



YENEPOYA

(DEEMED TO BE UNIVERSITY)

Recognized under Sec 3(A) of the UGC Act 1956

Accredited by NAAC with 'A' Grade

6.1.2 - Effective leadership is reflected in various institutional practices such as decentralization and participative management etc.

**Information/documents in
support of the case study**

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Establishment of Centre for Ethics




Recognized under Sec 3 (A) of the UGC Act 1956 as per notification number F-9-11/2007.U.3 (A) dated 27-02-2008

No.YU/GENL/ 025 /BOM/2010

22nd March, 2011

OFFICE ORDER.

The Board of Management at its 13th ordinary meeting held on 08-02-2011 has approved the proposal for establishment of a Centre for advanced study in Ethics in the Department of Forensic Medicine and creation of the post of Director, Centre for Ethics.


(DR. JANARDHAN KONAJE)
REGISTRAR.

To:

The Principal, Yenepoya Medical College,
The Principal, Yenepoya Dental College,
The Principal, Yenepoya Nursing College,
The Principal, Yenepoya Physiotherapy College,
Professor &HOD, Forensic Medicine Department.

Copy to - Hon'ble Vice Chancellor,
Controller of Examinations,
Finance Officer.
Special Officer (Establishment)

ATTESTED

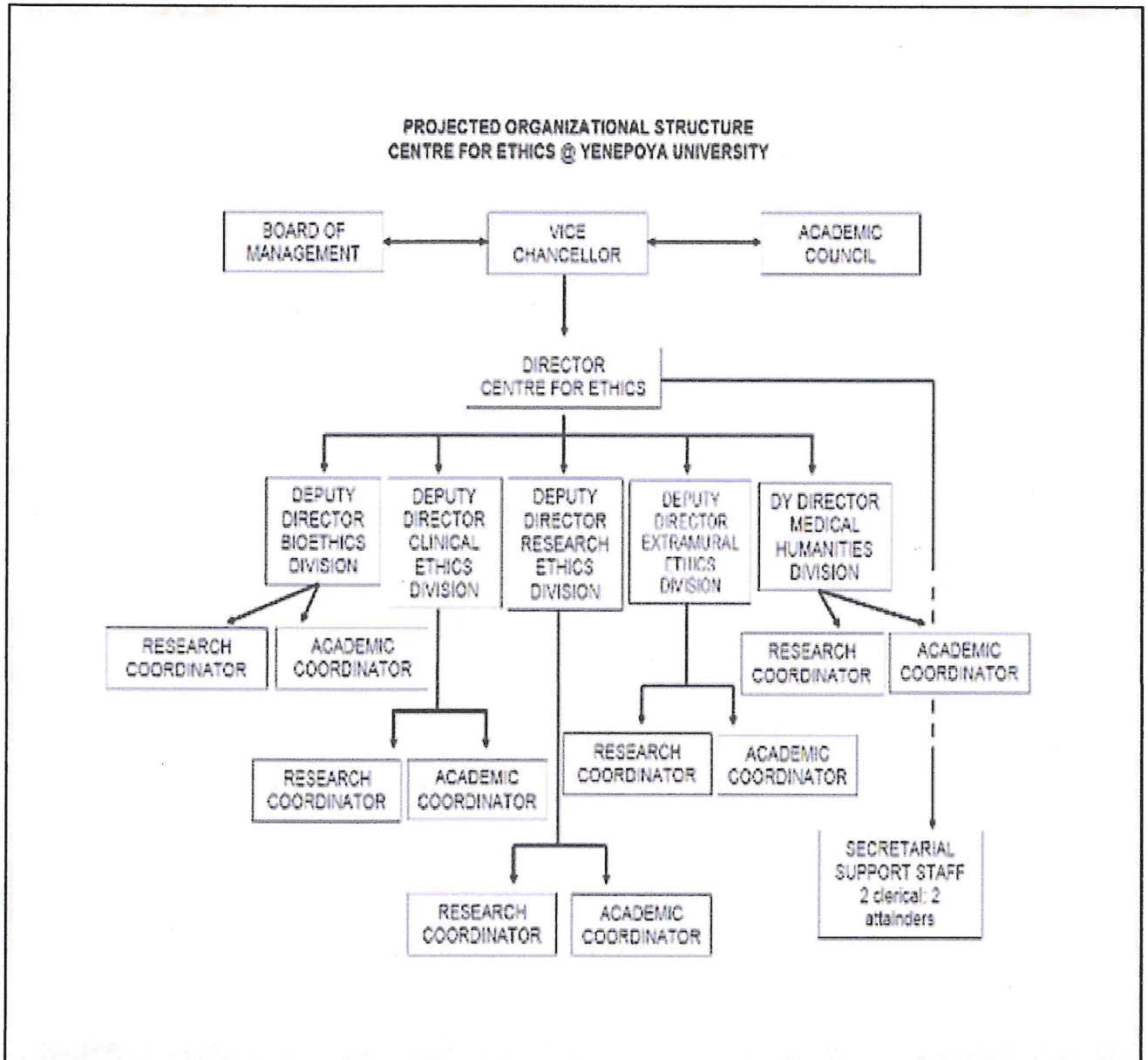


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

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www.yenepoya.org

Organizational Structure of Centre for Ethics

Organizational Structure of Centre for Ethics



ATTESTED

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

Academic Programmes



Recognized under Sec 3(A) of the UGC Act 1956 as per Notification No. F.9-11/2007-U.3 (A) dated 27th February 2008

