



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 meetings with Reference to the Code of Ethics

Sl. No.	Name of the Committee	No. of Meetings	Page Number
1.	Institutional Ethics Committee (YEC-1)	12	02 - 27
2.	Institutional Ethics Committee (YEC-2)	11	28 - 57
3.	Institutional Animal Ethics Committee (IAEC)	02	58 - 68
4.	Institutional Bio-safety Committee (IBSC)	01	69 - 71
5.	Institutional Committee for Stem Cell Research (YU-IC-SCR)	01	72 - 84



YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

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

Meeting Details and Minutes of Yenepoya Ethics Committee - 1

Sl. No.	Year	No. of Meetings
1.	2020-21	12



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

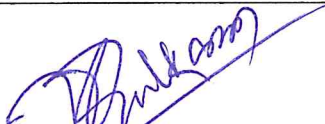
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Registrar
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Mangalore- 575 018, Karnataka
Page 1 of 11

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
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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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Mangalore, 575 018, Karnataka

Page 1 of 13


Secretary

			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
Page 07

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Dr. Gangadhara Somayaji K.S.
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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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 Secretary
 Yenepoya Ethics Committee-1

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 Registrar
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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

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

Uma Kulkarni
Secretary
Yenepoya Ethics Committee-1

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Gangadhara Somayaji K.S.
Dr.Gangadhara Somayaji K.S.
Registrar
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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.
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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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Page 12 of 12

Dr. Gangadhara Somayaji K.S.
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Minutes of the 114 Meeting of Yenepoya Ethics Committee- 1

The 114 meeting of the Yenepoya Ethics Committee – 1 was held on 04 February 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	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	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. Vindhya K and Ms. Jainabu Mufeeda (new Secretarial staff after signing the confidentiality agreement)

Guest observers: Dr. Mohammed Nasir Ahmed (after signing the confidentiality agreement)

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 113th YEC-1 meeting which were circulated to the members by email, were read out and unanimously approved.


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 Registrar
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 Mangalore- 575 018, Karnataka

Page 1 of 12

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

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 Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
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 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 14

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Page 1 of 11

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
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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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Mangalore-575 018, Karnataka

Page 1 of 10

Secretary

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

ATTESTED



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)

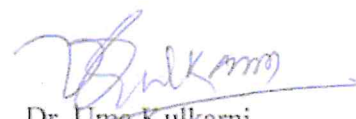
26. SOP change request: Nil

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

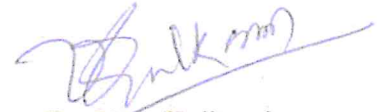
Leave of absence: 1


Secretary
Yenepoya Ethics Committee-1

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

ATTESTED



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



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

ATTESTED
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

ATTESTED



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:

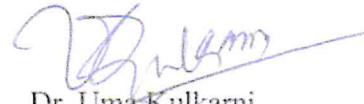
1. The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
2. The Chairperson confirmed that the quorum requirements were met and declared the meeting open.


 Secretary
 Yenepoya Ethics Committee-1

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

		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

Page 19 of 19



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:

- The Member-Secretary welcomed the members and handed over the proceedings to the Chairperson.
- The Chairperson confirmed that the quorum requirements were met and declared the meeting open.
- 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**
- 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.
- Initial Full Review protocols (N=1)**

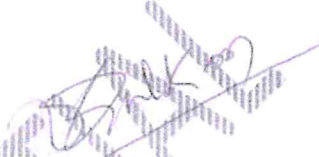
1.	Protocol number:	YEC-1/2020/029
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Secretary

	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.
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

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

Meeting Details and Minutes of Yenepoya Ethics Committee - 2

Sl. No.	Year	No. of Meetings
1.	2020-21	11



YENEPOYA

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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

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.

Wishet
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

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



YENEPOYA

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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

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

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

15



YENEPEYA

(DEEMED TO BE UNIVERSITY)

Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

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	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, Deralakatti,
 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
ly
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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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: 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 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	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 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

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


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, Derlakatte
Mangalore - 575 018, Karnataka

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Accredited by NAAC with 'A' Grade

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

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



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

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

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

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.

