



**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# **Research Policies and Guidelines**









## Contents

<b>Sl. No</b>	<b>Name of the Policy</b>	<b>Page No.</b>
1.	Research	1-10
2.	Startup	11-22
3.	Intellectual Property Rights	23-52
4.	Code of Research Ethics	53-64
5.	Publication	65-76
6.	Plagiarism	77-88
7.	Guidelines for Incentives on Research & Publications	89-94
<b>Standard Operating Procedures for Committees</b>		
8.	National Ethical Guidelines for Biomedical and Health Research Involving Human Participants	97-110
9.	Ethics Committee -1	111-128
10.	Ethics Committee -2	129-146
11.	New Drugs And Clinical Trials Rules 2019	147-153





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# Research





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

University Road, Deralakatte, Mangaluru – 575 018

No.YU/REG/PA/BOM-48/Not/09/2020

Date: 14.12.2019

## **NOTIFICATION**

**Sub: Approval of Yenepoya(Deemed to be University) Research Policy.**

**Ref: 48<sup>th</sup> meeting of BoM held on 13.12.2019 – Agenda 9.**

.....

As discussed under Agenda 9 of the 48<sup>th</sup> Board of Management meeting held on 13<sup>th</sup> December 2019, it was resolved to accept the Research Policy of Yenepoya (Deemed to be university). The policy shall be made available to all the stakeholders through the university website.

*les somayaj*

Registrar Registrar  
YENEPOYA  
(Deemed to be University)

**Copy to:**

IQAC / Academics  
YRC / PhD office / Ethics centre/ Library



# Research Policy

## Table of Contents

1. Preamble	6
2. Scope	6
3. Purpose	6
4. Objectives	6
5. Research Policy guidelines	6-9
5.1 Ethics in research	
5.2 Faculty support and promotions	
5.3 Student Support	
5.4 Training and Supervision-Role of supervisors	
5.5 Doctoral research	
5.6 Collaborative research (Inter Institutional)	
5.7 Research funds	
5.7.1 Fund Management	
5.8 Conflict of interest	
5.9 Research misconduct	
6. Quality of Publications	9
7. Plagiarism policy	9
8. Intellectual Property Policy	10
9. Policy term	10

# Research Policy

## 1. Preamble

Rapid transmission of knowledge in science is a central and complementary function of a higher education institution which impacts national development. In science and technology, research and innovation are the cornerstones helping in the continuous creation of knowledge contributing to social well-being, health, culture, economic development and the advancement of society. Hence the promotion of research and innovation is one of the key missions of Yenepoya (Deemed to be University).

## 2. Scope

This research policy applies to all research conducted by a researcher including under graduate, postgraduate students, internship students, doctoral students, faculties, Fellowship students, students/faculty from other institutions conducting research as a part of exchange program or fellowships etc. The aim of this policy is to establish the framework for the research activities. The University shall ensure that all faculties receive support to do research through various schemes and they shall have the right to disseminate the research outcomes through publications and patents. It is important that faculty adhere to the spirit, ethics and the letter of the policy.

## 3. Purpose

The purpose of the research policy is to prescribe standards of responsibility and ethical conduct expected of all persons engaged in research in the University. Further, to ensure that researchers are aware of and informed about the changes in the national and international regulatory framework relevant to research from time to time.

## 4. Objectives

- To maintain and adhere to the highest standards of honesty, research ethics and integrity
- To familiarize all researchers with and abide by the research policies and guidelines
- To evaluate the research/academic credentials
- To ensure that the policy, governance and administrative support creates an excellent research environment
- To use scientific rigor and integrity in obtaining, recording, analyzing data, reporting and publishing the results.

## 5. Research Policy guidelines

### 5.1 Ethics in research

The primary responsibility of all stake holders is to maintain the highest standards of honesty, integrity and ethical standards in research. All the research work shall be subjected to approval from the Scientific Review Board (SRB) and ethical committees to ensure ethical standards on all aspects of research including welfare and safety of the subjects. The principal investigator shall ensure that no research can be initiated without the appropriate approval of the concerned ethical committee. University shall not allow the initiation of any project without the approval of IEC/AEC. All the projects that are approved by the IEC/AEC shall be informed to the University through the heads of the constituent colleges/ centres. Even if the faculty leaves the Institute after



completing most of the research, the research work must be credited to Yenepoya (Deemed to be University)