No. YU/REG/ACA/A. Council/26/2016

26.10.2016

NOTIFICATION

Sub: Commencement of 2 year M.Sc. (Research Ethics) from the
Academic year 2017-18

Ref: Agenda-5 of the 26th meeting of the Academic Council held on
21.10.2016


The Academic Council at its meeting held on 21.10.2016, vide Agenda-5 and subsequently the Board of Management has approved the proposal to start 2 year M.Sc. (Research Ethics) during the academic year 2017-18.

Copy to:

1. The Principal – YMC
2. Director, Centre for Ethcis
3. The Controller of Examinations
4. Academic Section


REGISTRAR
mj
Registrar
Yenepoya University
University Road, Deralakatte
Mangalore - 575 018

ATTESTED


Dr. Gangadhara Somayaji K.S.
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Office of the Registrar
University Road,
Deralakatte
Mangalore - 575018
Ph: 0824-2204667/68/69/71
Fax: 0824-2203943

No.YU/REG/ACA/A Council -26/2016

26.10.2016


The Director
Centre for Ethics

Sub: Commencement of 2 year M.Sc. (Research Ethics) programme from
the academic year 2017-18


The proposal for starting 2 years Masters Programme in Research Ethics by the Centre for Ethics, forwarded through the Faculty of Medicine was placed before the Academic Council at its 26th meeting held on 21.10.2016.

Academic Council observed the uniqueness of the above programme and appreciated the efforts of the Centre for Ethics for starting the programme for the first time in the country. After considering the proposal in its entirety, the Academic Council approved the same. The Board of Management of Yenepoya University has also accorded its approval for the proposal.

You are requested to take further action to ensure implementation of the programme during the academic year 2017-18.


(Dr. G. Shreekumar Menon)
Registrar

ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
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Mangalore - 575018
Ph: 0824-2204667/68/69/71
Fax: 0824-2203943

Ref: No.YU/REG/ACA/3-ACM/2009

31.10.2009

NOTIFICATION

Sub: Starting of Postgraduate Diploma in Bioethics & Medical Ethics

Ref: Resolution of the Academic Council at its 3rd Academic Council meeting held on 31.10.2009, vide agenda - 5

The Academic Council at its 3rd meeting subsequently the Board of Management at its 9th meeting held on 31.10.2009 have resolved to approve the proposal to start the Postgraduate Diploma in Bioethics & Medical Ethics course in the department of Forensic Medicine & Toxicology.

This notification is issued for implementation with effect from the academic year 2011-2012.

REGISTRAR

Registrar
Yenepoya University
University Road, Deralakatte
Mangalore - 575 018

To:

The Principal - YMC

Copy to:

1. Controller of Examinations
2. Professor & HoD, Department of Forensic Medicine
3. Academic Section

ATTESTED

Dr. Gangadhara Somayaji K.S.
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No.YU/REG/ACA/ACM-11 (7)/2013

21.01.2013

NOTIFICATION

Sub: Proposals Board of Studies, Department of Forensic Medicine
Ref: Agenda 7 (6) of the 11th meeting of the Academic Council held on
15.01.2013

The Academic Council and subsequently the Board of Management at their meetings held on 15.01.2013 approved, in principle, the following proposals of the Board of Studies, Department of Forensic Medicine recommended by the Faculty of Medicine and is hereby notified for implementation.

- (1) Change in Academic structure of Certificate Course in Clinical Ethics Consultation (CCCEC) to Postgraduate Diploma in Clinical Ethics (PGDCE).
- (2) Proposal to start Postgraduate Diploma in Forensic Anthropology (PGDFA)
- (3) Proposal for starting of choice based credit modules on Basic Course in Environmental Ethics and Basic Course in Biomedical Ethics.
- (4) Collaborating with Department of Criminology, Roshni Nilaya for establishing linkages and enriching research in Criminology related areas.
- (5) Starting of Ph.D in Bioethics.

The Academic Council further resolved that Yenepoya University should write to the M.C.I. apprising the details of the courses.