Ushat

Member Secretary
Yenepoya Ethics Committee 2
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

ATTESTED

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 10.10.2020 at 10.00 am. through google meet

Meeting No: 18

Members Present

1. Dr. Vijaya Hegde
2. Dr. H.Hari Kishore Bhat
3. Dr. Padmini Thalanjeri
4. Dr. Rashmi Jain
5. Dr. Kumuda Rao
6. Dr. Leena Pramod
7. Dr. Prasanna Keshava B
8. Dr. Suphala S Kotian
9. Dr. Smitha. D
10. Mr. Jayaram Padakanayya
11. Dr. Prabhakar Adake
12. Dr. Thippeswamy H G
13. Mrs. Jameela

The following members were granted leave of absence:

1. Ms. Jaklin Mary

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 business on the agenda.

The following items as per the agenda were discussed

1. Discussion on Protocol for amendment
3. Discussion on Study completion report protocols
4. Discussion on Premature termination report protocols
5. Any other matter with the permission of the chair.

The members discussed about the full board review protocol. The decision taken

by full board review are as follows.

Minutes of the meeting YEC-2 2018-2020

Page 45 of 83

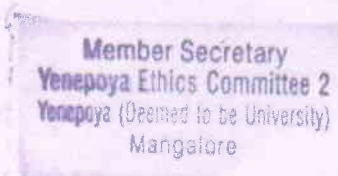
Page 49

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


2. Dr.H.Hari Kishore Bhat presented the progress report of the protocol till date 10.10.2020, Yenepoya ethics committee 2 received 521 protocol out of which 449 clearance has given .The rest of 11 protocol awaiting for reply from the principal investigator and 28 protocol yet to sent the comments to the Principal investigator and 18 protocol review is in pending, 16 protocol awaiting for reviewer reply. 1 protocol from Prosthodontics ,has been rejected by the YEC2, Out of 521 protocols 31 protocols submitted the study completion report and 9 protocols requested for premature termination.
3. Dr.H.Hari Kishore Bhat detailed explain regarding self assessment form,
- Self assessment is not format for informed consent, it is a self assessment for Principal investigator it will be helpful for the Principal investigator to prepare the Participant information sheet and Informed consent
 - Principal investigator need not to be submit the self assessment form
 - Self assessment form for PIS and IC now available in YEC2 website under Yenepoya ethics committee
4. And also member secretary explained about the annexure form .
- Annexure will be divided into 2 groups
1. Annexure for YEC2 office use and members of YEC2
2. Annexure for Principal investigator

Ujjwal



Dr.H.Hari Kishore Bhat
Member Secretary
Yenepoya ethics committee 2

ATTESTED


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

Minutes of the meeting held on 12.09.2020 at 1.30 pm. through google meet

Meeting No: 17

Members Present

Dr. Vijaya Hegde
Dr. H.Hari Kishore Bhat
Dr. Padmini Thalanjeri
Dr. Rashmi Jain
Dr. Kumuda Rao
Dr. Leena Pramod
Dr. Prasanna Keshava B
Dr. Suphala S Kotian
Dr. Smitha. D
Mr. Jayaram Padakanayya

The following members were granted leave of absence:

Dr. Prabhakar adake
Dr. Thippeswamy H G
Mrs. Jameela
Ms. Jaklin Mary

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 business on the agenda.

The following items as per the agenda were discussed

1. Discussion on Protocol for amendment
3. Discussion on Study completion report protocols
4. Discussion on Premature termination report protocols
5. Any other matter with the permission of the chair.

The members discussed about the full board review protocol. The decision taken by full board review are as follows.

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

Protocol Number : YEC2/398

Name of the PI: Dr. Nisamudheen MN BDS

Title: "An exploratory study on ethical issues perceived by Kodinhi research participants for repeated study recruitment."

Nature of amendment: Due to the corona pandemic, face to face interview and inform consent process by meeting the participant in person will be difficult and it may not be comfortable for the participants as I am staying 4 districts apart. Methodology and informed consent process will done via telephonic call, whatsapp or email as per the participant's convenience

Reason for requesting amendment: Due to the corona pandemic, face to face interview and inform consent process by meeting the participant in person will be difficult and it may not be comfortable for the participants as I am staying 4 districts apart.