## **5.2 Faculty support and promotions**

All the faculty members of Yenepoya (Deemed to be University) shall have to undertake quality research demonstrated with quality publications and participation in conferences. They shall also engage in translational research to address challenges that are socially relevant. The promotion of faculty shall significantly depend on the quality of research, especially publications and research grants. Based on the budgetary provisions available from time to time the following support shall be provided;

1. The University shall provide seed grants to conduct high quality research and to build enthusiastic teams with interdisciplinary research goals.
2. Faculty members shall be provided with manpower assistance in the form of JRF or SRF, doctoral and postdoctoral researchers.
3. Travel grants and financial support shall be provided to attend national/international conferences to disseminate research results to a wide audience globally for the regular faculty of the institution.
4. The University shall provide a fixed grant annually to constituent colleges and centres for imparting research training to gain knowledge through research and build research culture among undergraduate and postgraduate students.
5. Research incentives shall be given to appreciate and encourage high quality research outputs annually.
6. Promote and facilitate research collaborations with Institutes of State/National and International repute.

## **5.3 Student Support**

The University shall provide financial support to undergraduate and postgraduate students for such research projects that are additional to the mandatory research work. The number of fellowships to the research scholars enrolled for the Ph.D. program shall be based on the availability of the funds. The students/research scholars receiving the financial support shall acknowledge the same in the publications arising from the research. Additional financial support will be considered to exceptional candidates who wish to undertake research in the cutting edge areas, Student research mentorship program and ICMR student research projects.

## **5.4 Training and Supervision-Role of supervisors**

The University emphasizes on appropriate mentoring, training and supervision of undergraduate, postgraduate and doctoral students in research that demonstrates excellence, integrity, respect and recognition. A supervisor/mentor/guide for students shall be notified as per the eligibility requirement outlined in the respective statutory councils or UGC as applicable. Such faculty engaged in mentoring the research activities shall take reasonable measures to;

- i. ensure that the students have been advised of their obligations in respect of academic integrity and the ethical conduct of research;
- ii. ensure that the students have received a copy of the regulatory framework relevant to their particular research;

- iii. provide the students with a copy of any research related documents which the students have been asked to sign;
- iv. disclose to the students any special conditions concerning such matters as constraints on publication, limitations on the future use of data, and ownership of intellectual property that may influence a student's decision to participate in the research
- v. ensure that research data generated is free of any forms of malpractices (fabrication, plagiarism, etc..) and publication ethics is ensured.
- vi. not enter into an arrangement with a person to write or contribute to a publication/thesis without the researcher's contribution being publicly acknowledged. Such an arrangement is only acceptable if the researcher if so requested, is prepared to be publicly associated with the publication/report/thesis.
- vii. Ph.D. supervisor shall ensure that the regulations/guidelines provided by UGC on the Ph.D. program are adhered to.
- viii. acknowledge his or her affiliation with the university in all publications resulting from research undertaken with a member of the University or collaborators in other universities/institutions.
- ix. not enter into any arrangement with any person/organization to conduct any research under the auspices of the University, or on University premises or using students, academic, administrative or support staff, or University resources or facilities on the understanding that the conduct of the research is to be kept secret.
- x. shall comply with the regulatory framework governing the conduct of research activities that pose a recognizable inherent risk of accidental injury to persons or property activities; obtain all necessary approvals before accepting delivery of hazardous materials, or embarking on the activities in question; and notify those who may be placed at risk prior to the commencement of the activities.

The policy encompasses and encourages the faculty members to engage visiting scholars and interns from other organizations by providing an opportunity to pursue their research and professional interests in departments or centres of the campus. The number of research internships shall be decided by the department/centre based on the availability of resources and infrastructure. The above guidelines shall be applicable to the supervisors of internship students.

## **5.5 Doctoral research**

The institute offers Ph.D. in all the departments for eligible candidates as per criteria defined under the Ph.D. regulations of UGC and its amendments. The research supervisor shall ensure that;

- i. The quality of the thesis and publications are maintained to high standards.
- ii. All types of research output from the doctoral studies should be published with Yenepoya (Deemed to be University) affiliation.
- iii. The patents arising from the study shall be applied through Yenepoya (Deemed to be University).

## **5.6 Collaborative research (Inter Institutional)**

The Principal Coordinator (PC) shall take all responsibilities in the case of collaborative or team research involving multiple departments or institutions. The researchers from the participating institutions shall be aware of research policy and comply with the regulatory guidelines. The financial and resource sharing shall be decided on before the commencement of the project. An agreement between all the collaborating partners shall be made defining the roles of each part and

IP sharing among the collaborators.