J. Somayaji
REGISTRAR

To: The Principal – YMC

Copy to: 1. HOD, Forensic Medicine
2. Controller of Examinations
3. Academic Section ✓

ATTESTED

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



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No.YU/REG/AC(7-18)/Noti./2011

28.07.2011

NOTIFICATION

Sub: Curriculum for the proposed Certificate Course in Clinical Ethics Consultation

Ref: Agenda No.18 of the minutes of 7th Academic Council meeting held on 21st July 2011 and Board of Management on 22nd July 2011.

==XX==

The curriculum for the Certificate Course in Clinical Ethics Consultation proposed by the Board of Forensic Medicine & Toxicology and recommended by the Faculty of Medicine is approved by the Academic Council and Board of Management in their meetings held on 21st and 22nd July 2011 respectively and are hereby notified for implementation. Relevant provisions of the consumer protection act shall be complied with.

Gangadhara Somayaji
REGISTRAR

Cc to:

- Principal, YMC
- HOD, Dept. of Forensic Medicine
- Controller of Examinations

ATTESTED

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

Value Added Courses



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University Road,
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Mangalore - 575018
Ph: 0824-2204667/68/69/71
Fax: 0824-2203943

No.YU/REG/ACA/ACM-11 (7)/2013

21.01.2013

NOTIFICATION

Sub: Proposals Board of Studies, Department of Forensic Medicine
Ref: Agenda 7 (6) of the 11th meeting of the Academic Council held on
15.01.2013

The Academic Council and subsequently the Board of Management at their meetings held on 15.01.2013 approved, in principle, the following proposals of the Board of Studies, Department of Forensic Medicine recommended by the Faculty of Medicine and is hereby notified for implementation.

- (1) Change in Academic structure of Certificate Course in Clinical Ethics Consultation (CCCEC) to Postgraduate Diploma in Clinical Ethics (PGDCE).
- (2) Proposal to start Postgraduate Diploma in Forensic Anthropology (PGDFA)
- (3) Proposal for starting of choice based credit modules on Basic Course in Environmental Ethics and Basic Course in Biomedical Ethics.
- (4) Collaborating with Department of Criminology, Roshni Nilaya for establishing linkages and enriching research in Criminology related areas.
- (5) Starting of Ph.D in Bioethics.

The Academic Council further resolved that Yenepoya University should write to the M.C.I. apprising the details of the courses.

J. Gangadhara Somayaji
REGISTRAR

To: The Principal – YMC

Copy to: 1. HOD, Forensic Medicine
2. Controller of Examinations
3. Academic Section ✓

ATTESTED

[Signature]

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



Recognized under Sec 3(A) of the UGC Act 1956 as per Notification No. F.9-11/2007-U.3 (A) dated 27th February 2008
Accredited by NAAC with 'A' Grade

Ref: No. YU/REG/ACA/A. Council/22/2015

17.12.2015

NOTIFICATION – 22-ACM/08/2015 dtd. 15.12.2015

Sub: Starting of value added course in Clinical Ethics and Medical Humanities (CEMH) for undergraduate, postgraduate and faculty

Ref: Minutes of the 22nd meeting of the Academic Council held on 15.12.2015, vide agenda - 8

The Academic Council at its 22nd meeting held on 15.12.2015 & subsequently the Board of Management at its 33rd meeting held on 16.12.2015 have resolved to approve the proposal to start value added course in Clinical Ethics and Medical Humanities (CEMH) for undergraduate, postgraduate and faculty of Yenepoya University.


REGISTRAR
mj

To:


Dean, Faculty of Medicine

Copy to:

1. Controller of Examinations
2. Director, Centre for Ethics – {the certificate will be issued by the college}
3. HoD, Forensic Medicine
4. Academic Section

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ATTESTED


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

**Academic Programme
Related Memorandum of
Agreement**

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement is being entered into

Between

Yenepoya deemed to be University, Deralakatte, Mangaluru 575018 India
represented by Registrar, of the one part (hereinafter called first party)

And

Monash University, acting through its Faculty of Medicine, Nursing and Health
Sciences (ABN 12 377 614 012) of Wellington Road, Clayton, Victoria 3800 Australia
of the second part (hereinafter called second party)

Witnesseth as follows...

Whereas the National Institutes of Health, Bethesda, USA (hereinafter referred to as NIH), an agency funding research activities in the United States of America and the Fogarty International Center, a part of National Institutes of Health, funding research activities outside the United States of America had called for proposal under the Funding Opportunity Title "International Research Ethics Education and Curriculum Development Award" (Funding Opportunity Announcement No. PAR-13-027) to develop bioethics education related to research, in low and middle income countries.

And whereas, Yenepoya deemed to be University applied for and Dr. Vina Vaswani, Director, Centre for Ethics, Yenepoya University was made Principal Investigator for the purpose of this award, along with Dr. Bebe Loff, Director, Michael Kirby Centre for Public Health and Human Rights, Monash University as Co-Principal Investigator for educational research grant "Yenepoya University-Fogarty International Center's Research Ethics Master's Program for India".

