mice for this study.

4. Studies on Inflammatory cytokine mediated epithelial mesenchymal transition [EMT] during lung injury and pulmonary fibrosis
 PI: Dr. Yashodhar Bhandhary
 Ms. Sadegha Shaikh
 YU/IAEC/7/2017
 Faculty name should be included in Form B.
 Form B may be resubmitted after incorporating corrections.
 * Approved 30 mice for this study.

5. Development of mixed type urinary stones in Wistar rats ethylene glycol for the evaluation of the association between the bacteria and the urothelial cells
 PI: Dr. Rekha P.D
 Ms. Sajida Abdul Kadar
 YU/IAEC/8/2017
 Advised to get permission from TBSC.
 * Approved 30 Rats for this study.

6. Assessing the effect of metformin treatment on healthy gut microbiota recovery
 PI: Dr. Rekha P.D
 YU/IAEC/9/2017
 * Approved 24 mice for this study.

ATTESTED


7. Colonization sustainability and gut ecological co-occurrence network analysis of Lactobacillus sp.
 PI: Dr. Rekha P.D
 YU/IAEC/10/2017
 * Advised to use 6 animals in each group
 * Approved 30 mice for this study.

Dr. Sangadhar Somayaji K.S.
 Yenepoya (Deemed to be University)
 University Road, Derlakatte
 Mangalore - 575 019, Karnataka


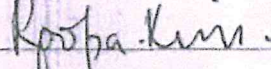
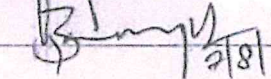
Megharaj
 Chairman / Member Secretary
 YU, IAEC

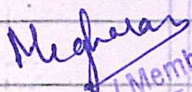
o After detailed discussion, the IAEC members approved 5 (five) Form Bs and approved the use of total number of 30 rats and 50 mice

* Member secretary proposed the vote of thanks for the members for attending the meeting.

Name

Signature

- | | | |
|---|---|---------|
| 1. Dr. Hemanna Gowda K (Main Nominator) |  | 10/8/17 |
| 2. Dr. Roopa P. Nayak (Chairman) |  | 11/8/17 |
| 3. Dr. Shyamjith M (Member Secretary) |  | 12/8/17 |


Chairman / Member Secretary
YU, IAEC

ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

YENEPOYA UNIVERSITY

INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]

18th Yenepoya Institutional Animal Ethics Committee meeting was held on 28th February 2017 at 10.30 am.

Venue: Department Seminar room, Pharmacology, Yenepoya Medical College.

The meeting was chaired by Dr. Roopa P Nayak, Chairman, Y.U - I.A.E.C.

The following members of the committee attended this meeting.

1. Dr. Roopa P Nayak [Chairman]
2. Dr. Hemanna Gowda [Main Nominee CPCSEA]
3. Dr. Shyamjith Manikkoth [Member Secretary]
4. Dr. K.L. Krishna [Scientist from outside the Institute]
5. Dr. Murali B [Socially Aware Nominee]
6. Dr. Bindu S [Member]
7. Dr. K B Melanta [Member]

Members absent:

1. Dr. Vidya Pai [Member]

AGENDA:

1. Study on antidiabetic activity of bioactive compounds isolated from *Syzygium kanarense* by Mr. Divakar M S, Guided by Dr. Shyamjith M.
2. Permission for the use of large animals – Sus/Scrofa domesticus (Pigs) for educational & training purpose.
3. Any other matter with the permission of chair.

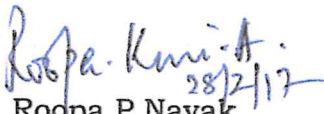
Nigharaj
Chairman / Member Secretary
YU, IAEC

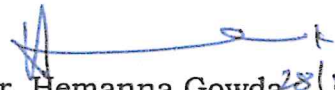
ATTESTED
W
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

MINUTES:

The Chairman welcomed all the members of IAEC.

1. Reconstituted IAEC meeting is being conducted. Seven IAEC members of newly constituted IAEC were present.
2. Mr. Divakar M S, PhD student of Mangalore University presented a protocol entitled "Study on antidiabetic activity of bioactive compounds isolated from *Syzygium kanarensis*". The members expressed that the protocol is not presented in the prescribed format of CPCSEA. The researcher failed to defend the queries and doubts of IAEC members. In this direction, the IAEC rejected Mr. Divakar's proposal and advised him to resubmit the proposal to the next IAEC meeting.
3. Dr. Mujeeburahiman, Professor, Dept. of Urology presented a research protocol entitled "Laparoscopic surgeries (viz for removal of tumors, cyst etc), transplant etc on large animals". He proposed to use *Sus/Scrofa domesticus* (Pig) for innovation in research and education in the field of surgery. IAEC recommended to forward the application of large animal facility for further approval by CPCSEA.
4. The Member Secretary IAEC thanked all the members for their presence and valuable remarks on the protocols.


Dr. Roopa P Nayak
Chairman, YU-IAEC


Dr. Hemanna Gowda
Main nominee CPCSEA

1. Dr. Shyamjith Manikkoth- [Member Secretary]



2. Dr. K.L. Krishna [Scientist from outside the Institute]

3. Dr. Murali B [Socially Aware Nominee]

4. Dr. Bindu S [Member]

5. Dr. K B Melanta [Member]


Meghala
Chairman / Member Secretary
YU, IAEC



ATTESTED
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

MINUTES OF INSTITUTIONAL ANIMAL ETHICS COMMITTEE MEETING

Yenepoya Institutional Animal Ethics Committee meeting was held on 18th January 2017 at 10.30 am.

Venue: Department of Pharmacology, Yenepoya Medical College.

The meeting was chaired by Dr. Roopa P Nayak, Chairman (Subject to approval CPCSEA), Y.U- I.A.E.C

The following members of the committee attended this meeting.

1. Dr. Roopa P Nayak- Chairman (Subject to approval CPCSEA)
2. Dr. N.A. Madhyastha- Main Nominee CPCSEA
3. Dr. Prema Saldanha - Member Secretary
4. Dr. Vidya Pai - Member
5. Dr. Kalpana - Member
6. Dr. Melanta - Member
7. Mr. Mohan Bhat - Member

1. In the meeting, the Chairman brought to the notice of the members that there is no in-house breeding done in our animal house (Bearing No. 347/CPCSEA) in Yenepoya Medical College. The animals are procured from the authorized dealer.
2. The following proposals were discussed and approved by the Institutional Animal Ethics Committee.
 - Pre-clinical screening of Paracetamol for its role in haloperidol induced catalepsy by Ms. Bindulatha, Guided by Dr. Roopa P Nayak. (30 - Swiss albino mice)
 - A Pre-clinical study to evaluate the effect of Olanzapine on cognition by Ms. Sushma, Guided by Dr. Shyamjith M. (18 - Wistar albino rats)
 - Preclinical evaluation of anxiolytic activity of *Adhatoda Vasica* leaf extract in Swiss albino mice by Ms. Sruthi Shajee, Guided by Dr. Prabhakar Adake. (36 – Swiss albino mice)
 - A Pre-clinical study to evaluate the role of *Coleus amboinicus* on alcohol induced anxiety in Swiss albino mice by Ms. Anusha Satheesh, Guided by Dr. Megha Rani N. (18 - Swiss albino mice)


Chairman / Member Secretary
YU, IAEC

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

- A novel strategy for enhancing the efficacy of Platelet Rich Plasma (PRP) in Diabetic Wound Care by Dr. Rekha P D. (36 - C57BL/6JJcl mice)

Roopa-Kirita

Dr. Roopa P Nayak
Chairman, YU-IAEC
(Subject to approval CPCSEA)

Dr. N.A. Madhyastha
Dr. N.A. Madhyastha
Main nominee CPCSEA

Ph:08202524570

Dr N A Madhyastha Ph.D
Inchara, Srinivasa Nagar,
Chitpadi, Udupi 576101

1. Dr. Prema Saldanha - Member Secretary *Prema*
2. Dr. Vidya Pai - Member *Vidya*
3. Dr. Kalpana - Member *Kalpana.B*
4. Dr. Melanta - Member *Melanta*
5. Mr. Mohan Bhat - Member *Mohan-Bhat*

Megharaj
Chairman / Member Secretary
YU, IAEC

ATTESTED
we

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

**MINUTES OF INSTITUTIONAL ANIMAL ETHICAL COMMITTEE
MEETING**

Yenepoya Institutional Animal Ethical Committee meeting was held on 19th October 2016 at 10.30 am.

Venue: Department of Pharmacology, Yenepoya Medical College.

The meeting was chaired by Dr. S.N. Rao, Chairman, Y.U- I.A.E.C

The following members of the committee attended this meeting.

1. Dr. S.N. Rao - Chairman
2. Dr. N.A. Madhyastha- Main Nominee CPCSEA
3. Dr. Prema Saldanha - Member Secretary
4. Dr. Vidya Pai - Member
5. Dr. Kalpana - Member
6. Dr. Melanta - Member
7. Mr. Mohan Bhat - Member

Dr. S.N. Rao, Senior Professor & H.O.D. Department of Pharmacology, Yenepoya Medical College, Yenepoya University, Mangalore, welcomed Dr. N.A. Madhyastha, Main Nominee CPCSEA from Udupi and all other members.

All researchers presented their protocols of their project for approval/clearance by Institutional Animal Ethical Committee.

Agenda of the meeting was discussed in details & the following projects approved.

1. Assessment of Neurotransmitters and Antioxidant levels in the brain to screen the effect of *Phyllanthus amarus* on Cognition in Diabetic rats by Mr. Kevin Joakim Pinto.
2. Molecular Mechanisms Involved in the Ameliorating Effects of *Tylophora indica* and Isoquinoline on Anxiety of Alcohol Withdrawn Wistar Albino Rats by Ms. Melinda Sequeira.
3. Probing the therapeutic role of *Phyllanthus amarus* in attenuating the neurotoxicity induced by arsenic: a pre-clinical study by Mr. Hashim A.
4. Role of curcumin in regulating epithelial mesenchymal transition (EMT) through inflammatory cytokine mediated changes in p53-fibrinolytic system during lung injury and fibrosis by Dr. Yashodhar Bhandary.

Megharaj
Chairman / Member Secretary
YU, IAEC

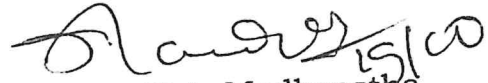
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

5. Oxidative damage to skin stem cells of mouse, in response to, bright and ultraviolet light and its associated mechanisms by Dr. Bipasha Bose.
6. Oxidative damage to ocular surface stem cells of mouse, in response to, bright and ultraviolet light and its associated mechanisms by Dr. Bipasha Bose.
7. Cellular, molecular and epigenetic changes, in response to low doses of γ -irradiation on embryonic stem cells by Dr. Sudheer Shenoy P.

The meeting ended with the thanks to the chair.

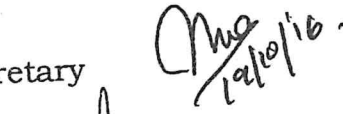



Dr. S.N. RaomD
Chairman, YU-IAEC



Dr. N.A. Madhyastha
Main nominee CPCSEA

1. Dr. Prema Saldanha - Member Secretary
2. Dr. Vidya Pai - Member
3. Dr. Kalpana - Member
4. Dr. Melanta - Member
5. Mr. Mohan Bhat - Member

Kalpana.B
19/10/16



NITolua.Rhat

Megharaj
Chairman / Member Secretary
YU, IAEC

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



YENEPOYA

(DEEMED TO BE UNIVERSITY)

Recognized under Sec 3(A) of the UGC Act 1956

Accredited by NAAC with 'A' Grade

Meeting Details and Minutes of Institutional Biosafety Committee (IBSC)

Sl. No.	Year	No. of Meetings
1.	2020-21	01
2.	2019-20	01
3.	2018-19	01
4.	2017-18	-
5.	2016-17	01

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore-575 018, Karnataka

Proceedings of the Second meeting of institutional biosafety committee (IBSC) for the year 2020, held on 23rd November 2020

The Second meeting of the newly constituted institutional biosafety committee (IBSC) for the year 2020, was held in the Vice Chancellors board room Yenepoya (Deemed to be University) on 23rd November, 2020 at 2 PM.