Decision taken by the meeting: Approved for amendment

Study completion report protocols:

Sl. no	Protocol Number	Name	Title	Date of completion	Decision taken in meeting
1	YEC2/242	Dr.Madhavi	Study of clinical profile and stressors in patients presenting with dissociative disorder to a tertiary care teaching hospital"	13.08.2020	Noted
2	YEC2/329	Dr.Abhilasha	Factors influencing career choice among optometry students: A questionnaire based study	27.08.2020	Noted

3.Dr.Padmini Thalanjeri Presented the Checklist for PIS and IC submission. Also Member secretary discussed regarding the PIS checklist

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar

Minutes of the meeting YEC-2 2018-2020
Page 43 of 83

(Seemed to be University)
University Road, Derlakatte
Mangalore- 575 018, Karnataka

Ushat

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

Dr.H.Hari Kishore Bhat
Member Secretary
Yenepoya ethics committee 2

ATTESTED



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

Minutes of the meeting held on 08.08.2020 at 2.00 pm. through google meet

Meeting No: 16

The following members were present:

Dr. Vijaya Hegde
Dr. H.Hari Kishore Bhat
Dr. Padmini Thalanjeri
Dr. Prabhakar Adake
Dr. Rashmi Jain
Dr. Kumuda Rao
Dr. Prasanna Keshava B
Dr. Suphala S Kotian
Dr. Smitha. D
Mr. Jayaram Padakanayya
Mrs. Jameela
Ms. Jaklin Mary
Dr. Leena Pramod

The following members were granted leave of absence:

Dr.Thippeswamy H G

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 business on the agenda.

The following items as per the agenda were discussed

1. Announcements by Dr. Vijay Hegde, Chairperson
2. Discussion on amended protocols
3. Discussion on Study completion report protocols
4. Discussion Full board review protocols.
5. Discussion on Retrospective study
6. Discussion on Continuing review protocols
7. Any other matter with the permission of the chair

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

Protocol Number : YEC2/97

Name of the PI: Dr. Kaushik S B

Title: "A study on the functional outcome of closed reduction and k wire fixation in the treatment of extra articular distal radius fractures."

Nature of amendment: The follow up protocol has been changed from 2 weeks, 4 weeks, 8 weeks and 3 months, to 4 weeks, 8 weeks, 3 months and 6 months.

Reason for requesting amendment : To further evaluate the patient clinically following the procedure, for betterment of the patient. No change in the outcome will be seen as there is no new intervention at this time.

Lead Discussants : Dr.Padm [REDACTED]

Comments of the reviewer


1.Approved

Ushat

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

Dr.H.Hari Kishore Bhat
Member Secretary
Yenepoya ethics committee 2

ATTESTED


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

Minutes of the meeting held on 13.07.2020 at 10.30 am through google meet

Meeting No: 15

The following members were 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

The following members were granted leave of absence:

Ms. Jameela

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 business on the agenda.

The following items as per the agenda were discussed

1. Discussion on amendment request protocol.
2. Discussion on extension of the study protocols.
3. Discussion Full board review protocols.
4. Discussion on SOP Committee meeting
5. Any other matter

1.The members discussed about the full board review protocol. The decision taken by full review protocol as follows.

Title: "Maternal and fetal outcome in antepartum haemorrhage : A study at tertiary care centre"

Name of the PI: Dr.Radhika Gadgi

Protocol Number: YEC2/452

Minutes of the meeting YEC-2 2018-2020
Page 31 of 83

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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.

Ushat

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

Dr.H.Hari Kishore Bhat
Member Secretary
Yenepoya ethics committee 2

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

Meeting Details and Minutes of Institutional Animal Ethics Committee (IAEC)