And whereas NIH was pleased to grant this award to Yenepoya deemed to be University as per final Notice of Award dated 12 December 2017 (Grant award no. 1R25TW010305-01 REVISED) (Enclosure 1).

Now this memorandum of agreement is being entered into between the two parties mentioned above, between the two universities in order to facilitate the

ATTESTED


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

disbursal of the payment earmarked for Co-Principal Investigator, Dr. Bebe Loff's educational research activities related to the abovementioned grant , and is agreed on the following terms and conditions:

1. This memorandum comes into force on the day it is signed by all signatories and shall continue until 31 August 2021, as specified in the NIH Notice of Award.
2. Payment of total costs of USD 200,000, payable over 5 years, comprising 5 payments of USD 40,000 per year, (with breakup under heads of salary, fringe benefits, travel and additional support for Co-PI as stated in the revised budget of September 2017 Enclosure 2, mutually agreed upon by both PIs and approved by NIH as per the NoA page 5) will be made to Monash University, Australia, subject to release of funds by the NIH for each budget period (Enclosure 1; page 9) in their abovementioned Notice of Award. Yenepoya deemed to be University will transfer this amount to Monash University, for Dr. Bebe Loff, for her role as Co-Principal Investigator for this grant, as described in the Revised Multiple Leadership Plan, mutually approved by both Principal Investigators and the NIH. Yenepoya deemed to be University will transfer this amount of USD 40,000 for each of the budget periods being for 5 years (as per NoA; page 9), (totalling USD 200,000) as and when the NIH funds are approved and released, and within 15 days of release of the funds by NIH.
3. This agreement will be in force as long as Dr. Bebe Loff is in service of Monash University and as long as the NIH grant (Grant no. 1R25TW010305-01 Revised) continues.
4. This memorandum will be terminated when the NIH grant period ends, or if and when the NIH prematurely terminates the grant, or when Dr. Bebe Loff resigns from the service of Monash University. Either party may terminate this Agreement immediately by written notice if the other commits a material breach of this Agreement which it fails to remedy within thirty (30) days of being notified of the breach. The Parties may immediately terminate this Agreement by mutual consent in writing.
5. If Dr. Vina Vaswani should resign from the service of Yenepoya deemed to be University, Yenepoya deemed to be University will continue to abide by the

ATTESTED



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

- terms and conditions laid down in this agreement, for the budget periods mentioned in the Notice of Award, with approval from the NIH.
6. Since the grant is sanctioned to Yenepoya deemed to be University, for running the educational program "Yenepoya University-Fogarty International Center Research Ethics Master's Program for India", after clearance and permission from Health Ministry Screening Committee, Government of India, and further since the entire teaching activity is in Yenepoya deemed to be University, Mangaluru, India any disputes arising in relation to this agreement will be governed by the laws of Mangaluru, India.
 7. a. Ownership of rights in any background intellectual property(background IP) will remain with the contributing party. Where the background property IP is contributed by Yenepoya, Monash is licensed to use, modify or adapt that background IP for the performance of the education research program. Where the background IP is contributed by Monash, Yenepoya is licensed to use, modify or adapt that background IP for the use of the education research program.
b. Rights of intellectual properties created by Yenepoya using the funding for this educational research program, rest with Yenepoya deemed to be University and rights of intellectual properties created by Monash using the funding for this educational research program rest with Monash. All manuscripts arising out of this education research program and submitted for publication, will follow the authorship guidelines as laid down in International Committee for Medical Journal Editors recommendations (www.icmje.org) and the NIH requirements for publication.
 8. Final NIH Notice of Award of 12/12/2017 for grant no. 1R25TW010305-01 REVISED and Revised Multiple Leadership Plan submitted to NIH in October 2016 are to be considered as part and parcel of this agreement.
 9. Neither party will use the other party's name or the name of any employee of the other party in any publication or promotional material without the other party's written consent.
 10. Neither party will represent that the other or that any of their respective employees in any way endorse, support or approve of any product, service, intellectual property or business, without prior written consent from the other party.


ATTESTED



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

11. a. If any dispute arises between the parties out of or in relation to this Agreement, the parties will endeavour to resolve that dispute by negotiation in good faith.
- b. If the dispute is not mutually resolved within thirty (30) days of a party serving on the other a written dispute notice, each party must nominate one senior representative who will meet in India, as soon as practicable for the purpose of endeavouring to resolve the dispute.
- c. The provisions of this clause will not preclude a party from seeking urgent interlocutory relief in a court of competent jurisdiction.
14. This Agreement may only be varied in writing by the parties.
15. This Agreement may be executed in counterparts, which taken together will constitute one document. Counterparts may be exchanged by digital scan which may be relied upon by the receiving party as having the same legal force and effect as the original signed counterpart.
16. This Agreement does not create a partnership, agency, fiduciary or other relationship, except the relationship of contracting parties. No Party is liable for the acts or omission of any other Party, save as set out in this Agreement.
17. Both parties undertake not to engage in any act which may result in the contravening of any law prohibiting or restricting dealings with proscribed states, persons or entities or seeking to prevent the proliferation of weapons, including but not limited to laws implementing the sanctions imposed by the United Nations Security Council.