Members present

Prof. M. Vijaya Kumar, Vice chancellor, Yenepoya (Deemed to be University)	Chairman
Dr. Chandrakala Shenoy, Professor, Dept. of Biosciences, Mangalore University	DBT Nominee
Dr. Sudheer Shenoy P, Associate Professor, Yenepoya (Deemed to be University)	Member Secretary
Dr. Srikala Baliga, Professor, Dept. of Microbiology, K.M.C. Mangalore	External Expert
Dr. K. M. Irfan, Associate Professor, Dept. of Pulmonary Medicine, Yenepoya (Deemed to be University)	Biosafety Officer
Dr. Rouchelle Tellis Additional Professor, Yenepoya (Deemed to be University)	Internal Member
Dr. R.C. Koumar, Associate Professor, Yenepoya (Deemed to be University)	Internal Member
Dr. Prashant Modi, Assistant Professor, Yenepoya (Deemed to be University)	Internal Member
Dr. Raghu Bhushan, Assistant Professor, Yenepoya (Deemed to be University)	Internal Member
Dr. Suparna Laha, Assistant Professor, Yenepoya (Deemed to be University)	Internal Member

Members excused:

Nil

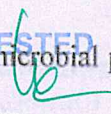
Agenda discussed

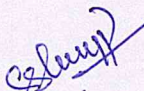
Agenda 1: To discuss on the two research proposals received

A) Title of the project: Determining the mechanism of action of a novel antimicrobial peptide with an objective to decipher new epitope for drug designing (Ref. No. YU-IBSC-004/2020). The principal investigator **Dr. Sebanti Gupta**, Assistant Professor, at Yenepoya Research Center presented the proposal.

Following questions were raised:

- 1) What is the control peptide the PI is going to use along with the novel anti-microbial peptide (AMP) isolated from centipede (positive control and negative control)?
- 2) How the PI going to discard the E. coli Waste? After treatment with novel AMP.

ATTESTED

Dr. Gangadhar Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka


Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee

- 3) Does the PI know if anything like scrambled peptide is commercially available, which can be used as a negative control with does not show any activity (anti-microbial).
- 4) The PI had mentioned about sucrose gradient isolation: what is the percentage of sucrose the PI is going to use for isolation?
- 5) What is the rationale of using HEK cells to test cytotoxicity by the PI?
- 6) Is there any structural domain in the sequence for the interaction? In that case how the PI will standardize the interaction or mechanism of action?
- 7) Will there be any off-target binding sites for AMP?
- 8) Has the PI chosen the bacteria to be used for the experiments?
- 9) How the mechanism of action will change after binding to the protein?
- 10) Why did the PI choose to use a resistant strain such as MRSA and a sensitive strain of E. coli, it would be good if the PI had used standard strain of staphylococcus.

B) **Title of the project:** Evaluation of the efficacy of manual and mechanical instrumentation in regaining apical patency during retreatment: an in vitro study (Ref. No. YU-IBSC-005/2020). The principal investigator **Dr. Reshma Pradeep**, Final year PG, Dept. of conservative dentistry and endodontics, YDC, Yenepoya University presented the proposal.

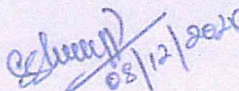
Following questions were raised:

- 1) What are statistical analytical methods will the PI use to evaluate the three methods (Instrument)? in regaining apical patency
- 2) How did the PI come to the conclusion on number of sample size (14/14)?
- 3) How does this current study taken up by the PI differ from other studies done so far?
- 4) What is the percentage of EDTA solution used for washing the samples? Since the PI is going to use 17% EDTA + Hypochlorite solution (2.5%), one of the members had raised this question and has asked the PI to recheck on the strength of EDTA solution which is to be used before going ahead with the work.

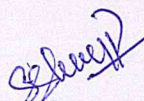
All the members came to the conclusion that there are no biosafety issues in the two proposals presented. Both the projects will be approved once all the questions raised by the members are answered satisfactorily and changes are incorporated in the proposal and submitted again.

The committee decided to convene the next meeting within next 6 months

Finally, the chairman thanked all the members for their inputs on the projects and discussion and concluded the meeting as closed at 3:00 pm.


Member Secretary
YU-IBSC

Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee


Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee

ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Proceedings of the first meeting of institutional biosafety committee (IBSC) for the year 2020, held on 03rd March 2020

The first meeting of the newly constituted institutional biosafety committee (IBSC) for the year 2020, was held in the Vice Chancellors board room, Yenepoya (Deemed to be University) on 03rd March, 2020 at 12 PM.

Members present

Prof. M. Vijaya Kumar, Vice chancellor, Yenepoya (Deemed to be University)	Chairman
Dr. Chandrakala Shenoy, Professor, Dept. of Biosciences, Mangalore University	DBT Nominee
Dr. Sudheer Shenoy P, Associate Professor, Yenepoya (Deemed to be University)	Member Secretary
Dr. Srikala Baliga, Professor, Dept. of Microbiology, K.M.C. Mangalore	External Expert
Dr. Rouchelle Tellis Associate Professor, Yenepoya (Deemed to be University)	Internal Member
Dr. R.C. Koumar, Associate Professor, Yenepoya (Deemed to be University)	Internal Member
Dr. Prashant Modi, Assistant Professor, Yenepoya (Deemed to be University)	Internal Member
Dr. Raghu Bhushan, Assistant Professor, Yenepoya (Deemed to be University)	Internal Member

Members excused

Dr. K. M. Irfan, Associate Professor, Dept. of Pulmonary Medicine, Yenepoya (Deemed to be University)	Biosafety Officer
Dr. Suparna Laha, Assistant Professor, Yenepoya (Deemed to be University)	Internal Member

Agenda discussed

Agenda 1: To discuss on the three research proposals received

A) Title of the project: Deconstruction of protein secretion systems for development of nanogel encapsulated vaccine against MDR strains of enteric fever (Ref. No. YU-IBSC-001/2020). The principal investigator **Dr. Rajesh Shastry**, Assistant Professor, Microbiology Dept. of YRC presented the proposal.

Following questions were raised:

1) In the immunization schedule The PI has written the mouse will be immunized intra nasally or intra venously. Is it correct? In the discussion the members have recommended vaccination by intra muscular injection.

Member Secretary
Yenepoya University
Institutional Biosafety Committee

ATTESTED
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

- 2) During discussion the external expert asked the PI how he will confirm that the vaccine is only immunogenic and not pathogenic.
- 3) Why there is deconstruction and MDR in the title of the study? During discussion members have recommended the PI to modify the title.
- 4) The external expert pointed out that the end point of the study is not clearly defined.
- 5) In the animal experiments it has been suggested to the PI to take one set of animals as vaccine control.

B) Title of the project: Development of antifungal hydrogels against dermatophytes (Ref. No. YU-IBSC-002/2020). The principal investigator **Dr. Rajesh Shastry**, Assistant Professor, Microbiology Dept. of YRC presented the proposal.

Following questions were raised:

- 1) Results will be highly inconsistent
- 2) How the PI will control the size of the lesions?
- 3) How the animals will be caged after the lesions are created?
- 4) Since all the animals (rats) taken are females how the PI can control the variations in the results.

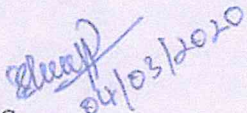
C) Title of the project: Bioengineering of a Polyethylene Terephthalate (PET) degrading bacteria from the land fillings of pet bottles flakes and scrape industry for efficient biodegradation of plastics (Ref. No. YU-IBSC-003/2020). The principal investigator **Dr. Divya Lakshmanan**, Assistant Professor, YRC presented the proposal.

Following questions were raised:


- 1) How will the PI identify PETase/BHETase/MHETase
- 2) How many years the PI will work in this project
- 3) PI has mentioned in the presentation current PET degradation methods are poor and ineffective. How the current enzymatic method helps in efficiently degrade PET?

All the projects will be approved once all the questions raised by the members are answered satisfactorily and changes are incorporated in the proposal and submitted again. The committee decided to convene the next meeting within next 6 months


Finally, the chairman thanked all the members for their inputs on the projects and discussion and concluded the meeting as closed at 1:15 pm.


04/03/2020
Member Secretary
YU-IBSC

Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee


Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee

ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



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Proceedings of the first ordinary meeting of Institutional Biosafety Committee (IBSC) for the year 2018, held on 7th August, 2018

The first ordinary meeting of Yenepoya University Institutional Biosafety Committee (IBSC) for the year 2018 was held in the Scholar's Room, Administrative Block, Yenepoya (Deemed to be University) on 7th August, 2018 at 2.00 pm.

Members present

Prof. M. Vijaya Kumar, Vice Chancellor, Yenepoya University	Chairperson
Dr. Monika Sadananda, Associate Professor, Dept. of Biosciences, Mangalore University	DBT Nominee
Dr Yashodhar P Bhandary, Assistant Professor, Yenepoya University	Member Secretary Biosafety Officer
Dr. K.M. Irfan, Assistant Professor, Dept. of Pulmonary Medicine, Yenepoya University	Internal Member
Dr. Rekha P.D. Deputy Director, Yenepoya Research Centre	Internal Member
Dr. Aditi Chatterjee, Faculty, Yenepoya Research Centre	Internal member
Dr. Bipasha Bose, Asst. Professor, Yenepoya Research Centre	Internal Member
Dr. Vidya Pai, Dept. of Microbiology, Yenepoya University	

Member on leave

Prof. Arunkumar Govindakamnavar, Head, Manipal Centre for Virus Research, Manipal University	External Expert
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Agenda discussed

The meeting started at sharp 2.00 pm in the Scholar's Room, Administrative Block, Yenepoya (Deemed to be University). All the members were present except the external expert and one internal member. The member secretary briefed the proceedings of last meeting and the proposals were discussed.

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[Signature]
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

[Signature]
Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee

Agenda 1: To discuss on the project proposal received

The committee received 12 proposals. The list of the project proposal is included in Annexure-1. Respective PI's presented their proposal. The committee discussed the proposal and suggested their view regarding the proposal and approved the proposals.

Agenda 2. Any other matter

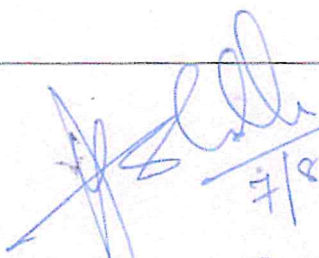
With permission of the chair, the following recommendations were made.

- i) To develop a Standard Operating Procedure (SOP) on scrutiny of the proposals by the IBSC.


Action: Done

- ii) The committee decided to nominate new members for IBSC reconstitution for the next three years (2019-2021).

The meeting concluded at 4:30 pm.


7/8/2018
Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee


Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka



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Proceedings of the first ordinary meeting of Institutional Biosafety Committee (IBSC) for the year 2017, held on 31st January, 2017

The first ordinary meeting of Yenepoya University Institutional Biosafety Committee (IBSC) for the year 2017 was held in the Scholar's Room, Administrative Block, Yenepoya University on 31st January 2017 at 10.00 am.

Members present

Prof. M. Vijaya Kumar, Vice Chancellor, Yenepoya University	Chairperson
Dr. Monika Sadananda, Associate Professor, Dept. of Biosciences, Mangalore University	DBT Nominee
Dr Yashodhar P Bhandary, Assistant Professor, Yenepoya University	Member Secretary Biosafety Officer
Dr. K.M. Irfan, Assistant Professor, Dept. of Pulmonary Medicine, Yenepoya University	Internal Member
Dr. Rekha P.D. Deputy Director, Yenepoya Research Centre	Internal member
Dr. Bipasha Bose, Asst. Professor, Yenepoya Research Centre	Internal Member
Dr. Vidya Pai, Dept. of Microbiology, Yenepoya University	

Member excused

Prof. Arunkumar Govindakamnavar, Head, Manipal Centre for Virus Research, Manipal University	External Expert
Dr. Aditi Chatterjee, Faculty Scientist, YU-IOB CSBMM	Internal Member

Agenda discussed

Agenda 1: To discuss on the project proposal received

Title of the project: Cellular, molecular and epigenetic changes in response to low dose of γ -irradiation on embryonic stem cells (Ref. No. YU- IBSC- 001 / 2017). The principal investigator Dr Sudheer Shenoy, Assistant Professor Stem Cell and Regenerative Medicine division of YRC

[Signature]
Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee

[Signature]
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

presented the proposal and explained on the storage and disposal of the waste (γ -irradiated cells) after the procedure.