## **5.7 Research funds**

The University provides all the support to mobilize resources for research through extramural grants from the government and non-governmental organizations. The Principal Investigator shall ensure that all research funds administered by her/him are used with honesty, integrity and accountability is maintained. The source of funding shall be acknowledged, in all publications generated by the funding support including seed grants from the institute.

### **5.7.1 Fund Management**

The University shall take all the required financial and administrative responsibilities for the management of research grants/funds and allow the Principal Investigator (PI) to utilize the amount for which it has been sanctioned.

The extramural grants will be maintained generally in the University savings bank account. However, if the sanctioning agency requires a separate account will be opened for the maintenance of the funds.

The finance office shall maintain the audited annual statement of the accounts and utilization certificates.

Copies of the sanction orders, terms of reference and other documents shall be submitted by the PI to the Head of the University and any agreement that has to be entered with the funding agency, the University shall do so with a tripartite agreement between the PI and University and agency. A completion report of the grants with outputs and milestones achieved shall be submitted to the University.

## **5.8 Conflict of interest**

All researchers comply to disclose to all relevant persons any conflict of interest that might influence such persons' decisions (including other institutions, agencies, conference organizers, conference/workshop participants, and journals and publishers).

## **5.9 Research misconduct**

In order to ensure the continued integrity of research, any research misconduct that is inconsistent with honesty or the University regulation, Vice Chancellor may constitute a disciplinary committee headed by Pro Vice Chancellor, Registrar and shall be investigated in accordance with the University regulations and disciplinary procedures as per the policy for Prevention of malpractices in research. Vice Chancellor shall be the appellate authority.

## **6. Quality of Publications**

The University intends to maintain the high quality of research outputs by promoting research publications in journals of high standards, indexed in leading databases, such as Clarivate Analytics (Web of Science) and Scopus (Elsevier), and PubMed.

## **7. Plagiarism policy**

University has adopted a policy for the prevention of plagiarism in line with UGC (Promotion of Academic integrity and prevention of plagiarism in HEI) regulations 2017.

## **8. Intellectual Property Rights Policy ( IPR)**

As per the IPR policy of the University.

## **9. Policy term**

The University research policy shall be subject to review annually on the basis of suggestions received from the stakeholders.



**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# Startup





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

University Road, Deralakatte, Mangaluru – 575 018

No.YU/REG/PA/BOM-48/Not/2020

Date: 02.01.2020

## **NOTIFICATION**

**Sub: Approval of Yenepoya (Deemed to be University) Start Up Policy.**

**Ref: 48<sup>th</sup> meeting of BoM held on 13.12.2019 – Agenda 8.**

.....

It was resolved to accept the Start Up Policy of Yenepoya (Deemed to be University).  
The Vice Chancellor shall have the powers to manage the operational issues and ratify  
the same in subsequent Board of Management meetings.

Registrar  
Yenepoya (Deemed to be University)

To:

✓ Dy. Director, QAC  
Academics







**YENEPOYA**

**(Deemed to be University)**

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

Accredited by NAAC with 'A' Grade

## **University Startup Policy**

**Version: May 2019**

### **Table of Contents**

<b>ARTICLE 1 - PREFACE</b>	16
<b>ARTICLE 2 - DEFINITIONS</b>	17
<b>ARTICLE 3 – SCOPE OF THE POLICY</b>	19
<b>ARTICLE 4 – GOVERNANCE AND OPERATION</b>	19
<b>ARTICLE 5 – INVOLVEMENT IN THE COMPANY</b>	20
<b>ARTICLE 6 – USE OF UNIVERSITY RESOURCES AND IP RIGHTS</b>	21
<b>ARTICLE 7 – UNIVERSITY SUPPORT</b>	21
<b>ARTICLE 8 - DISPUTE</b>	22

## ARTICLE 1-PREFACE

### 1.1. University Mission and Context

- 1.1.1. The core mission of the Yenepoya (Deemed to be University) is creation of knowledge through scientific research which can reach the masses and impact the society.
- 1.1.2. The University recognises the impact entrepreneurship can have in terms of identifying and solving scientific and technical challenges and acknowledges the role of Startups in commercialising the Intellectual Property (IP) emanating from its Research activities.
- 1.1.3. The University will endeavour to promote entrepreneurship to be taken up by its Staff and Students and it prioritises commercialisation of its IP in a manner that encourages and fosters entrepreneurship by Staff Members and others.