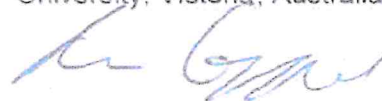
In witness whereof this memorandum is signed and sealed by the parties mentioned above, this _____ day of 2018.


Signatory from Yenepoya
deemed to be University
Mangaluru, India

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 013

Date: 2.7.2018

Signatory from Monash
University, Victoria, Australia



Date: 02.07.2018

ATTESTED



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

Professor Ross Coppel
Deputy Dean & Director of research
Faculty of Medicine, Nursing and Health Sciences
Monash University

Letter of Award from National Institute of Health

Notice of Award

Federal Award Date: 12/12/2017



RESEARCH EDUCATION PROJECT
Department of Health and Human Services
National Institutes of Health



FOGARTY INTERNATIONAL CENTER

Grant Number: 1R25TW010305-01 REVISED
FAIN: R25TW010305

Principal Investigator(s):
Bebe Loff
Vina Vaswani (contact), MBBS

Project Title: Yenepoya University-Fogarty International Center Research Ethics Master's Program for India

Mr. Yenepoya, Farhaad
Director R&F
University Road
Derlakatte
Mangalore, 575018
IND

Award e-mailed to: registrar@yenepoya.edu.in

Period Of Performance:
Budget Period: 09/27/2016 – 08/31/2018
Project Period: 09/27/2016 – 08/31/2021

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to YENEOYA UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under Award Number R25TW010305. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

ATTESTED

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

Sincerely yours,

Mollie Shea
Grants Management Officer
FOGARTY INTERNATIONAL CENTER

Additional information follows

ATTESTED



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

SECTION I – AWARD DATA – 1R25TW010305-01 REVISED**Award Calculation (U.S. Dollars)**

| | |
|----------------------------|----------|
| Salaries and Wages | \$81,972 |
| Fringe Benefits | \$18,000 |
| Personnel Costs (Subtotal) | \$99,972 |
| Consultant Services | \$475 |
| Equipment | \$5,000 |
| Materials & Supplies | \$597 |
| Travel | \$11,866 |
| Other | \$49,022 |
| Publication Costs | \$1,000 |
| Participant Subsistence | \$8,955 |
| Participant Stipends | \$57,313 |
| Participant Travel | \$1,493 |
| Participant Other | \$31,343 |

| | |
|---|------------------|
| Federal Direct Costs | \$267,036 |
| Federal F&A Costs | \$20,963 |
| Approved Budget | \$287,999 |
| Total Amount of Federal Funds Obligated (Federal Share) | \$287,999 |
| TOTAL FEDERAL AWARD AMOUNT | \$287,999 |

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$0

| SUMMARY TOTALS FOR ALL YEARS | | |
|------------------------------|------------|-------------------|
| YR | THIS AWARD | CUMULATIVE TOTALS |
| 1 | \$287,999 | \$287,999 |
| 2 | \$288,383 | \$288,383 |
| 3 | \$288,383 | \$288,383 |
| 4 | \$288,383 | \$288,383 |
| 5 | \$288,383 | \$288,383 |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: International Research and Research Training
CFDA Number: 93.989
EIN: 1900217626A1
Document Number: RTW010305A
PMS Account Type: B (Subaccount)
Fiscal Year: 2016

| IC | CAN | 2016 | 2018 | 2019 | 2020 | 2021 |
|----|---------|-----------|-----------|-----------|-----------|-----------|
| TW | 8476374 | \$287,999 | \$288,383 | \$288,383 | \$288,383 | \$288,383 |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: BIOETH / **OC:** 415A / **Released:** MSHEA 12/11/2017
Award Processed: 12/12/2017 12:01:54 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R25TW010305-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III – TERMS AND CONDITIONS – 1R25TW010305-01 REVISED**ATTESTED**

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R25TW010305. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and

administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – TW Special Terms and Conditions – 1R25TW010305-01 REVISED

REVISED AWARD--

This award is revised to lift funding restrictions. The revised budget with budget justification dated November 27, 2017 is incorporated herein by reference and no grant funds may be used for the LCD Projector, voting system and printer or for an Outreach Innovation Program.

Supersedes the Notice of Award (NoA) issued: 09/14/2017.