The committee approved the proposal.

Agenda 2: Orientation programme on biosefty aspects to the members of IBSC, researchers and principal investigators.

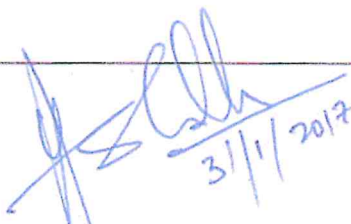
The committee resolved to conduct orientation programmes on biosafety issues on regular basis to familiarize the researchers with IBSC guidelines and institutional policies.


Agenda 3. Any other matter

With permission of the chair, the following recommendations were made.

- i) To develop a Standard Operating Procedure (SOP) on scrutiny of the proposals by the IBSC.
- ii) PI shall submit the proposal after obtaining the approval from the respective Scientific Review Board (SRB) to the IBSC before sending to the ethical committee (AEC or IEC). PI shall be responsible for obtaining the approval from IBSC or other committees.
- iii) Committee recommended for the establishment of BSL3 facility in the Microbiology department for the benefit of all the researchers. In this regard the committee requested the Dr Vidya, Head, Department of Microbiology to submit a proposal for further action.
- iv) The committee resolved that, the chairperson shall nominate a new internal member (pathologist) in place of Dr. Raghuv eer, former Professor, Dept of Pathology, who has left the institution.

The meeting concluded at 11:30 am.


3/1/2017
Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee


Member Secretary
Yenepoya (Deemed to be University)
Institutional Biosafety Committee

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka



YENEPOYA

(DEEMED TO BE UNIVERSITY)

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Meeting Details and Minutes of Yenepoya University Institutional Committee for Stem Cell Research (YU-IC-SCR)

Sl. No.	Year	No. of Meetings
1.	2020-21	01
2.	2019-20	01
3.	2018-19	-
4.	2017-18	01
5.	2016-17	01

ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Minutes of the meeting (MOM) for 5th Yenepoya University Institutional Committee for Stem Cell Research (YU-IC-SCR) meeting.

Date of the meeting: 31.10.2020

Venue: Online mode on google meet with link: <https://meet.google.com/dgu-sstz-svk?hs=122&authuser=0>

Time: 11 am to 12.30 PM

The following members were present in the meeting:

1. Prof. Polani B. Seshagiri- Chairman and Stem Cell Expert
2. Prof Mohan Wani- Vice Chairman and Stem Cell Expert
3. Dr. Smita Sudheer- Stem Cell Expert
4. Dr. Bhanuprakash Reddy, Molecular Biologist
5. Dr. Rameela Shekar- Social Scientist
6. Dr. Anirban Chakraborty- Molecular Biologist
7. Dr. Suresh P.S.- Molecular Biologist
8. Mr. Ranjan Rao- Legal Expert
9. Dr. Sheetal Ullal-Ethics Expert
10. Mr. Pushparaj-Layperson
11. Father Sibi Areeparambil - Religious Expert
12. Dr. Raghunath Bhushan-Member Secretary

Agenda items discussed:

1) Overview on the functioning of IC-SCR committee

The Chairman presented the key points as mentioned in the most recent National guidelines (2017) required to do stem cell research in India. Various levels of stem cell guidelines include the approval of projects related to stem cell research first at the institutional level followed by reporting them to the National Apex committee for Stem Cell Research and Therapy (NAC-SCRT). The Chairman advised the project principal investigators to keep the presentation in the simple/layman terms since the committee is heterogeneous and have personnel from other mandatory areas such as social sciences, legal background etc. The chairman invited the principal investigators to present their projects.

Ref: YU/IC-SCR/05/2020/01:

Project title: *Efficient in vitro differentiation of human dental pulp stem cells into odontogenic lineage using a combination of growth factors and platelet rich plasma (prp) and platelet rich fibrin (prf) and associated molecular mechanisms*

Principle Investigator and Affiliation: Dr Sharan S Sargod, Yenepoya Dental College, Yenepoya (Deemed to be University) and Co-investigator(s) and Affiliation: Co-investigator(s) and Affiliation: Dr. Bipasha Bose and Dr. Sudheer Shenoy, Yenepoya Research Centre Yenepoya (Deemed to be University)

Sudheer

Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

Dr. Gangadhara Somayaji K.S.

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangaluru- 575 018, Karnataka

Project was presented by PI Dr. Sharan

Clarifications from the committee:

- **Prof. Wani:** What's the age group of patients selected?
- **Dr. Sharan's answer:** Average age group will be 12-17 years of permanent teeth.

- **Prof. Wani:** 12 will be too young individual as already there will be a lot of regenerative potential in dental pulp stem cells from that young individuals.
- **Dr. Sharan's answer:** We are collecting teeth from individuals indicated for orthodontic extraction, who are mostly adolescents & young adults and root apex would have already matured.

- **Dr. Wani:** The PI should consider taking old individuals only where they can see the benefit of PRP and PRF. Please comment
- **Dr. Sharan's answer:** As the clinical applicability of regenerative endodontics is mostly in young individuals we have considered it. However, in future we will consider adult pulp as well

- **Prof. Wani:** Are you going to use the suboptimal doses of PRPs and PRFs to observe synergistic effects?
- **Dr. Sharan's answer:** Yes- A standardization will be made

- **Dr. Sheetal Ullal:** Since you will be supported by Orthodontics department? Do you have a written understanding with them? If yes, a copy of that should be attached as an annexure to this proposed protocol.
- **Dr. Sharan's answer:** There is no need to have an understanding with orthodontics department, since the patients requiring extraction are referred to our own department or oral surgery department.

- **Dr. Sheetal Ullal:** How quickly will you extract the pulp tissue?
- **Dr. Sharan's answer:** Within 30 min

- **Dr. Siby:** There is a mention of Human Wharton Jelly mesenchymal stem cells will be used to perform the comparative studies? What is this about?
- **Dr. Sharan's answer:** Yes -for comparison and standardization.

Ref: YU/IC-SCR/05/2020/02.

Project title: Odontogenic differentiation potential of deciduous teeth stem cells (dtscs) and dental pulp stem cells (dpscs) isolated from inflamed versus healthy pulp tissue.

Principle Investigator and Affiliation: Dr Sharan S Sargod, Yenepoya Dental College Yenepoya (Deemed to be University)

Co-investigator(s) and Affiliation: Dr. Bipasha Bose and Dr. Sudheer Shenoy, Yenepoya Research Centre, Yenepoya (Deemed to be University)

Member Secretary

Yenepoya University

Institutional Committee on Stem Cells Research

Page | 2

Yenepoya (Deemed to be University)

Deralakatte, Mangaluru-575018

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Dr. Sangeeta Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangaluru- 575 018, Karnataka

Project was presented by Co-investigator: Dr. Kavya Manoj. The chairman commented that the project needs to be presented by the PI. However, the chairman gave special permission and requested the PI of the project to be online during the presentation.

Clarifications from the committee:

- **Dr. Rameela:** Your inclusion criteria for the study includes healthy individuals without any history. Will this information be taken before the start of research? What will be the duration you expect the study to be finished?
- **Dr. Sharan's answer:** Only healthy individuals without any history of systemic illness or under medication will be considered.
- **Dr. Raghu:** You are using n=4 groups? Isn't it too much of work?
- **Dr. Sharan's answer:** We are evaluating the odontogenic differentiation potential of both primary and permanent teeth; hence 4 groups are considering.
- **Dr. Bhanu:** What is the larger perspective of using the stem cells from the inflamed pulp? What are the underlying causes for pulp inflammation?
- **Dr. Sharan's answer:** Studies have shown that inflamed pulp tissue can have equal or increased differentiation potential. Dental caries and tooth trauma are the causes of pulp inflammation. Only caries without direct involvement of pulp will be considered.
- **Dr. Wani:** You are considering young individuals for the study. I would do this kind of study in old individuals as the regenerative potential of dental pulp in young individuals is higher as the proliferation rate of cells is higher unless you are going to use it for allogenic transplantation. Please clarify.
- **Dr. Sharan's answer:** We will consider doing the study on older individuals in future.
- **Dr. Suresh:** Similar studies are carried in the age groups of 6-40 years' individuals. Please comment.
- **Dr. Sharan's answer:** since we are from dept of paediatric dentistry we are collecting pulp samples from children and adolescents
- **Prof. Seshagiri:** When you say we are using inflamed pulp tissue. How sure are you, if the pulp tissue is infected? How can you say that the tissue is completely microbes free?
- **Dr. Sharan's answer:** Standard protocols for asepsis and disinfection will be followed and harvested pulp tissue will be treated with povidine iodine solution.
- **Prof. Seshagiri:** You have used pluripotent stem cells as terms in the proposal. Which these cells are strictly not. Please change the term.
- **Dr. Sharan's answer:** Sure we will change it to multipotent

General comments on Projects #YU/IC-SCR/05/2020/01 & #YU/IC-SCR/05/2020/02: The

Members should clarify the points raised by specific members during the both the project presentations in the written bulleted format to the committee. This would also be the part of

Page | 3

Yenepoya (Deemed to be University)
Deralakatte, Mangalore-575018

Dr. Gangadhar K.S.
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575018, Karnataka

MOM. Consequently, the project can be considered as approved with aforementioned changes are incorporated and also the project has an IEC approval. The clarification to the project presentations from the PI are mentioned in the project presentation section.

YU/IC-SCR/05/2020/03. Project title: *Comparison of characteristics of periodontal ligament stem cells in diabetic and non-diabetic patients with periodontitis*

Principle Investigator and Affiliation: Dr. Maji Jose, Yenepoya Dental College, Yenepoya (deemed to be University)

Co-investigator(s) and Affiliation: Dr. Sudarvizhi. T, Yenepoya Dental College, Yenepoya (deemed to be University).

Project was presented by PI Dr. Maji Jose

- **Dr. Anirban:** What do you mean controlled diabetes individuals? Do you mean controlled diabetes using medicines or life style changes?
- **Dr. Jose's answer:** Controlled diabetes individuals are the patient with good glycemc control having HbA1c $\leq 7\%$ either through medication or diet and lifestyle modifications will be included in this study.

- **Dr. Anirban:** How severe is diabetes in periodontitis patients? Please clarify
- **Dr. Jose' answer:** Periodontitis is a microbial disease that is commonly seen in people with poor oral hygiene. The incidence of Periodontitis is 59% more in Diabetic patients with more tissue destruction when compared to non-diabetic people. According to Loe, periodontitis is the sixth complication of diabetes mellitus; the mechanism involved is similar to that of other systemic complications, via inflammatory cytokines. Diabetes and periodontitis are two way connected i.e. periodontitis is more in diabetic patients and periodontitis makes glycemc control in a diabetic patient, difficult.

- **Dr. Smita:** How do you compare the periodontal ligament stem cells between diabetic vs non-diabetic patients? Please comment
- **Dr. Jose' answer:** It has been reported that stem cell's regenerative potential is reduced in periodontitis. In diabetic patients, PDLSCs may be further affected by hyperglycemia induced detrimental effect. So the study will evaluate the difference in characteristics of cells from these two conditions, if any.

- **Dr. Smita:** What is the justification of using different CD markers for your comparisons?
- **Dr. Jose' answer:** Periodontal ligament stem cells (PDLSC's) is a heterogeneous group of stem cells and possess the characteristic of mesenchymal stem cells which have CD 45, CD 90, CD 73, CD 44, CD 31 & CD 105 as a positive CD antigens. So in order to eliminate embryonic stem cells and hematopoietic stem cells from the cells these markers will be used in the study.