### 1.2. Purpose of the Startup Policy

- 1.2.1. **Promotion of Entrepreneurship.** The intent of the Startup Policy is to foster entrepreneurial ecosystem which encourages co-creation by involving students, faculty and professionals from multiple disciplines. Also, it lays down guidelines for the involvement of the University's Staff and Students.
- 1.2.2. **Entrepreneurship management.** The Startup Policy seeks to set the framework for the involvement of the University's Staff and Students in Commercialising University's Research into products, services and processes. It encourages Staff Members, Students and Visitors to become Entrepreneurs. It also establishes clear rules and procedures for the creation/participation of Staff and Student led Startups which may or may not be based on the University IP.
- 1.2.3. **Entrepreneurship guidance.** The University has established Technology Incubator in the University campus to provide the entrepreneurs with the necessary guidance, mentorship and infrastructure support in order to nurture their ideas and help translate them into successful Startups.
- 1.2.4. **Balance of interests.** The Startup Policy seeks to reiterate that the employee's primary commitment of time and intellectual contributions should be to the education, research and other obligations of the University and they have a primary professional obligation to act in the best interests of the University. Hence, care must be taken to avoid any cases of Conflict of Interest (COI) and Conflict of Commitment (COC) by all the Staff Members, Students and the Visitors of the University.

## ARTICLE 2- DEFINITIONS

Without prejudice to any applicable laws, in this Policy the definitions set out below shall apply:

- 2.1 **Appointment.** A formal agreement for a Visitor at the University, which is a pre requisite to participate in or conduct Research, scholarship, creative work, or teaching at the University.
- 2.2 **Author.** Any person to whom this Policy is applicable, who individually or jointly with others makes a design, a mark or copyrightable work and who meets the criteria for authorship under the IP laws of India.
- 2.3 **Conflict of Commitment (COC).** Any situation in which an individual Staff Member's or Visitor's primary professional loyalty is not to the University because the time devoted to outside activities adversely affects their capacity to meet their responsibilities as set out in their employment contract of Appointment.
- 2.4 **Conflict of Interest (COI).** Any situation in which real or perceived interests of an individual Staff Member, Visitor or Student may run counter to the interests of the University or negatively affect their employment or duties.
- 2.5 **Gross Non-IP Revenue.** All revenue received by the University for Execution of Projects / Scientific or Clinical Work as part of the Research Contract before any cost recovery or deductions for the incurred Expenses, as defined in Article 7.
- 2.6 **University.** Yenepoya (Deemed to be University).
- 2.7 **University IP.** IP owned or co-owned by the University.
- 2.8 **Intellectual Property (IP).** All outputs of creative endeavour in any field at the University for which legal rights may be obtained or enforced pursuant to the law. IP may include:
  - a. Literary works, including publications in respect of Research results, and associated materials, including drafts, data sets and laboratory notebooks;
  - b. Teaching and learning materials;
  - c. Other original literary, dramatic, musical or artistic works, sound recordings, films, broadcasts, and typographical arrangements, multimedia works, photographs, drawings, and other works created with the aid of University resources or facilities;
  - d. Databases, tables or compilations, computer software, preparatory design material for a computer program, firmware, courseware, and related material;
  - e. Patentable and non-patentable technical information;
  - f. Designs including layout designs (topographies) of integrated circuits;
  - g. Plant varieties and related information;
  - h. Trade secrets;

- i. Know-how, information and data associated with the above;  
and
  - j. Any other University-commissioned works not included above.
- 2.9 **IP Management Cell (IPMC).** The administrative unit established in terms of Article 4.2, responsible for day-to-day management of all IP-related activities of the University.
- 2.10 **Policy.** This, Yenepoya (Deemed to be University) Start-up Policy.
- 2.11 **Staff Member.** Any person who is under a contract of employment with the University including academic, research, technical, administrative and adjunct staff, whether full-time or part-time or on a temporary basis.
- 2.12 **Student.** Any student registered for an approved course at the University.
- 2.13 **Substantial Use.** Extensive use of the University's resources which include but are not limited to facilities, equipment, human resources or funds. Not included is routine use of libraries and/or office space or the IP has been written or developed in the personal (unpaid) time of the Inventor.
- 2.14 **University Incubator.** Yenepoya Foundation for Technology Incubation also referred to as Yenepoya Technology Incubator (YTI) or Incubator or Technology Incubator.
- 2.15 **Visitor.** Any person who is neither a Staff Member nor a Student of the University who engages in work at the University, including visiting professors, adjunct and conjoint professors, teachers, researchers, scholars and volunteers; and who concludes an Appointment agreement with the University.