01-YEAR EXTENSION

The 01 year is being extended 12 months due to lack of activity from the initial award (01 year). The Grantee has access and can use FY16 funds from the 01 year during this extension.

The following term is added:

KEY PERSONNEL

For purposes of this award the following person(s) are considered key personnel in addition to the PI(s) already named on this Notice of Award. All policies that apply to the PI(s) (e.g. the requirement to obtain NIH prior approval for personnel changes and to supply information about other support with each progress report) are hereby applied to the following person(s):

Bebe Loff, Ph.D., Monash, Australia

In addition to the PI, any absence, replacement, or substantial reduction in effort of the individual(s), requires the written prior approval of the National Institutes of Health awarding component.

REVISED AWARD --

This award is revised to lift funding restrictions for Monash University, Australia, Dr. Bebe Loff, total costs, \$40,000

A revised Leadership Plan, Updated Other Support for Drs. Vaswani and Loff, and budget justification for Dr. Bebe Loff, Monash University for \$40,000 total costs and the Indian Government's approval of the Master's Program Curriculum have been received and approved.

Supersedes the Notice of Award (NoA) issued: 09/26/2016.

FUNDING LEVEL

Direct costs are awarded based on the IRG/FIC Advisory Board recommended level. Your institution may re-budget in accordance with the NIH Grants Policy Statement to best utilize the funds.

FUNDING ANNOUNCEMENT

This award is subject to the conditions set forth in PAR-TW-13-027: RFA International Research Ethics Education and Curriculum Development Award (R25). The RFA can be found at: <http://grants.nih.gov/grants/guide/pa-files/PAR-13-027.html>

ATTESTED



OMB's final Uniform Grant Guidance in 2 CFR part 200 with certain amendments, based on existing HHS regulations, to supplement the guidance as needed for the Department effective December 26, 2014. Additional final guidance from HHS and NIH is anticipated and will be distributed once available.

Per NOT-OD-15-087 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-087.html>) a revised NIH Grants Policy Statement was published on March 31, 2015. Links to the revised Grants Policy Statement and a document summarizing the significant changes that were implemented are provided in the Notice.

Highlighted below are some select items of costs of particular note to FIC grant recipients:

- **F&A for Foreign and International Organizations:** NIH and FIC continue to provide F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of modified total direct costs, exclusive of equipment, consistent with existing policy.
- **F&A for Career/Fellowship/Training Awards:** NIH and FIC continue to provide F&A costs under research training, some education grants, and Career (K) awards will be funded at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, health insurance (when awarded as part of tuition and fees), equipment, and consortiums in excess of \$25,000, consistent with existing policy.
- **Value Added Tax:** Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. However, for many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.
- **Visa Costs:** Allowable as a direct cost as part of recruiting costs on an NIH grant. Allowable as a trainee cost and not allowable for other non-trainee project personnel, consistent with existing FIC policy.

eRA Commons User IDs to Individuals in Graduate and Undergraduate Student Project Roles with Measurable Effort on an NIH Annual Progress Report

In accordance with [NOT-OD-13-097](http://www.fic.nih.gov/Grants/Pages/progress-reports.aspx), any trainee or individual with an Undergraduate, Graduate Student, and/or Postdoctoral Role who participates in an NIH-funded project for at least one person month (160 hours) or more training in the reporting period must be registered in the eRA Commons. This is required regardless of whether salary is actually charged to the project.

Grant recipients must provide the list in Section D.1 of the RPPR for each trainee/scholar supported by the grant award during the reporting period. Additional information on this requirement can be found in the FIC Progress Report Supplemental Guidance on the FIC webpage: <http://www.fic.nih.gov/Grants/Pages/progress-reports.aspx>

CHANGES IN SCOPE

Prior approval must be obtained from the NIH awarding component for any changes in the direction, type of research or training, the use of human or animal subjects, or other areas that constitute a significant change from the aims, objectives, purpose, or scope of the approved project.

F&A COSTS

Limited F&A of 8% for administrative costs is provided to support the administrative needs of managing this project. F&A charges are limited to eight percent for both domestic and foreign research training partners. Consortia institutions also may only charge eight percent of applicable direct costs for F&A.

RESTRICTION AGAINST MEAL COSTS

In accordance with the NIH Grants Policy Statement, when certain meals are an integral and necessary part of a meeting or conference (i.e., a working meal where business is transacted), grant funds may be used for such meals. Unless part of a working meal, grant funds may not be used. Recurring business meetings, such as staff meetings, should not be broadly considered as working meetings in order to justify charging meals or refreshment costs to grants.

RESTRICTION AGAINST VISA COSTS

Visa costs are allowable only as a trainee/student expense or as described in the NIH Grants Policy Statement. Visa costs requested that are not for trainees are unallowable and must be re-budgeted.