Member Secretary
Yenepoya University
Institutional Committee
Yenepoya (Deemed to be University)
Deralakatte, Mangalore - 575018

Page | 4

Dr. Gangadara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575018, Karnataka

- **Prof. Wani:** Is there any delayed healing in periodontitis in diabetes patients? If yes, when you characterise you may not see any difference in expression of MSC markers but you may see a difference in differentiation markers.
- **Dr. Jose' answer:** In diabetes mellitus there will be delayed healing in these patients. As mentioned earlier, it has been reported that stem cell's regenerative potential is reduced in periodontitis. In diabetic patients, PDLSCs may be further affected by hyperglycemia induced detrimental effect. So the study will evaluate the difference in characteristics of cells from these two conditions, if any. In this study we will also be seeing a difference in differentiation markers
- **Prof. Wani:** These cells you are isolating should be CD34 negative?
- **Dr. Jose' answer:** CD 34 is a hematopoietic stem cell antigen which is a negative marker in this study.
- **Dr. Ullal:** Usually, if it is a PG dissertation, the PG should be PI. Please check with the university rules.
- **Dr. Jose' answer:** As we are applying for the university seed grant, the guide Dr.Maji jose will be the PI and Dr. Sudarvizhi.T will be the co- PI. As the current ICSCR proposal is a PG dissertation Dr.Sudarvizhi.T will be the PI and Dr. Maji Jose will be the co-PI.
- **Prof. Seshagiri:** How are you going to fund the research?
- **Dr. Jose' answer:** For evaluating the differentiation potential we will be applying for university seed grant.
- **Dr. Smita:** Are the consent forms missing for this study and previous proposed protocols? Please clarify?
- **Dr. Jose' answer:** The informed consent forms and participation information sheets in English and in regional languages was included in the presentation, same will be submitted for Institutional ethical clearance for verification.

General comments: The PI should clarify the points raised by specific members during the project presentation in the written bulleted format to the committee. This would also be the part of MOM. Consequently, the project can be considered as approved with aforementioned changes are incorporated and also the project is subject to an IEC approval. The clarification to the project presentation from the PI are mentioned in the project presentation section.

YU/IC-SCR/05/2020/04. Project title: *Establishment and biological characterization of oral cancer stem cell lines in Oral Squamous Cell Carcinoma (OSCC) as in vitro models to study a disease prevalent in India.*

Shrey
 Member Secretary
 Yenepoya University Research
 Stem Cells Research
 The University
 Mangalore-575018
 Institutional Office
 Yenepoya
 Deralekatti

REGISTERED
U. S. Shivu
 Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya Deemed to be University
 University Road, Deralekatti
 Mangalore-575018, Karnataka

Principle Investigator and Affiliation: Dr. Sudheer Shenoy P, PhD, Yenepoya Research Centre, Yenepoya (deemed to be University).

Co-investigator(s) and Affiliation: Dr. Bipasha Bose, PhD, Yenepoya Research Centre, Yenepoya (deemed to be University), Mangalore 570018

Project was presented by PI Dr. Sudheer Shenoy

Clarifications from the committee:

- **Dr. Bhanu:** Please clarify - how are you going to use the in vitro model system to study the disease prevalence in India? Prof. Seshagiri agreed with Dr. Bhanu. Please clarify and modify the title accordingly.
- **Dr. Shenoy's answer:** Since this proposal was prepared in a hurry without consulting an Oral Pathologist or a Maxillofacial Surgeon. I now feel the title was not appropriate, so I have modified it as per the suggestions given by IC-SCR members "Establishment and characterization of oral cancer stem cell lines in Oral Squamous Cell Carcinoma (OSCC) in vitro"
- **Dr. Bhanu:** 5 samples representing 4 areas is a good idea. But I am not sure considering the variability of disease in patients, if this is enough? Also, I feel 5 samples from 4 areas may give a lot of variability. Please comment.
- **Dr. Shenoy's answer:** First of all there is very less information about research conducted on comparison or cells isolated from different areas of oral cavity. It is also extremely difficult to establish epithelial cells (require special media) from each sample. We thought that if we take 5 samples from each area, we will be able to establish cells from at least two samples from each area.
- **Dr. Suresh:** Selection of patients can be a bit more specific? What kinds of patients are they going to examine?
- **Dr. Shenoy's answer:** After consulting Oral Pathologist and Maxillofacial Surgeon we have decided that will be collecting samples from tobacco related and histo-pathologically proven OSCC lesions from floor of the mouth, surface of the tongue, sides of the tongue, buccal cavity.
- **Dr. Sibi:** How is the study going to benefit the patients with advanced oral cancers?
- **Dr. Shenoy's answer:** There is no benefit to the patients. After going through the literature and consulting the dental surgeon, if we take samples of advanced oral cancers we might be able to establish the cell lines. If we take the samples from early stages the cells may not survive in culture.
- **Dr. Anirban:** Agree with Suresh – Clarification on identification and selection of patients is critical and has to be addressed as OSCCs are very heterogeneous
- **Dr. Shenoy's answer:** So here we will be taking samples from only those patients with tobacco related and histo-pathologically proven OSCC. (Cancer cells from floor of the mouth and on the tongue will be more aggressive and cancer cells from the buccal cavity will be less aggressive).

Shenoy
Member Secretary
Yenepoya University
Institutional Office
Yenepoya (Deemed to be University)
Derlakatte, Mangalore 570018

AB. Bose
Dr. Gangadhara Somayaji K.S.
Yenepoya University
University Road, Derlakatte
Mangalore-575 018, Karnataka

- **Dr. Anirban:** How effective would be the in vitro model system to understand the differences between the specialized cells vs. undifferentiated cells?
- **Dr. Shenoy's answer:** When we perform the primary culture from the tumor biopsy we get a mix culture of cancer associate fibroblasts/stromal cells, and epithelial cells. We then perform differential trypsinization and separate the two cells types. If the epithelial cells survive for at least 2-3 passages we can consider them as cell line and can be used for various experiments.
- **Prof. Seshagiri:** In your second objective, you mentioned CAF? Please expand this in the protocol. Also, it is imperative that you should mention about the clinical phenotypes of the biopsy tissues
- **Dr. Shenoy's answer:** CAF: Cancer associate fibroblasts. When we collect the biopsy from the oral cavity we will be mentioning the tumor site, nodal involvement and metastasis (TNM).
- **Dr. Bhanu:** Just to reinforce that there should be some stringent inclusion/exclusion criteria while selecting clinical phenotypes
- **Dr. Shenoy's answer:**

Inclusion criteria:

- 1) Healthy subjects enrolled in the study as control.
- 2) All patients having advanced stage oral squamous cell carcinoma

Exclusion criteria:

- 1) Patients with human immunodeficiency virus or hepatitis B virus infections will be excluded.
- 2) Patients with SCCs that either has or had in past any other malignancy.
- 3) Patients with terminal period of a disease and

General comments: The PI should clarify the major points raised by committee members during the the project presentation in the written bulleted format to the committee. This would also be the part of MOM. Consequently, the project can be considered as approved with aforementioned changes are incorporated and also the project is subject to an IAEC and IEC approval, respectively. The clarification to the project presentation from the PI are mentioned in the project presentation section.

Ref: YU/IC-SCR/05/2020/05

Project title: *Peripheral blood mobilized CD34 positive stem cells for possible cancer stem cell tropism and transformation: an in-vitro mechanistic study*

Principle Investigator and Affiliation:

B. Shyam
TESTED

Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Derlakatte
 Mangalore-575 018, Karnataka

Dr. Bipasha Bose, PhD, Stem Cells and Regenerative Medicine Centre, Yenepoya Research Centre, Yenepoya (Deemed to be University), Mangalore 570018, Karnataka, India

Co-investigator(s) and Affiliation:

- I. Dr. Rajesh Krishna, MD, Department of Hemato-Oncology, Yenepoya Medical College and Hospital, Yenepoya (Deemed to be University), Mangalore 570018, Karnataka, India
- II. Dr. Sudheer Shenoy P, PhD, Stem Cells and Regenerative Medicine Centre, Yenepoya Research Centre, Yenepoya (Deemed to be University), Mangalore 570018, Karnataka, India

Project was presented by PI Dr. Bipasha Bose

Clarifications requested from the committee:

- **Prof. Wani:** You have planned *in vitro* experiments. I think, there is a lot of literature might be available with *in vitro* data. Are you planning *in vivo* experiments to validate your hypothesis? For example: you can take nude mice and perform an orthotopic transplantation of cancers and characterize the CSCs in tissues. May it be its worth to characterize the cancer stem cells in different tissues?

Dr. Bose's answer: We have now checked the literature. As per the best of our understanding there is no literature available as of now regarding the CSC tropism of breast and colon CSC. Hence, we intend to use breast and colon CSCs for our study. It is a very good suggestion to validate our hypothesis using orthotopic cancer stem cell models. However, currently, we want to generate sufficient *in-vitro* mechanistic data before proceeding towards animal studies.

- **Prof. Wani:** Are you going to do cell sorting to separate the cancer stem cells and tumour cells?

Dr. Bose's answer: Yes, we will perform fluorescence activated cell sorting (FACS) to separate cancer stem cells from non-stem cancer cells. Before performing FACS, we will assess the percentage of cancer stem cells using analytic flow Cytometry.

- **Dr. Suresh:** Why do we have to do the bone marrow transplantation in leucoporosis patients? What's the reason? What conditions do these leucoporosis patients? How does the disease phenotype influence your interpretation of results with the specific CD markers you are investigating in your current study? This needs to be addressed.

Dr. Bose's answer: There is no-disease/term called 'Leucoporosis' to the best of our knowledge and understanding. In my opinion, the learned reviewer wrongly heard "Leukapheresis" as "Leucoporosis". Bone marrow transplantations are mostly carried out in haematological disorders. Hence, rest of the questions are not valid. Regarding "Leukapheresis", it is a technology in which the apheresis machine draws the complete peripheral blood from the patient, separates out only one component (here the WBC) are separated and rest of the blood is returned back the patient. The systemic circulation, in this case is mobilized by cytokines such as G-CSF or GM-CSF so that the CD34+ cells from the bone-marrow appear abundantly in the peripheral blood. This technique has been used routinely since decades to harvest

Member Secretary
Yenepoya University
Institutional Committee
Yenepoya (Deemed to be University)
Deralakatte, Mangalore - 575018

ATTESTED
Dr. Ganesh Somayaji K.S.
Yenepoya University Registrar
University Road, Deralakatte
Mangalore-575 018, Karnataka

CD34+ cells. In our study, also, the clinician collects the CD34+ cells using leukopheresis.

- **Dr. Suresh:** You had mentioned co-culture of cells? Is it possible to co-culture these cells? Are you using conditioned medium? Please clarify.
- **Dr. Bose's answer:** Yes, we will use both co-culture and conditioned media. For co-culturing, transwell plates will be used. For conditioned media, we will culture the CSCs in bulk and then use the spent media as the conditioned media for growing the CD34+ stem/progenitor cells.
- **Prof. Seshagiri:** You are doing CD24 and CD44 enrichment to get CSCs population, what % of cells you get as an input to start?
- **Dr. Bose's answer:** For pre-sorting validation we go for analytical flow cytometry, there we assess the percentage of cancer stem cells present in the heterogeneous or parent population. In our study, the commercially available colorectal cancer lines (HT-29 and HCT-15) were assessed for the percentage of CD44+ cell population. We found CD44+ cell percentage was 62.7% in HT-29 and 35.52% in HCT-15 cell line, respectively (See attached Annexure 1, section-1A) for details on published results from our laboratory
- **Prof. Seshagiri:** From my understanding, I think, it is a very less population of CSCs, even in cancer cell-lines? May be your CD24 and CD44 may give you a higher % of CSC? and these CD24 and CD44 may also be present in normal cancer cells?
- **Dr. Bose's answer:** The percentage of the CSC population is not very less. Actually, it's a high percentage of CSC present in the commercially available cell lines such as MDA-MB-468 and MDA-MB-231. To corroborate our findings, there is an earlier report suggesting ~ 90% CSCs. Chu et al., 2018, found reported 92% of CSCs in MDA-MB-468 cell line, Similarly, in our study (Sen et al., 2020) we have identified and isolated 80% of cancer stem cells from TNBC lines (See attached Annexure 1, section-1B)
- **Prof. Seshagiri:** I am not sure about the discriminatory power of CD44 and CD24 in isolating CSCs and I feel, you should have a very specific CD marker to isolate your CSCs. Please check the literature and clarify.
- **Dr. Bose's answer:** The combination of CD44 and CD24, or aldehyde dehydrogenase 1 (ALDH1) alone, is a widely used cancer stem cell marker in breast cancer. However, no conclusion has yet been reached as to which marker is the best for characterizing cancer stemness (See attached Annexure 1, section-1C for details on literature).
- **Prof. Seshagiri:** There are 2 different experimental systems in the study: 1. Two different cell types co-cultures 2. The CD34 cells being exposed to conditioned media of the CSCs isolated from colon or breast. This experimentation seems huge. Hence, in terms of the numbers, how many n number of times you would perform these experiments?