## ARTICLE 3-SCOPE OF THE POLICY

- 3.1. **Applicability.** This Policy applies to all Staff Members, Students and Visitors who are willing to or may have started a commercialisation entity (Company/Startup) which may or may not be based on the University IP. Rights and obligations under this Policy shall survive any termination of employment, enrolment or Appointment at the University.
- 3.2. **Binding effect of the Policy.** This Policy constitutes an understanding that is binding on the University, Staff Members, Students and Visitors, once adopted by the Board of Management (BOM) of the University.
- 3.3. **Type of Companies.** This University encourages and promotes the following companies.
  - 3.3.1. Companies jointly owned by the Staff Members and Students/Alumni (along with possibly others)
  - 3.3.2. Companies owned by the Staff Members (one or many) along with possibly others.
  - 3.3.3. Companies owned by the Graduating Students, Alumni along with possibly others

In such cases, the Staff Members and Students will be known as founding members of the board of the company. The use of the term ‘company’ in throughout this document refers to the types of companies mentioned above unless specified otherwise.

## ARTICLE 4-GOVERNANCE AND OPERATION

- 4.1. **Responsibilities.** The ultimate decision making authority in the determination of the permission to the Staff and Student led Startup will be the Vice Chancellor of the University.
- 4.2. **Entrepreneurship Promotion Cell (EPC)**
  - 4.2.1. **Purpose.** The University has established an Entrepreneurship Promotion Cell (EPC) to assist the University in promotion of entrepreneurship and organising relevant activities.
  - 4.2.2. **Responsibilities.** The responsibilities of the EPC shall include, but are not limited to:
    - a. Outreach/awareness;
    - b. Relationship management with potential entrepreneurs;
    - c. Coordinating with the IPMC for IP licensing;
    - d. Organising entrepreneurship promotion activities and events;

## ARTICLE 5-INVOLVEMENT IN THE COMPANY

### 5.1. Role of the Staff Members

It is expected that the staff members would be owners of companies defined in Article 3 and be a Director on the Board. Also, the staff member may choose to play an operational role (Technical Advisor, CEO, CTO, MD, etc).

#### 5.1.1. **Startup engagement.** The staff member can choose one of the following options:

- a. Take a sabbatical and work full-time in the business.
- b. Dedicate up to 4 working days per month for the Startup related activities with due permission from the Registrar of the University.

#### 5.1.2. **Conflict of Interest and Conflict of Commitment.** It should be noted that the staff should take all possible steps to ensure that his/her duties and responsibilities of the University take precedence over all other activities.

### 5.2. Role of the Students

During their enrolment the students will be allowed to be owners of the companies, as defined in Article 3, be a Director on the Board or be employed in a staff member led company. Also, they may be free to play an operational role (Technical Advisor, CEO, CTO, MD, etc).

#### 5.2.1. **Startup engagement.** Students will be free to dedicate any time outside their regular academic hours and duties towards their companies. However, if deemed necessary, they may be allowed special leave towards startup activities subject to approval from the respective department heads and under no circumstance they will be allowed to avail this leave during the time of their scheduled exams.

#### 5.2.2. **Theses or dissertations.**

The Student may be allowed to base their Start-up on their theses or dissertation with due approval from their supervisor. All the University regulations related to Theses or dissertation including the University IP policy will apply.

### 5.3. Incubation

#### 5.3.1. **University IP.** If a Staff or a Student intends to base their Startup on the University owned IP for which they may or may not be the inventors, they will be required to incubate their company in the University Incubator. Licensing or allocation of the IP will be governed as per the University IP Policy.

#### 5.3.2. **No IP / External IP.** In case the Staff or Student led Startup is based on IP not owned by the University or if no IP is involved, they may be free to incubate their company either in the University Incubator or outside the University. However, if the company

is housed outside the University Incubator, the benefits outlined in Section 5.1.1 and Article 6 and 7 may not be applicable.