WELWAG [For all First-time grantee organizations]

First-time NIH grantee organizations can find information about funding, policy, and administrative issues by visiting our "Welcome Wagon letter"

(<http://grants.nih.gov/grants/funding/welcomewagon.htm>).

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Mollie Shea

Email: mshea@niaid.nih.gov **Phone:** 240-669-2960 **Fax:** 301-493-0597

Program Official: Barbara J Sina

Email: barbara.sina@nih.gov **Phone:** 301-402-9467 **Fax:** 301-402-0779

SPREADSHEET SUMMARY

GRANT NUMBER: 1R25TW010305-01 REVISED

INSTITUTION: YENEOYA UNIVERSITY

| Budget | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|----------------------------|-----------|-----------|-----------|-----------|-----------|
| Salaries and Wages | \$81,972 | \$76,972 | \$76,972 | \$76,972 | \$76,972 |
| Fringe Benefits | \$18,000 | \$4,000 | \$4,000 | \$4,000 | \$4,000 |
| Personnel Costs (Subtotal) | \$99,972 | \$80,972 | \$80,972 | \$80,972 | \$80,972 |
| Consultant Services | \$475 | \$475 | \$475 | \$475 | \$475 |
| Equipment | \$5,000 | | | | |
| Materials & Supplies | \$597 | \$1,194 | \$1,194 | \$1,194 | \$1,194 |
| Travel | \$11,866 | \$10,821 | \$10,821 | \$10,821 | \$10,821 |
| Other | \$49,022 | \$37,037 | \$37,037 | \$37,037 | \$37,037 |
| Publication Costs | \$1,000 | \$1,000 | \$1,000 | \$1,000 | \$1,000 |
| Participant Subsistence | \$8,955 | \$17,910 | \$17,910 | \$17,910 | \$17,910 |
| Participant Stipends | \$57,313 | \$114,626 | \$114,626 | \$114,626 | \$114,626 |
| Participant Travel | \$1,493 | \$2,986 | \$2,986 | \$2,986 | \$2,986 |
| Participant Other | \$31,343 | | | | |
| TOTAL FEDERAL DC | \$267,036 | \$267,021 | \$267,021 | \$267,021 | \$267,021 |
| TOTAL FEDERAL F&A | \$20,963 | \$21,362 | \$21,362 | \$21,362 | \$21,362 |
| TOTAL COST | \$287,999 | \$288,383 | \$288,383 | \$288,383 | \$288,383 |

| Facilities and Administrative Costs | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|-------------------------------------|-----------|-----------|-----------|-----------|-----------|
| F&A Cost Rate 1 | 8% | 8% | 8% | 8% | 8% |
| F&A Cost Base 1 | \$224,999 | \$229,984 | \$229,984 | \$229,984 | \$229,984 |
| F&A Costs 1 | \$18,000 | \$18,399 | \$18,399 | \$18,399 | \$18,399 |
| F&A Cost Rate 2 | 8% | 8% | 8% | 8% | 8% |
| F&A Cost Base 2 | \$37,037 | \$37,037 | \$37,037 | \$37,037 | \$37,037 |
| F&A Costs 2 | \$2,963 | \$2,963 | \$2,963 | \$2,963 | \$2,963 |

ATTESTED

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

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Agreement

**on scientific co-operation as
Centers of Excellence in Clinical Ethics Consultations**

between

Yenepoya University, Mangalore, India
represented by Dr. Raghuv eer CV, Registrar, Yenepoya University
Executing Unit: Centre for Ethics Department of Forensic Medicine & Toxicology
Director: Dr. Vina Vaswani MD, M Phil, MA

and the

University Medical Center of Johannes Gutenberg-University Mainz (UMC-Mainz)
represented by its Board of Directors which, in turn, is represented by
Prof. Dr. Ulrich Förstermann, Chief Scientific Officer, Dean
Langenbeckstraße 1, 55131 Mainz, Germany
executing unit: Institute for the History, Philosophy and Ethics of Medicine
Director: Prof. Dr. Norbert W. Paul, MA

In order to promote medical, scholarly and cultural co-operation, the Medical and Dental College of the Yenepoya University in Mangalore, India, and the University Medical Center hereby agree upon co-operating directly as follows:

Article 1

The institutions consider a partnership and co-operation in Excellence in medical research and education with a current focus on clinical ethics. Based on mutual relationships they agree upon cooperative projects in research and education.

Article 2

Joint projects, which will be carried out by the *Working Group on Clinical Ethics, Medical Faculty of the Yenepoya University* and the *Institute for the History, Philosophy and Ethics of Medicine at the University Medical Center of Johannes Gutenberg University Mainz* will focus on research and education, including objectives in the theoretical foundations and methodologies of clinical ethics, practices and quality assurance of clinical ethics consultations and the clinical impact of clinical ethics.