- **Dr. Bose's answer:** We plan to perform the experiment in triplicates. Please find the table in Annexure-A for the plan of experiments. Indeed, the experimentation work appears to be huge. However, we plan to split it up into small segments and perform experiments in a staggered manner, possibly for one cell line at a time for a span of say 6 months. So, in total for all four cell types, we plan to take 2-3 years to finish the work.
- **Prof. Seshagiri:** Are you actually going to work with colon or breast cancer excised tissues? It is not a part of this, right? Please clarify.
- **Dr. Bose's answer:** No, we do not want to use excised tissue from colon or breast cancer. Only CSCs isolated from the commercially available cell lines will be used for this study.
- **Dr Suresh:** For this study, is it essential to know the specific haematological disorder for which BMT is done and BMT can be autologous/allogeneic?
- **Dr. Bose's answer:** (as responded by the clinician Co-PI Dr Rajesh): The transplants currently planned are autologous (patient's own stem cells to be mobilized after they are treated with chemotherapy and have achieved remission. Autologous stem cell transplant is done to increase depth of response and kills residual cancer cells. Autologous transplant is basically a rescue regimen using collected and cryopreserved stem cells for high dose chemotherapy which wipes out patients stem cells whilst killing residual cancer cells. The haematological disorders will be lymphoma, myeloma or neuroblastoma.
- **Dr Suresh:** Mobilization regimens are different based on the underlying haematological disease and prior treatment (non hodgkins/MM etc.,)
- **Dr. Bose's answer:** (as responded by the Clinician Co-PI Dr Rajesh): The stem cell mobilisation regime will be same for all patients. It will be G-CSF (granulocyte colony stimulating factor-G-CSF) along with plerixafor.

General comments: The PI should clarify the major points raised by committee members during the project presentation in the written bulleted format to the committee. This would also be the part of MOM. Consequently, the project can be considered as approved with aforementioned changes are incorporated and also the project is subject to an IBSC and IEC approval, respectively. The clarifications to the project presentation from the PI are mentioned in the project presentation section. There was a discussion on projected budget that needs to be included by the PIs for their own benefit to understand the feasibility of executing the proposed objectives.

Conclusion:

Towards the conclusion, the chairman enquired with the members, if there are any further comments/suggestions on the projects discussed in the meeting. Since there were none from the members, the following points were discussed on progress of the 3 previously sanctioned projects:

Suresh
 Member Secretary
 Yerrapeta University
 Yerrapeta
 Dist. Nellore
 5018

Ms. Suresh
 REGISTERED
 Dr. Ganagadhara Somayaji K.S.
 Registrar
 Yerrapeta (Affiliated to Yerrapeta University)
 University Road, Deralakurthi
 Bangalore-575 016, Karnataka

1. Chairman enquired with the members, if they have any comments on the progress of the 3 previously sanctioned projects that were submitted to the committee by the individual project PIs.
 2. Chairman, Dr. Wani and other members also made a point that the progress reports of previously approved projects are satisfactory.
 3. Chairman also mentioned about the missing project registration numbers in the submitted documents.
 4. In addition, Dr. Chairman made a point that annual reports of the IC-SCR meetings conducted along with project approvals and status of ongoing projects, has to be sent to NAC-SCRT, New Delhi.
 5. Dr. Bhanu: made a general comment that the PIs of the projects, may think of adding a translational value to the projects that they are proposing to the committee in future as this would further enhance the project translational applicability.
 6. Dr. Smita: commented on the progress of pancreatic beta cell project and suggested that it fine to use NTERA-2 cells for optimization experiments but may not be accepted as the project deals with differentiation of human pluripotent stem cells and their differentiations to pancreatic beta cells.
 7. Dr. Bipasha's response: They had procured human pluripotent stem cell line from Thailand and they failed to culture them. However, they bought human pluripotent stem cell line from Thermo fisher Scientific, which are in culture and the experiments will be reproduced in these cells.
 8. An additional comment from the committee concerning the pancreatic beta cell project was that PI Dr. Bipasha Bose could think of using at least two different human pluripotent stem cell lines to validate the differentiations as this add on the significance and reproducibility of the findings and also could help the PI during manuscript publication.
 9. Chairman made a general comment and appreciated that he observed a good blend of basic scientists and clinicians coming together to design the stem cell related program and suggested that YRC should cache in on nucleating this activity in a big way and generate some external funds to run some of these research programs.
- Chairman thanked the PIs for their participation and requested them to leave.

Finally, the chairman thanked all members for their inputs on the projects and lively discussions and concluded the meeting as closed.

Dr. Raghu Bhushan
Member Secretary
YU-IC-SCR

Prof. Polani B. Seshagiri
Chair
YU-IC-SCR.

Prof. Polani B. Seshagiri, FNASc, FAWs,
Department of Molecular Reproduction
Development and Genetics
Indian Institute of Science
Bangalore - 560 012, INDIA

ATTESTED
Chairman
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

Thara Somayaji K.S.
Registrar
Yenepoya University
Deralakatte, Mangaluru-575018

Annexure-A: Plan of experiments pertaining to project # YU/IC-SCR/05/2020/05.

Sr No	Cancer cell type	Cell Type	Condition	Specific experiments	Replicates
1	Triple negative breast cancer (TNBC)	MDAMB-231 CSC	Co-culture With CD34+ cells	Cell migration assays, qRT-PCR gene expression analysis, immunofluorescence analysis for EMT, Cell Cycle analysis, metabolomics profiling	3 biological replicates and 3 technical replicates
2		MDA-MB 231-CSC	Conditioned media with CD34+ cells		
3		MDAMB-231-Control-WT	Co-culture With CD34+ cells		
4		MDAMB-231-Control-WT	Co-culture With CD34+ cells		

Similarly, another three sets with the cell types [TNBC-MDA-MB-468] and colon cancer cell lines HT-29 and HCT-15 will be performed.

Shrey
Member Secretary
Yenepoya University
 Institutional Committee for Stem Cells Research
 Yenepoya (Deemed to be University)
 Deralakatte, Mangaluru-575018

ATTESTED

Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Deralakatte
 Mangalore-575018, Karnataka

Minutes of the meeting (MOM) for 4th Yenepoya University Institutional Committee for Stem Cell Research (YU-IC-SCR) meeting.

Date of the meeting: 29.07.2019

Venue: IQAC Board Room, 2nd Floor, Yenepoya Medical College Building, Yenepoya (Deemed to be University)

Time: 10 am to 12 noon

The 4th meeting for the YU-IC-SCR was conducted on July 29th, 2019 at the Yenepoya University.

The following members were present in the meeting:

1. Prof. Polani B. Seshagiri- Chairman and Stem Cell Expert
2. Prof. Mohan Wani- Vice Chairman and Stem Cell Expert
3. Prof. Dr. G. Bhanuprakash Reddy, Molecular Biologist
4. Dr. Smita Sudheer- Stem Cell Expert
5. Mr. Ranjan Rao- Legal Expert
6. Prof. Rameela Shekar- Social Scientist
7. Dr. Anirban Chakraborty- Molecular Biologist
8. Dr. Suresh P.S.- Molecular Biologist
9. Dr. Sheetal Ullal-Ethics Expert
10. Mr. Pushparaj-Layperson
11. Father Sibi Areeparambil - Religious Expert
12. Dr. Raghu Bhushan-Member Secretary

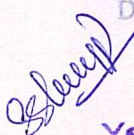
Members absent from the meeting with prior consent were:

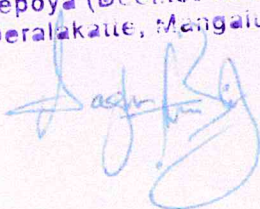
1. Dr. Anirban Chakraborty - Molecular Biologist

New member introduced in this meeting.


Religious Expert: Father Sibi Areeparambil, from Mangalore, India

Dr. Raghu Bhushan served as the "repertoire" for this meeting


Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018



ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Minutes of the meeting for the IC-SCR

Agenda discussed:

1) **Overview on the functioning of IC-SCR committee**

The Chairman presented the key points as mentioned in the most recent National guidelines (2017) required to do stem cell research in India. Various levels of stem cell guidelines include the approval of projects related to stem cell research first at the institutional level followed by reporting them to the National Apex committee for Stem Cell Research and Therapy (NAC-SCRT). The Chairman advised the project principal investigators to keep the presentation in the simple/layman terms since the committee is heterogeneous and have personnel from other mandatory areas such as social sciences, legal background etc.

The principal investigators of the projects updated the previously approved (dated 23rd June 2018) and ongoing research proposals by YU-IC-SCR meeting.

a) **Differentiation of human pluripotent stem cells into functional β -islets using bioactive lipids:**

Project was presented by Dr. Bipasha Bose.

1. **Question from Dr. Ullal** - How different is the secreted insulin in normal vs differentiated beta cells?
2. **Chairman** - consolidated the answer from Dr. Suresh (below mentioned):
1) Dr. Suresh: This can be known by C-peptide cleavage as it happens only, if its structural conformation is maintained.
2) For any of the stem cell differentiated approaches to prove the differentiated cell-types, the ultimate proof of principle is that the differentiated cell-types need to be transplanted into Mouse/Rat should be able to alleviate clinical phenotype in animal models.
3) A copy of MTA on embryonic stems from Mahidol University, Thailand needs to be submitted.

b) **In vitro manipulation of human umbilical cord Wharton jelly mesenchymal stem cells for cancer cell therapeutics.** Project was presented by Dr. Sudheer Shenoy.

Comments:

Chairman: Please check the project title, it needs a correction.

Dr. Suresh: Normoxia and Hypoxia doesn't show any differences/effects on migration potential?

Dr. Bhanu/Chairman: Any precedence that the secretome of cells have inhibitory effect or there is differential secretome being regulated in these cells cultured with normoxia vs hypoxia?

Chairman: Write a paragraph of progress of this project

Chairman: Isolation, purification and characterization of mesenchymal stem cells from fracture hematoma. Project was presented by Dr. Sudheer Shenoy (Co-PI).

Comments:

Chairman: Requested Dr. Shenoy to be brief in his presentation. Ideally, PI of the project has to present the project. 3 clinical samples have been collected and out of which one sample processed for isolation of cells. The data was shown for this particular sample. 1 Hematoma sample has been collected from the clinician and it is driven towards identifying MSC populations.

S. Suresh
Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

Sudheer Shenoy

ATTESTED
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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangaluru-575013, Karnataka

1. **Prof. Wani:** Hematoma will be having both HSCs and MSC populations. 1) When was the hematoma collected from the patient and it should have HSCs too? "What was the percentage of HSCs that were present in these cells isolated from Hematoma and how much is the literature available in this direction? 2) Dr. Shenoy - should, also characterize both the HSCs (Floating cells isolated from hematoma contain HSCs) and MSCs (adherent cells isolated from Hematoma).
 2. **Dr. M. S Moosabba:** What is the Translational clinical potential of HSC and MSC arising from this hematoma tissue, eventually? Dr. Sudheer's answer: useful for non-healing fractures. Study the non-healing bone fractures.
 3. **Prof. Wani's suggestion:** Are you receiving the hematomas from the non-healing fracture cases? Dr. Shenoy should characterize both cell populations (MSCs and HSCs) in hematoma and compare normal healing or delayed in healing cases vs non-healing fractures cases and then can ask some key questions such as: is non-healing because of less MSCs or etc.
- d) Molecular changes associated with acute UV exposure to Ocular surface stem cell populations – An *in vitro* study. Project was presented by Dr. Bipasha Bose.