#### ARTICLE 6-USE OF UNIVERSITY RESOURCES AND IP RIGHTS

- 6.1. **Staff and Students.** The Staff Members and Students who are the promoters of the Startup housed in the University Incubator may be allowed to use University resources such as labs and other such facilities for their company purposes. Use of any such facilities and resources may not be charged during the incubation period, except for facilities and instruments which are not free for the internal users. To enable free access to the staff and student led companies, an equity may be retained by the University which will also ensure IP ownership by the company as detailed in the section 6.3. The use of space and resources of the University Incubator will be governed as per the norms of the University Incubator.
- 6.2. **Company Employees.** The University resources are generally not accessible to anyone who is not associated with the University, either as an employee or a student. When involving company employees who are not associated with the University, permission from the facility in charge or department head will be required.
- 6.3. **IP Rights and Ownership.** Any IP developed by the incubated company while using University resources shall be the property of the company. However, before filing such IP application the permission of IPMC is necessary. The company is expected to grant non-exclusive, royalty-free license to the University to the IP generated by the company while using University resources for non-commercial purposes.

#### ARTICLE 7-UNIVERSITY SUPPORT

- 7.1. **Incorporation.** The University may support the staff members and the students in the incorporation of the company in the form of incorporation fees and guidance. This may also include support extended to the company for annual maintenance of the company and any charges incurred towards its compliance.
- 7.2. **Funding.** The University may provide funding support to the companies in the form of grant in aid, seed grant and loan. Equity in the supported companies may be taken up as described in the Article 8.
- 7.3. **Mentorship and Guidance.** University will provide necessary mentorship and guidance through the Incubator free of cost.
- 7.4. **Special Leaves.** Staff Members are expected to ensure success of their Startups by dedicating efforts and time required. Keeping this in view University will allow Staff to involve in their companies in one of the following ways.
  - a. Take a sabbatical and work full-time in the company.

- b. Dedicate up to 4 working days per month for the Startup related activities with due permission from the Registrar of the University.
- 7.5. **Equity.** The University, either directly or through a designated individual or organisation, may exercise its discretion in taking up equity in the company in the following cases.

- 7.4.1 Equity against freedom to use University resources including the IP.
- 7.4.2 Equity against incubation.
- 7.4.3 Equity against seed grant and/or grant in aid.
- 7.4.4 Equity against loan provided by the University.

For sections 7.4.1, 7.4.2 and 7.4.3 the maximum Equity University may take up in the company should not exceed 10%. Equity against any loan provided by the University will be independent of this equity limit.

## ARTICLE 8-DISPUTE

- 8.1. **Violation.** Breach of the provisions of this Policy shall be dealt with under the normal procedures of the University, and in accordance with the relevant provisions of laws and regulations in force.
- 8.2. **Dispute Resolution.**
- 8.2.1. Any internal disputes or questions of interpretation arising under this Policy must in the first instance be referred to IPMC and EPC.
  - 8.2.2. If the matter cannot be resolved by the IPMC and EPC within two months, then the dispute or question of interpretation must be referred to the Vice Chancellor for mediation.
  - 8.2.3. The Vice Chancellor may at their sole discretion refer the matter to University's Executive Committee and/or an independent committee for arbitration as final arbiter of any disputed issues or for final determination.





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# **Intellectual Property Rights**





**YENEPOYA**

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

University Road, Deralakatte, Mangaluru – 575 018

No.YU/REG/PA/BOM-48/Not/06/2019

Date: 16.12.2019

## **NOTIFICATION**

**Sub: Approval of Yenepoya (Deemed to be University) Intellectual Property Rights Policy.**

**Ref: 48<sup>th</sup> meeting of BoM held on 13.12.2019 – Agenda 12.**

.....

It was resolved to accept the Intellectual Property Rights Policy of Yenepoya (Deemed to be University) as proposed by Yenepoya Incubation Centre.

*ks Somayaj*

Registrar  
Yenepoya (Deemed to be University)

Registrar  
YENEPOYA

To: (Deemed to be University)

Dy. Director, QAC  
Academics





**YENEPOYA**  
**(Deemed to be University)**  
Recognized under Sec 3(A) of UGC Act, 1956  
Accredited by NAAC with 'A' Grade