Other Institutes and working groups of both universities are strongly encouraged to develop their own programs in medical research and education, including programs in maxillofacial, dental, and oral medicine, for which the Clinic for Maxillofacial, Dental and Oral Diseases at the University Medical Center of Johannes Gutenberg-University Mainz offers to serve as cooperation partner.

Article 3

The institutions nominate a representative who will co-ordinate and supervise all aspects of co-operation. For the institution in Mangalore, this will be Dr. Vina Vaswani MD, M Phil, MA Organizing Secretary International Indo-German CME on Clinical Ethics Consultation Yenepoya University, Mangalore, for the University Medical Center of Johannes Gutenberg-University Mainz this will be Prof. Dr. Norbert W. Paul, M.A., Director of the Institute for the History, Philosophy and Ethics of Medicine and chair of the Clinical Ethics Committee.

Article 4

All partners shall endeavor to promote the following aspects of scholarly and cultural co-operation in accordance with the applicable laws and faculty resolutions.

1. Exchange of visiting teachers and academic staff
2. Exchange of postgraduate students and postdoctoral scholars with the emphasis on short-term stays (2 to 6 months; possibly to be financed by scholarships from sponsoring organisations)
3. Exchange of students
4. Assistance for exchange students in applying for admission and enrolment, in procuring housing/dormitory accommodation, and in procuring internships
5. Exchange of publications, teaching and research programs, and guidelines for the clinical practice.
6. Co-operation in scholarly research, exchange of research findings and publications
7. Mutual invitations to participate in scholarly seminars, lectures, educational programs and clinical ethics consultations as long as legally permitted.
8. Making arrangements for guest professors on short or long term teaching appointments
9. Co-operation in education includes the opportunity for joint excursions and the auditing of clinical ethics consultations with guidance from the host institution.
10. Guests at the respective host institutions will be granted access to research facilities such as libraries, manuscript collections, archives, laboratories, etc.

Special agreements concerning future projects will be negotiated and decided depending upon the availability of equipment and finances in written form. The execution of these agreements will not cause any financial obligations for either side.

Article 5

Results of joint research projects are to be published in Germany and India, however, the preference is to collaboratively publish results in international journals. The German university will be responsible for the publication of results in Germany, and the Yenepoya University will be responsible for the publication of results in India. All publications on the international level have to be signed by all parties. All publications shall be in accordance with the usual academic practices.

Article 6

This agreement will be valid for 5 years after the signature date. It is the intention of both parties to consider extending this contract by the end of the contract term for another period of 5 years by signing an amendment to this contract.


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

Article 7

Following mutual consultations, the partners may agree upon the inclusion of other international Centers of Excellence. A review and assessment of scholarly and clinical excellence is the pre-condition for the inclusion into the cooperation. In this case, additional partners will have to sign an amendment to this agreement to become equal partners with all rights and duties.

Article 8

The parties' liability regarding the conduct of this contract is limited to gross negligence and willful misconduct. No party shall be responsible for any lost profits, lost opportunities, or other consequential damages.

If any provision of this Agreement shall be found to be void, invalid or unenforceable, such provision shall be enforced to the maximum extent permissible by applicable law so as to effect the intent of the Parties, and the remainder of this Agreement shall continue in full force and effect. The Parties shall negotiate in good faith an enforceable substitute provision for any invalid or unenforceable provision that most nearly achieves the intent and economic effect of such provision.

Any changes or additions to this Agreement shall be made in writing. The same applies to any amendment of the clause stipulating the requirement for the written form itself.

Signed by its duly authorised representatives, this agreement becomes valid on February 15, 2016.

Mainz, 15th of February 2016



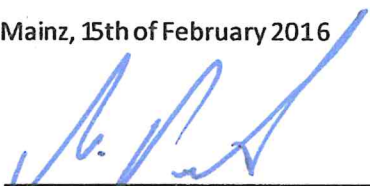
Prof. Dr. Ulrich Förstermann
Chief Scientific Officer, Dean,
University Medical Center of the
Johannes Gutenberg-University Mainz,
Germany

Mangalore, 15th of February 2016



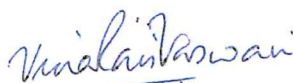
Dr. Raghuveer CV
Registrar,
Professor of Pathology
Yenepoya University, Mangalore, India

Mainz, 15th of February 2016



Prof. Dr. Norbert W. Paul, MA
Director and Chair
Institute for the History, Philosophy
and Ethics of Medicine &
Chair of the Clinical Ethics Committee,
University Medical Center of the
Johannes Gutenberg-University Mainz,
Germany

Mangalore, 15th of February 2016



Dr. Vina Vaswani MD, M Phil, MA
Director, Centre for Ethics
Professor & Head,
Department of Forensic Medicine & Toxicology
Yenepoya University, Mangalore, India

ATTESTED



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

Link to the Website of Centre for Ethics

<http://www.ethics.edu.in/>