Comments: No presentation done. Clinical material not obtained from the clinician. Hence, also no progress in the project.

1. Approval of the new proposals:

a) **Project 1: YU/IC-SCR/04/2019/01:**

Targeting of breast and colon cancer stem cells using Vitamin C- in vivo validation using cell-line derived tumor xenograft models and derivation of primary cells from human patient samples (colon and breast cancer). Project was presented by Dr. Bipasha Bose.

Comments:

Chairman: Requested Dr. Bipasha to be brief in his presentation and keep it less scientific for all the members to understand.

Prof. Wani: How do you differentiate the cancer stem cells vs primary cells from Patient material as it contains heterogeneous population of cells. How do you do this technically?

Chairman: Elaborated the question from Prof. Wani by asking: "After trypsinising the patients material, would you sort the cancer stem cells and perform experiments on this?"

Prof. Wani: Do you want to check an effect of Vitamin C on primary cells isolated from Patients material? Not clear to me

Dr. Bipasha: Explained going to the methodology figure by explaining the n=20 from each colon and breast cancer biopsies. Each of Biopsies will be put into culture and expanded to get a heterogeneous cell population. From this population of cells, I will sort the cancer stem cells assays, based on marker expression and characterize the cancer stem cells properties such as clonogenic assays, CD44-ICD, CD24 (low) etc. Once they are CSC are characterized and established only then will they will be exposed to vitamin C.

Dr. Bhanu: Why do you expect that these (CSCs from primary tumors) will be different from the CSCs isolated from your cancer cells cell-lines?

Dr. Bipasha: Because of the clinical component here. There are differences in stages and aggressiveness of CSC present in the primary tumor that would vary.

Dr. Suresh: added that there can be genetic changes that may be different too.

Chairman: Type Clinical presentation (Genetic/environment) in the primary tumors is different than the CSCs isolated from individual cancer cell lines. In addition, there could be patient specific differences in CSC properties between patients too.

Dr. Suresh: What your choice of patients?

Dr. Bipasha: Triple negative Breast cancer patients

Shenoy
Member Secretary
Yenepoya University Research
Institutional Committee for Stem Cells Research
 Yenepoya (Deemed to be University)
 Deralakatte, Mangalore - 575 018

Sudheer

ATTESTED
GP

Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Deralakatte
 Mangalore - 575 018, Karnataka

Dr. Bhanuprakash: You are providing high doses of vitamin C and it has been observed that the activity of Vitamin C cells depends on the media composition and concentrations. What is the concentration of vitamin C you plan to use?

Dr. Bipasha: In colon cancers we gave 5-25 uM in media and in breast cancers we have used high concentrations such as from 100-10,000 uM. In breast CSC, 3mM is killing the CSCs.

Dr. Smita: Are you going to save some patient material or cells (in LN2) for other purposes? Has this been mentioned in the consent form.

Dr. Bipasha: We may not have more tissue as some needs to be sent to histopathology. Hence, we will not preserve. Concerning cells isolated from CSCs, we will mention this in the consent form.

Chairman: 1) When you said 20 each of colon and breast cancer tissue for your CSC isolations - this is not explicitly mentioned in the project protocol. This has to be mentioned 2) When enriching CSCs from patient sample, you will be checking CD44+ or CD24- and this is not mentioned in the protocol. 3) In your experimental design, after enriching CSCs, the cultured CSC as well will be exposed to vitamin C. You have one set of experiments with patients derived CSCs and another with cells exposed to vitamin C. Next you would go for Xenografts with both.

Dr. Bipasha: The xenograft model - we will do only with in vitro derived CSCs and it is mentioned as the third objective of our project protocol.

Dr. Bhanuprakash: Out of these 20 tissues - can you grade these tissues too while performing these studies?

Dr. Bipasha: Sir, we may not have a choice as we are dependent on the clinicians completely.

Dr. M. S Moosabba: I think, whenever the sample comes to you, the clinician should be able to inform you if it is an early or late breast cancer.

Dr. Ullal: Are you procuring nude mice?

Dr. Bipasha: They are being procured from ACTREC

Mr. Ranjan Rao: What do you mean by a nude mouse?

Dr. Bipasha: They are immune compromised mouse. It is immune cell deficient.

Chairman: The reason why we need this nude mouse you should explain.

Dr. Bipasha: Human immune system will reject other organs from other animals because a we have strong immune system

Dr. Wani/Chairman: You can add a term "athymic" without immune system.

Chairman: Since you are planning to use both human patient material and animals, this protocol should also be validated through IEC and IAEC

Dr. Bipasha: mentioned that IAEC is done and IEC need to be done.

- b) **Project 1: YU/IC-SCR/04/2019/02: Fucoidan beads containing hydroxyapatite and graphene oxide for Human bone tissue repair and regeneration.** Project was presented by Dr. Venkatesan.

Chairman: requested Dr. Venkatesan to introduce himself.

Dr. Venkatesan: Introduced himself followed by the project presentation.

Prof. Wani: Are these nanoparticles from hydroxyapatite

Dr. Venkatesan: agreed

Prof. Wani: are you making porous nanoparticles?

Dr. Venkatesan: mentioned that he is interested in making both porous and nonporous nanoparticles. Dr. Venkatesan wants to compare the roles of both.

Chairman: Which one do you want use (porous and nonporous) when you plan to use MSCs?

Dr. Venkatesan: answered both

Prof. Wani: Why are you buying the cells? You can MSCs from any ongoing projects

Chairman: What is the role of Dr. Kaushik HSc. in this project?

Chairman: you had mentioned that you will source the human MSCs either from Lonza or Stempeutics companies? Stempeutics may only have clinical grade MSCs and they are very expensive. I think, you don't need clinical grade. You may think of academic grade. Perhaps, you

Shree P
Member Secretary
Yenepoya University
Department of Stem Cells Research
Yenepoya University
Mangalore - 575018

ATTESTED
be

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Darlakatte
Mangalore - 575 018, Karnataka

can borrow within the institute or may think of using Mouse MSCs (acquiring IAEC) and this will save a lot of funds for you.

Dr. Bipasha: Mentioned that she can share MSCs isolated from Wharton jelly MSCs project.

Chairman: Thanked Dr. Bipasha and requested her share.

c) Project 1: YU/IC-SCR/04/2019/03: Osteogenic differentiation of Human mesenchymal stem cells using sulfated polysaccharides from Indian brown seaweeds.

Project was presented by Dr. Venkatesan. He mentioned that this project is a part of the above project (1b).

Chairman: Do you have a presentation or Objectives?

Dr. Venkatesan: answered no

Chairman: read all objectives from the protocol submitted to the committee.

Prof. Wani: your methodology may be same but not objectives

Dr. Bhanuprakash: Are you comparing your polysaccharides to any other established or available ones?

Dr. Venkatesan: mentioned he will be comparing with sulfated polysaccharides from sigma.

Chairman: Your third objective only is dealing with the stem cells and hence this is important for the IC-SCR committee and would request you elaborate on this rather than first two objectives. Also suggested to rope in other stem cell scientist for using MSCs rather than buying these cells commercially.

Dr. Smita: As sir, suggested it would be good to try first in Mouse MSCs or may be use mouse origin skeletal muscle cells.

Dr. Suresh: What will be the fate of these modified stem cells after conversion using sulfated polysaccharides and how is disposed later?

Chairman: This will be considered as a bio-waste and I believe, since Yenepoya being a hospital, all the protocols should be in place to dispose bio-waste.

Chairman: enquired, if there are any further discussion on the project.

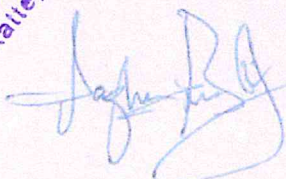
MoM Conclusion:

Towards the conclusion of MoM, the chairman enquired with the members, if there are any further comments/suggestions on the projects discussed in the meeting. Since there were none from the members, the following points were discussed:

General comments:

1. For all 4 previously approved projects, a document (of one paragraph) needs to be prepared and submitted to the committee, mentioning the details of each of the projects such as, what has been achieved or what has not been achieved and the reasons for unachieved tasks in the project.
2. For project: Differentiation of human pluripotent stem cells into functional β -islets using bioactive lipids with YU/IC-SCR/03/2018/1, a copy of MTA on embryonic stems from Mahidol University, Thailand needs to be submitted.

COI is not required from the committee members involved in the ICSCR. According to the chairman and other members, if someone has a conflict of interest, then they will declare. If they are not declaring means they have no COI with the projects. If a member has a COI concerning a project, then they will inform the chairman and that particular member will not be involved in the decision making process concerning that project.



Shree
Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

ATTESTED
te

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575018, Karnataka

New Approvals:

General comments:

All the three new projects require scientific background and rationale.

a) Project 1: YU/IC-SCR/04/2019/01:

Targeting of breast and colon cancer stem cells using Vitamin C- in vivo validation using cell-line derived tumor xenograft models and derivation of primary cells from human patient samples (colon and breast cancer). Project was presented by Dr. Bipasha Bose.

Comments:

- 1) The project nowhere mentions about CD44 enrichment and CD24+ and negative selection. This needs to be specified in the project.
- 2) The exact number numbers of patients for breast cancers and colon cancers needs specification in the project protocol.
- 3) Since the project is approved by IAEC, for animal xenograft experiments, a copy of the same needs to submitted to IC-SCR.
- 4) The project needs approval of Institutional Ethics Committee (IEC) for procurement and handling of the clinical samples.
- 5) Consequently, the project will be approved with aforementioned minor changes are incorporated.

b) Project 2: YU/IC-SCR/04/2019/02: Fucoidan beads containing hydroxyapatite and graphene oxide for Human bone tissue repair and regeneration. Project was presented by Dr. Venkatesan.

c) Project 3: YU/IC-SCR/04/2019/03: Osteogenic differentiation of Human mesenchymal stem cells using sulfated polysaccharides from Indian brown seaweeds. Project was presented by Dr. Venkatesan.

Comments:

1. Both the project requires a revision of the protocol. First two objectives need to be deleted and the third objective needs to be elaborated, which is important for ICSCR.

Concerning the MSC sourcing, the proposed project doesn't require the clinical grade MSCs. It only requires academic grade MSCs. The committee suggested in house available MSCs can be used alternatively Mouse derived MSCs with approval of IAEC. Details on functional experiments needs to be elaborated (such as Cell density, proliferation assays, migration assays). Both projects require Institutional Ethics Committee (IEC), if human MSCs are used and if Mouse MSCs are used then it requires Institutional Animal Ethics Committee (IAEC).

Shrey
Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

Sagnika
Member Secretary
Yenepoya University

Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

ATTESTED
CP

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

3. The projects will be recommended with subject the aforementioned comments are incorporated.

Finally, the chairman thanked all the members for their inputs on the projects and lively discussions and concluded the meeting as closed.

[Handwritten Signature]
Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

[Handwritten Signature]
Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

ATTESTED
[Handwritten Signature]
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Minutes of the meeting (MOM) for 3rd Yenepoya University Institutional Committee for Stem Cell Research (YU-IC-SCR)

Date of the meeting: June 23, 2018

Venue: IQAC Board Room, 2nd Floor, Yenepoya Medical College Building, Yenepoya University

Time: 10 am to 12 noon

The second meeting for the YU-IC-SCR was conducted on June 23, 2018 at the Yenepoya University.