## **Intellectual Property Rights Policy**

**Version: May 2019**

### **Table of Contents**

<b>ARTICLE 1 - PREFACE</b>	29
<b>ARTICLE 2 - DEFINITIONS</b>	30
<b>ARTICLE 3 – SCOPE OF THE POLICY</b>	34
<b>ARTICLE 4 – GOVERNANCE AND OPERATION</b>	35
<b>ARTICLE 5 - OWNERSHIP OF IP AND RIGHTS OF USE</b>	36
<b>ARTICLE 6 – PUBLICATION, NON-DISCLOSURE AND TRADE SECRETS</b>	39
<b>ARTICLE 7 –RESEARCH CONTRACTS</b>	39
<b>ARTICLE 8 – DETERMINATIONS BY THE IPMC</b>	43
<b>ARTICLE 9 - COMMERCIALIZATION OF IP</b>	45
<b>ARTICLE 10 - INCENTIVES AND DISTRIBUTION OF REVENUES</b>	46
<b>ARTICLE 11 – IP PORTFOLIO MAINTENANCE</b>	50
<b>ARTICLE 12 - DISPUTE</b>	50
<b>ARTICLE 13 - AMENDMENT</b>	51

## Foreword

Universities and research institutions have a fundamental role in socio-economic development. Innovation and scientific development are the basis for economic, technological and social mobility as well as for economic growth. Universities and research institutions are a main arena in which scientific development and innovation takes place and the intellectual property Rights (IPR) system is the main mechanism that enables universities and society at large to capture the value of innovation.

It is the IPR system that assists Universities and research institutions to commercialize their knowledge assets and by doing so potentially obtain additional sources of funding, which may be channeled into, amongst other, further research. At the same time, partnerships with the private sector and other organizations can ensure that academic research outcomes have broader impact, including competitiveness of industry and the regions, establishment of new companies, or addressing a variety of socio-economic challenges.

This approach requires support for the entrepreneurial dimension of knowledge transfer, where strategies that leverage IPR assets at the same time place emphasis on how academic research and the resultant IP best provide economic, environmental and social benefits for society at large.

Yenepoya (Deemed to be University) has a very clear vision in creating new knowledge through scientific research which can reach the masses and impact our society. The knowledge is an intellectual asset and needs protection. Hence, Yenepoya (Deemed to be University) has taken the necessary steps to create an Intellectual Property Management (IPM) cell.

This IPR policy is the very foundation of IP management in that it:

- serves as the starting point for a common understanding about IPR, IPR rights and incentives for researchers;
- Establishes the structure for the way the University deals with the ownership and disposition of its IP. As such, it ensures certainty and transparency to reinforce the links between the University and industry; and
- Is also fundamental in helping the University address social commitments, and especially, in ensuring the dissemination of knowledge and technology for the public good.

This **Intellectual Property Rights Policy** aims to provide a compendium of key issues that are essential in an IP policy, including ownership, incentives, confidentiality and publication, IP management and commercialization, recording and maintenance of IPR, and IPR-related conflicts of interest. The aim is to promote reflection and critical thinking; to stimulate certainty in terms of IPR ownership; to encourage responsible IPR commercialization of research results.

## ARTICLE 1-PREFACE

### Context and University Mission

The core mission of the Yenepoya (Deemed to be University)(“University”) is creation of knowledge through scientific research which can reach the masses and impact the society.

The University is committed to ensuring that Intellectual Property Rights (IPR)emanating from its Research activities is used in accordance with its legal obligations, for the benefit of the University, the Inventors and, most importantly, society-at-large.

### Purpose of the IPR Policy

**Promotion of IPR utilization.** The intent of the IPR Policy is to facilitate the widespread use of, through various modalities of access to, the University’s IP.

**IPR management.** The IPR Policy seeks to set the framework for the translation of the IPR arising from the University’s Research into products, services and processes. It encourages Staff Members, Students and Visitors to become Inventors and to identify IP with potential commercial value. It also establishes clear rules and procedures for the management and Commercialization of such IPR generated at the University.

**Balance of interests.** The IPR Policy seeks to ensure the legal protection, where applicable; effective management and Commercialization of University IP; while at the same time not impeding with the traditions of education and scholarship, academic freedom, open and timely publications, University sovereignty, and the University’s mission serving the public interest.

### Overall Principles

The University operates under the following overall principles:

**Responsible Commercialization.** Where IP arises that has commercial potential as a result of Research, the University intends to make such IPR available in a form that will most effectively promote its development and use for economic and social benefit.

**Incentives.** The University wishes to recognize and reward Staff Members, Students and Visitors whose IP generates a demonstrable socio- and/or economic impact.