Sl. No.	Year	No. of Meetings
1.	2020-21	02

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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		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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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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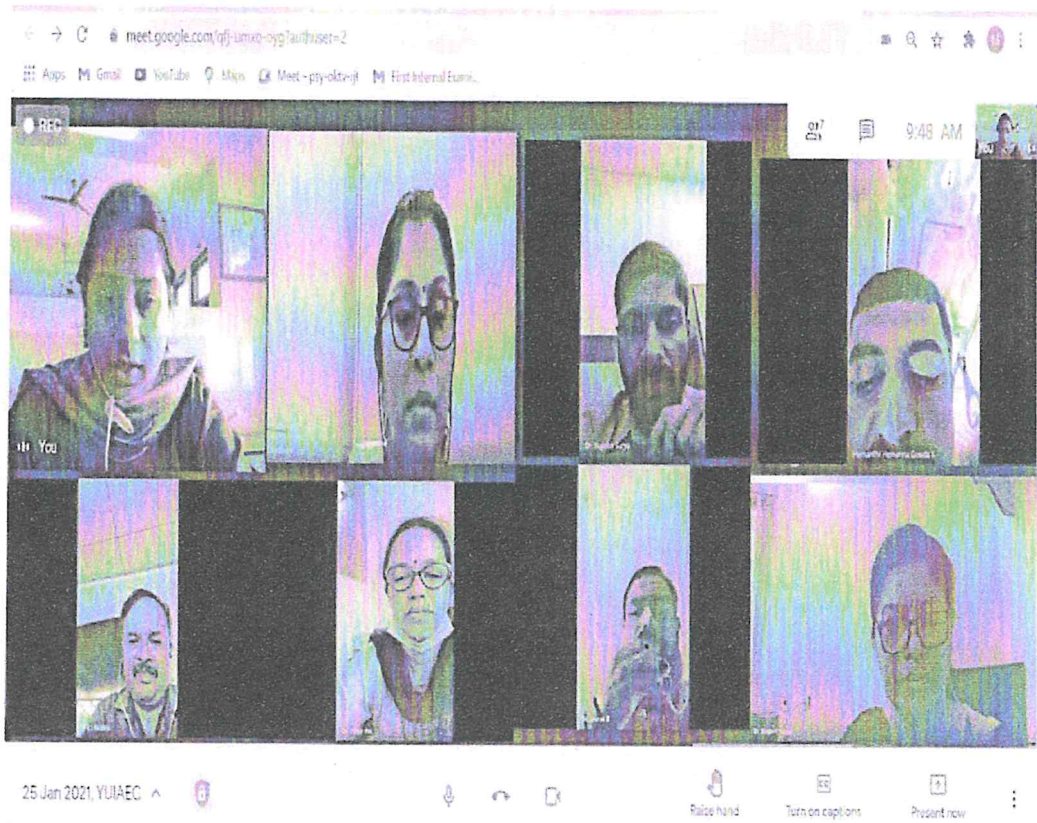
3	<p>Breeding approval and amendment in Registration No</p> <p>The YU animal house inspection for the purpose of breeding was conducted on 28/08/2020 by Dr. Ravikumar C and the CPCSEA permission was received 09/11/2020. The registration No is amended to 347/PO/ReBi-S/Rc-L/01/CPCSEA</p>
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After 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
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YENEPOYA (DEEMED TO BE UNIVERSITY)
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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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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3.4.1. The Institution has a stated Code of Ethics for research, the implementation of which is ensured by the following:

Meeting Details and Minutes of Institutional Biosafety Committee (IBSC)

Sl. No.	Year	No. of Meeting
1.	2020-21	01

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

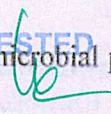
Agenda discussed

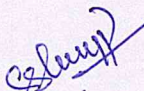
Agenda 1: To discuss on the two research proposals received

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.

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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.

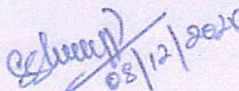
Following questions were raised:

- 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.

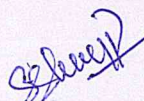
All the members came to the conclusion that there are no biosafety issues in the two proposals presented. Both the projects will be approved once all the questions raised by the members are answered satisfactorily and changes are incorporated in the proposal and submitted again.

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

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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:

Meeting Details and Minutes of Yenepoya University Institutional Committee for Stem Cell Research (YU-IC-SCR)

Sl. No.	Year	No. of Meeting
1.	2020-21	01

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. Raghu 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

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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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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

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Page | 3

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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 glycemie 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 glycemie 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 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.

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- **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.*

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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).

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- **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:

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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

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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:

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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.

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Prof. Polani B. Seshagiri
Chair
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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.

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