The following members were present in the meeting:

1. Prof. Polani B. Seshagiri- Chairman and Stem Cell Expert
2. Prof Mohan Wani- Vice Chairman and Stem Cell Expert
3. Dr. Smita Sudheer- Stem Cell Expert
4. Mr. Ranjan Rao- Legal Expert
5. Prof. Rameela Shekar- Social Scientist
6. Dr. Anirban Chakraborty- Molecular Biologist
7. Dr. Suresh P.S.- Molecular Biologist
8. Dr. Sheetal Ullal-Ethics Expert
9. Mr. Pushparaj-Layperson
10. Mr. Illyas Saqafi- Religious Expert
11. Dr. Raghu Bhushan-Member Secretary

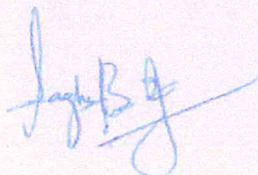
Members absent from the meeting with prior consent were:

1. Dr. Bhanuprakash Reddy- Molecular Biologist

New members were introduced in this meeting.

1. Stem Cell Expert: Dr. Smita Sudheer-Assistant Prof. Dept. of Genomic Sciences, Central University of Kerala, India.
2. Molecular Biologist: Dr. Anirban Chakraborty- Nitte University Center for Science Education and Research, Paner Campus, Mangalore, India.
3. Molecular Biologist: Dr. Suresh P.S. - Assistant Prof. National Institute of Technology, Calicut, Kerala, India.
4. Ethics Expert: Dr. Sheetal Ullal- Associate Prof. Dept. of Pharmacology, Kasturba Medical College, Manipal University, Mangalore.
5. Layperson-Mr. Pushparaj-Accounts officer, Mescom, Bejai, Mangalore.

Dr. Raghu Bhushan served as the "repertoire" for this meeting



ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Minutes of the meeting for the IC-SCR

Agenda discussed:

1) Overview on the functioning of IC-SCR committee

The Chairman presented the key points as mentioned in the most recent National guidelines (2017) required to do stem cell research in India. Various levels of stem cell guidelines include the approval of projects related to stem cell research first at the institutional level followed by reporting them to the National Apex committee for Stem Cell Research and Therapy (NAC-SCRT). The Chairman advised to keep the presentation in the layman terms since the committee is heterogeneous and have personnel from other mandatory areas such as social sciences, legal background etc. This advice was supported by all the members present.

1. Project 1: YU/IC-SCR/03/2018/1

Differentiation of human pluripotent stem cells into functional β islets using bioactive lipids

Comments about this project:

- I. The name of the all cell lines needs to be specified to IC-SCR and later on the National Apex Committee for Stem Cell Research (NAC-SCR).
- II. Execution of the project initially with one cell line is recommended by the IC-SCR committee.
- III. The ID of the human ES cell line to be procured needs to be specified.
- IV. Once the results are established with one cell line, if the PI intends to repeat the experiments with additional human pluripotent stem cell line (hPSC). The names/ID of the additional hPSC lines also need to be informed to the IC-SCR at a later point of time during the procurement of such lines.
- V. Details of experimental methodologies need to be incorporated under Section 9B of the IC-SCR application proforma.

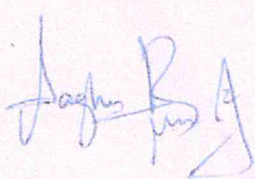
Decision: The project can be approved once the aforementioned comments are incorporated. The duration of approval is for 03 years

2. Project 2: YU/IC-SCR/03/2018/02.

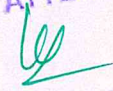
Wharton's jelly mesenchymal stem cells (WJ-MSCs) from human umbilical cord for cancer stem cell therapeutics

Comments about this project:

- I. The title needs modified and the term 'therapeutics' needs to be removed
- II. Third objective needs to be modified (secretome).
- III. Fourth objective needs to be deleted.



ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

- IV. Cancer cell lines needs to be specified with passage number and use of cancer stem cells.
- V. Derivation of cancer stem cells needs to be elaborated.
- VI. Section 9B of the IC-SCR application proforma needs to be elaborated.
- VII. This project needs the final approval of vice chairman Prof. Mohan Wani.

Decision: The project can be approved, once the aforementioned comments are incorporated. The duration of approval is for 03 years

3. Project 3: YU/IC-SCR/03/2018/03

Isolation, Purification and Characterization of mesenchymal stem cells from fracture hematoma/periosteum/skeletal muscle

Comments about this project:

- 1. There was a confusion about the number of samples to be taken (n=10/n=20). It was decided that n=10 samples will be taken.
- 2. Strictly 10 hematoma samples will be taken. There should not be any classification of early vs. late hematoma samples
- 3. Name of Sudheer Shenoy P to be in Co-PI instead of Co-Investigator.

Decision: The project can be approved once the aforementioned comments are incorporated. The duration of approval is 03 years

4. Project 4: YU/IC-SCR/03/2018/4

Molecular changes associated with acute UV exposure to ocular surface stem cells (OSSC) populations: an in vitro study.

Comments about this project:

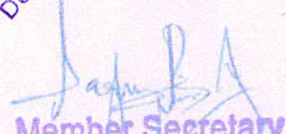
- 1. The primary stem cells derived for this study need to be strictly used for research purpose by the PI/Co-PI and never be commercialized.
- 2. The Institutional Ethics Committee (IEC) need to be informed regarding the detailed use, storage of the derived primary stem cells and duration of storage.

Decision: The project can be approved once the aforementioned comments are incorporated. The duration of approval is 03 years


MoM Conclusion:

Towards the conclusion of MoM, the chairman enquired with the members, if there are any further comments/suggestions on the projects discussed in the meeting. Since there were none from the members, the following points were discussed I) SOP was discussed in the meeting and was decided that it will be circulated to all the members. II) The chairman summarized all the key discussions on all the projects and concluded the meeting as closed.

Member Secretary
 Yenepoya University
 Institutional Committee for Stem Cells Research
 Yenepoya (Deemed to be University)
 Deralakatte, Mangaluru-575018


 Member Secretary
 Yenepoya University

Institutional Committee for Stem Cells Research
 Yenepoya (Deemed to be University)
 Deralakatte, Mangaluru-575018

ATTESTED


Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 Deralakatte
 Mangaluru, J.S, Karnataka

Minutes of the meeting for 2nd Yenepoya University Institutional Committee for Stem Cell Research (YU-IC-SCR)

Date of the meeting: Nov 03, 2016

Venue: IQAC Board Room, 2nd Floor, Yenepoya Medical College Building, Yenepoya University

Time: 10 am to 12 noon

The second meeting for the YU-IC-SCR was conducted (date, venue and time mentioned above). New members were introduced in this meeting. *Four new members* including the Chairman of the committee who were introduced in this meeting were as follows:

1. *Chairman and Stem Cell Expert:* Prof. Polani B Seshagiri from the Indian Institute of Science, Bangalore, India.
2. *Stem Cell Expert:* Prof. Mohan Wani, Scientist F, National Centre for Cell Science, Pune, India.
3. *Stem Cell Expert:* Prof. Basan Gowda Kurkalli, Nitte University, Mangalore, India.
4. *Religious person:* Mr. Islyas Saqafi, Yenepoya University, Mangalore, India.

The members present in the meeting were:

1. Prof. Polani B. Seshagiri- Chairman and Stem Cell Expert
2. Prof Mohan Wani- Stem Cell Expert
3. Prof. Basan Gowda Kurkalli- Stem Cell Expert
4. Dr. Sudheer Shenoy- Stem Cell Expert and Member Secretary
5. Mr. Ranjan Rao-Legal Expert
6. Prof. Rameela Shekar-Social Scientist
7. Prof. R M Shenoy- Orthopaedic surgeon and Member
8. Prof. Rajagopal-Professor of OBG and Member
9. Prof. Rekha PD-Prof. and Deputy Director of Yenepoya Research Centre (YRC), Member
10. Dr. Shyamjith Manikkot-Animal research and Member

Members exempted from the meeting were:

1. Prof. Joseph Thomas-Bioethicist and member
2. Prof. Vidya Hegde-Professor of Ophthalmology and member
3. Dr Aswini Dutt-Bioethicist

The Principal Investigators/Co-Principal Investigators present were:

1. Prof. Cynthia Arunachalam-Professor of Ophthalmology
2. Prof. RM Shenoy-Professor of Orthopaedics
3. Dr. Bipasha Bose- Faculty, Stem Cells and Regenerative Medicine, YRC
4. Dr. Sudheer Shenoy-Faculty, Stem Cells and Regenerative Medicine, YRC

Dr Bipasha Bose served as the "minute taker" of this meeting

Member Secretary
Yenepoya University
Institutional Committee for Stem Cell Research
Yenepoya Medical College Building
Derlakatte, Mangalore-575 018

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Dr. Gangadhara Semayaji K.S.
ATTESTED

Dr. Gangadhara Semayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore- 575 018, Karnataka

The following agenda was discussed in the meeting:

The Chairman presented the key points as mentioned in the most recent National guidelines (2013) required to do stem cell research in India. Various levels of stem cell guidelines include the approval of projects related to stem cell research first at the institutional level followed by enrolling them in the National Apex committee for stem cell research and therapy (NAC-SCRT). At the institutional level researchers are allowed to *carry out stem cell research and not therapy*. Hence, as per the revised National guidelines, the committees are termed as IC-SCR and *not IC-SCRT* (Institutional Committee for Stem Cell Research and Therapy) *as termed earlier*. Furthermore, the Chairman also commented that these are the National Guidelines only at present and have not yet been enforced as laws by the Government of India.

PART 1-GENERAL

1. *Frequency of the meetings*: It was advised by the Chairman to conduct YU-IC-SCR meeting twice a year as per the National guidelines and was agreed upon by the members present
2. *Review of progress of the approved/ongoing projects*: Once a year, as advised by the Chairman as per the National guidelines and was agreed upon by the members present.
3. *Evaluation of the urgent research proposals*: This point was raised by one of the members. Chairman of the committee advised that urgent proposals can be taken up for review through emails under exceptional cases (if the project is already recommended for funding by an external agency and is awaited for YU-IC-SCR). All the members need to review the electronic version of such projects on a priority basis and approve/disapprove accordingly. Chairman's recommendation was unanimously agreed by all the members.
4. *Conducting meetings if there are less stem cell projects such as only one project for evaluation by YU-IC-SCR*: The Chairman advised that under such circumstances, there is a provision in the National guidelines for the stem cell research that the Yenepoya University Institutional Ethics Committee (YU-IEC) can take up the role of YU-IC-SCR for evaluation and further approval/disapproval. All the members agreed to the advice.
5. *Research proposals pertaining to derivation and use of cancer stem cells from human tissues*: The Chairman strongly advised that it is mandatory for all the research proposals pertaining to the use of human tissues for the derivation and use of cancer stem cells to be reviewed and approved by YU-IC-SCR before commencing the study as per the National guidelines and agreed upon by the members present.
6. *Member secretary of YU-IC-SCR and his simultaneous role as a PI/Co-PI in the evaluated/discussed projects*: The Chairman strongly advised that as per the National guidelines, the member secretary should have least number of stem cell projects as a PI/Co-PI for evaluation in the YU-IC-SCR. This was suggested for preventing the bias in decision making for the projects in which the member secretary is a PI/Co-PI. However, due to the lack of suitable personnel to serve as the member secretary of YU-IC-SCR, it was suggested that the current member secretary can continue till one new member secretary is appointed. This advice was unanimously agreed upon by all the members present.

Storage and disposal of the primary cells, cell lines and tissues: This point was raised by one of the members. Chairman and one of the stem cell experts Prof. Mohan Wani suggested that the

Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangalore-575018

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ATTESTED.
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575018, Karnataka

primary cells, cell lines and tissues can be stored under standard practice of cryopreservation for infinite time for research use under a particular project approved by YU-IC-SCR. However, if the same material needs to be used for another new project, the project needs a fresh approval from the YU-IC-SCR.

8. *Comments on the suggestions from the previous meeting for the smooth functioning of YU-IC-SCR:*

Sr No	Points	Suggestions in the previous meeting and action taken	Comments by the new committee
1.	Office space for YU-IC-SCR	Separate office space required No action has been taken	Not required
2.	Office staff for managerial work and documentation	Required No action has been taken	Not required. However, a part-time person can be appointed if the work load increases
3.	Separate desktop, email and phone number	Required Actions taken: Separate email ID has been created stemcellresearch@yenepoya.edu.in for all the communications needed for YU-IC-SCR New extension number has been created. Phone number-+91-8242204668 Extn (2056)	Can be managed with the existing resources of the stem cell group of YU
4	Logbook and inventory for maintaining records for ongoing projects, storage and disposal of cell lines	Mandatory Action taken: Records are being maintained for the ongoing projects and the new projects will be added to the same. Existing inventory is there for the storage of cells in the liquid nitrogen tank	Mandatory and action is being taken

Shreyas
Member Secretary
Yenepoya University
Institutional Committee (Stem Cells Research)
Yenepoya Deemed to be University
Derakatte, Mangalore 575018

Part II-REVIEW OF THE PROJECTS

Formal presentation of the projects: The Chairman advised to keep the presentation in the layman terms since the committee is heterogeneous and have personnel from other mandatory areas such as social sciences, legal background etc. The points the Chairman suggested to be included in the presentations were the need of the study, rationale, and benefit to mankind and amount of human tissue to be used. This advice was supported by all the members present.

Shreyas
ATTESTED
Sharan Somayaji K.S.
Chairman
Yenepoya Deemed to be University
Derakatte, Mangalore
Karnataka

Research proposal 1: YU/IC-SCR 01/2016

Title: Fabrication of hybrid-biocomposite nanofibrous scaffolds for loading dental stem cells and their evaluation in pre-clinical cellular models for myocardial infarction and muscular dystrophy.

Comments:

1. Anonymous dental pulp cannot be used
2. Need to specify the tissue source such as dental pulp
3. Number of samples to be included in the study design
4. Material toxicity to be included in the study design
5. Animal model-Either mouse or rat
6. CD146⁺ cells as the main component need to be emphasized
7. Need to mention the duration of the study (3 years)
8. Administration of immunosuppressant's for animal transplantation experiments
9. No need of GLP/GMP grade laboratory. BSL 2 facility is sufficient

Outcome: The project can be approved once the aforementioned comments are incorporated

Research proposal 2: YU/IC-SCR 02/2016

Title: Isolation, Purification and Characterization of mesenchymal stem cells from fracture hematoma/periosteum and skeletal muscle.

Comments:

1. Specify the type of fracture-Long bone fracture
2. Specify the inclusion and exclusion criteria
3. Define the time for the collection of hematoma-2-7 days (as feasible from the clinician's viewpoint and rationally correct from the cell biologist's viewpoint)
4. Please mention as exploratory study, maximum sample size-20
5. Please mention the type of stem cell for the study as MSC and HSC
6. Omics approach was suggested
7. Duration of the study-3 years

Outcome: The project can be approved once the aforementioned comments are incorporated

Research proposal 3: YU/IC-SCR 03/2016

Title: Cellular, molecular and epigenetic changes, in response to, low doses of γ -irradiation on embryonic stem cells (ESC)

Comments:

1. Please mention the physiological relevance of the chosen doses of γ -irradiation
2. Please mention three names each of human and mouse ES cell lines to be used in the study
3. Biosafety committee approval is required for the radiation treated ES cell lines
4. Nude or SCID mice that are available in India can be used and included in the study because of the complications associated with the import of Rag2 γ chain null mice

Outcome: The project can be approved once the aforementioned comments are incorporated

4/5 Page

ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Research proposal 4: YU/IC-SCR 04/2016

Title: Oxidative damage to the human ocular surface stem cells in response to bright and ultraviolet light and its associated mechanisms

Comments:

1. Please include the duration of the study-3 years
2. Number of samples, n=30, 10 samples per year
3. Mention the time of removal of the cadaveric eye and processing of the sample
4. Mention the name of the eye bank from which the tissue will be sourced

Outcome: The project can be approved once the aforementioned comments are incorporated

Part III-SUMMARISING BY THE CHAIRMAN

1. All the projects need to be written in the recommended template without much of technical detail
2. Approval certificate needs to be prepared, circulated and approved by the committee members
3. Approved projects from YU-IC-SCR can only be started after the approval from the YU-IEC

Part IV: COMMENTS ON THE INFRASTRUCTURE AND COMPETENCE OF THE PI/CO-PI TO CARRY OUT THE DISCUSSED PROJECTS

The committee members visited the laboratories for carrying out the stem cell work and commented the facility as excellent. However, the stem cell experts suggested for the immediate procurement of additional dedicated equipments for the stem cell culture laboratory namely an inverted microscope with phase contrast and image capturing facility, fluorescence microscope with image capturing facility and a stereo zoom microscope. The YU-IC-SCR stem cell expert members evaluated the competence of the PI/CO-PI to carry out the discussed projects as adequate.

Shrey

Member Secretary
Yenepoya University
Institutional Committee for Stem Cells Research
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

ATTESTED

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Dr. Gangadhara Somayaji K.S.
Registrar
(Yenepoya University)
Shrey

Minutes of the meeting of first Yenepoya University Institutional Committee for Stem Cell Research (YU-IC-SCR)

The first meeting of YU-IC-SCR was held on 29th march 2016 at IQAC board room 2nd floor Yenepoya medical college building, Yenepoya University, Mangalore between 10 am -12:30 pm.

In the SOP following things were suggested by the members to be included

Scope: It was decided that:

- 1) The proposals submitted to the YU-IC-SCR also need to be approved prior by Institutional Ethics committee (IEC).
- 2) The sequence of submission and approval of a stem cell related proposal is first from the IEC followed by the YU-IC-SCR.
- 3) Chairman of the YU-IC-SCR will give the final approval to the proposals submitted to the stem cell committee.
- 4) Any external member of YU-IC-SCR (outside Yenepoya University) if willing to get a stem cell proposal reviewed by YU-IC-SCR can only do so after having the proposal approved by the IEC of that institute. YU-IC-SCR is willing to take up the review of such proposal only on payment basis.

Composition:

- 1) It was decided by all the members to include qualifications of the members.
- 2) It was also decided to encourage the members to have a degree in Bio-Ethics/Medical Ethics.
- 3) Chairman suggested finding the composition of National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT).

Quorum:

- 1) It was decided to highlight the number of members

Total members =13

Quorum & minimum number of members to be present to conduct a meeting should be = 07

Out of 07 members 04 should be external members

It was decided that if the Chairman is absent the members can nominate another external member as an acting chairman.

ATTESTED

[Signature]
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road
Mangalore - 575 014

- 3) It was decided that if the Member Secretary is absent the members can nominate another external member as an acting Member Secretary.
- 4) It was also decided that Member Secretary (having research proposals) will be a part of the quorum, but will not take part in decision making.

Conflict of Interest (COI):

- 1) It was decided that if COI is raised by a member for a particular proposal during discussion, that member needs to willingly step out of the meeting room during the decision making that will be documented in the minutes of the meeting.

Terms of reference of members and frequency of meetings

- 1) The current committee will function for 3 years.
- 2) Meeting can be more frequent if required or as and when convened by the chairman.
- 3) The normal frequency of the meeting was decided as quarterly.

Progress of the proposals

- 1) It was decided that every proposal will have an identification number with the year and University initials e.g. (YU-IC-SCR\01\2016).
- 2) Co-PI's names should also be included in the Ethics approval certificate.
- 3) It was decided that proposals submitted for the approval to YU-IC-SCR should carry a detailed 20 point subject information sheet and the patient consent form. If the patient is unable to provide the consent for collection of samples, the consent needs to be obtained from the patient's relative.
- 4) The patient consent form should be in three different languages such as Hindi, English, Kannada and Malayalam.
- 5) It was decided that the status of each of the approved proposals will be updated in the next meeting (once in three months).
- 6) The detailed progress of each of the approved proposals will only be evaluated on a half-yearly basis.

Infrastructure
Following was decided to be established for the smooth functioning of YU-IC-SCR

- 1) Office space for YU-IC-SCR
- 2) Office staff for managing the activities of YU-IC-SCR
- 3) Dedicated computer, Separate E-mail ID, Phone number
- 4) To maintain a record of storage and disposal of cell lines or material.

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ATTESTED
Shree
 Dr. Gangadhara Semayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Deralakatte
 Mangalore-575 918, Karnataka

- 5) The cell lines derived from the patient samples need to be stored/cryopreserved for at least for a period of 7 years after patenting and/or publishing the data obtained from such cell lines for defending the genuineness of the data afterwards, if needed.

Annexure in the current SOP:

- 1) It was decided not to have annexure 3 and 4 in the current SOP.

Decision regarding various projects that were discussed in the meeting

- 1) **Project YU-IC-SCR/01/2016: Fabrication of hybrid-biocomposite nanofibrous scaffolds for loading dental stem cells and their evaluation in pre-clinical cellular models for myocardial infarction and muscular dystrophy.**

Response of the committee

- a) The project is approved in the present form
- b) Additional documents to be submitted in the next meeting:
 - i. Clearance from the Institutional Animal Ethics committee
 - ii. Patient consent form if the patient is identifiable, otherwise if the tooth is collected from the trash bin and the patient is, hence, anonymous need to mention anonymous in that case

- 2) **Project YU-IC-SCR/02/2016: Isolation, Purification and Characterization of mesenchymal stem cells from fracture hematoma.**

Response of the committee

- a) The project is not approved in the present form
- b) Additional documents to be submitted in the next meeting:
 - i. Clearance from the Institutional Ethics committee (approval letter needs to be shown in the next meeting).
 - ii. Tissue specimen such as hematoma, periosteum and damaged muscle of the patients taken probably during surgery. This is not part of routine procedure though mentioned as biological waste. This need to be clarified by the PI.
 - iii. There is a mention of timings: samples will be collected at different time points and with different age group. This needs to be clarified by the PI.
 - iv. There is no informed consent, patient information sheet, mention about the samples is for research only, risk benefit ratio, adult/pediatric. These papers need to be submitted in the next meeting.
 - v. What happens to the stem cell isolated and how long it will be retained? What about further use?

S. S. S.
Member Secretary
Yenepoya Deemed to be University
Institutional Animal Ethics Committee
Yenepoya (Deemed to be University)
Deralakatte, Mangaluru-575018

S. S. S.

ATTESTED
S. S. S.
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575018, Karnataka

- 3) Project YU-IC-SCR/03/2016: Oxidative damage to limbal stem cells of eye in response to bright and ultraviolet light and its associated mechanisms

Response of the committee

- a) The project is not approved in the present form
- b) Additional documents to be submitted in the next meeting:
 - i. There is no informed consent for the study, detailed patient information sheet and consent form detailing the nature of research has to be mentioned. This should be presented in the next meeting.
 - ii. The study involves taking specimen (biopsy) limbal samples, during eye surgery (50 samples above 20 years of age). It is not standard procedure to take specimen during the planned eye surgery other than for research. Ophthalmologist has to specifically mention the study details in the consent and information sheet.
 - iii. Clearance from the Institutional Animal Ethics committee (already approved). The certificate will be presented in the next meeting.

- 4) Project YU-IC-SCR/04/2016: Cellular, molecular and epigenetic changes, in response to, low doses of γ -irradiation on embryonic stem cells

Response of the committee

- a) The project is approved in the present form
- b) Additional documents to be submitted in the next meeting:
 - i. Clearance from the Institutional Animal Ethics committee
 - ii. The details of the human ES cells that will be procured for this study needs to be submitted to NAC-SCRT as well

- 5) Project YU-IC-SCR/05/2016: Efficient and cost effective strategies for obtaining pancreatic beta cells from pluripotent stem cells.

Response of the committee

- a) The project is approved in the present form.
- b) Additional documents to be submitted in the next meeting:
 - i. Clearance from the Institutional Animal Ethics committee
 - ii. The details of the human ES cells that will be procured for this study needs to be submitted to NAC-SCRT as well

Shrey
Member Secretary
Yenepoya University
Institution:
Yenepoya
Date: 05/05/16

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Shrey
REGISTERED
Dr. Gangadhara Somavaji K.S.
Registrar
Yenepoya Deemed to be University
University Road, Channarayana
Mangalore-575 018, Karnataka