## ARTICLE 2-DEFINITIONS

Without prejudice to any applicable laws, in this Policy the definitions set out below shall apply:

**Appointment.** A formal agreement for a Visitor at the University, which is a prerequisite to participate in or conduct Research, scholarship, creative work, or teaching at the University.

**Author.** Any person to whom this Policy is applicable, who individually or jointly with others makes a design, a mark or copyrightable work and who meets the criteria for authorship under the IPR laws of India.

**Background IPR.** Any pre-existing IP created before the execution of any Research Project, or prior to an Inventor becoming subject to this IPR Policy, by virtue of Appointment in the case of a Visitor, employment contract in the case of a Staff Member, or registration in the case of a Student.

**Commercialization.** Any form of utilization of IP intended to generate value, which may be in the form of a marketable product, process or service, commercial returns, or other benefit to society. **Commercialize** is similarly defined.

**Commercialization Entity.** A company that has access to the IP of the University, through any one or more of the available Commercialization modes, to produce new products, processes or services. This can be a spin-off or start-up.

**Conflict of Commitment (COC).** Any situation in which an individual Staff Member's or Visitor's primary professional loyalty is not to the University because the time devoted to outside activities adversely affects their capacity to meet their responsibilities as set out in their employment contract of Appointment, respectively.

**Conflict of Interest (COI).** Any situation in which real or perceived interests of an individual Staff Member, Visitor or Student may run counter to the interests of the University or negatively affect their employment or duties.

**Collaborative R&D.** In this category of R&D, would comprise projects that are jointly conceived, planned, and executed by the Institute Personnel, in collaboration and partnership with, the representatives, personnel, and staff of the Sponsor/ Funding Agency/ Industry/ Collaborator, including Inter-University Collaborator(s). Such projects will be characterized by substantial inventive and financial contributions from the Sponsor/ Funding Agency/ Industry/ Collaborator, including Inter-University Collaborator(s). Consequently, the Institute would be amenable to



considering joint ownership of the IP, with the corresponding Sponsor/ Funding Agency/ Industry/ Collaborator, including Inter-University Collaborator(s).

**Contract R&D.** Contract R&D is the kind of R&D performed by Institute Personnel, when a Sponsor/ Funding Agency/ Industry sets out a specific problem/ research agenda/scope of work, and the Institute Personnel work on the same, in a “work for hire” mode.

**Course Materials.** All materials used in, or in connection with, and for the purpose of, teaching an education course through the provision of lectures, tutorials, seminars, workshops, field or laboratory classes, assessments, practicum and other teaching activities conducted by the University; and all IP in such materials.

**Enabler.** Any assistants, technicians, and other individuals who have indirectly contributed to the creation/commercialization of IP - and as such may not be listed themselves as an author or inventor in terms of statutory IPRs - but without whose practical contribution the Commercialization would not have been possible.

**Gross IP Revenue.** All revenue received by the University on Commercialization of University IP before any deductions for IP Expenses, as defined in Article 10.

**Gross Non-IP Revenue.** All revenue received by the University for Execution of Projects / Scientific or Clinical Work as part of the Research Contract before any cost recovery or deductions for the incurred Expenses, as defined in Article 7.

**University.** Yenepoya (Deemed to be University).

**University IP.** IP owned or co-owned by the University.

**Intellectual Property Rights (IPR).** All outputs of creative endeavor in any field at the University for which legal rights may be obtained or enforced pursuant to the law. IPR may include:

- a. literary works, including publications in respect of Research results, and associated materials, including drafts, data sets and laboratory notebooks;
- b. teaching and learning materials;
- c. other original literary, dramatic, musical or artistic works, sound recordings, films, broadcasts, and typographical arrangements, multimedia works, photographs, drawings, and other works created with the aid of University resources or facilities;
- d. databases, tables or compilations, computer software, preparatory design material for a computer program, firmware, courseware, and related material;
- e. patentable and non-patentable technical information;
- f. designs including layout designs (topographies) of integrated circuits;
- g. plant varieties and related information;
- h. trade secrets;
- i. know-how, information and data associated with the above; and j. any other University-commissioned works not included above.

**Intellectual Property Rights (IPRs).**The proprietary rights that may be granted for an invention, mark, design, plant variety, or other type of IP, should the statutory requirements for protection be met to result in a patent, trade mark, registered design or plant breeders' right, respectively.

**Invention.** Section 2(1)(j) of Indian Patents Act (2005), defines "invention" as a new product or process involving an inventive step capable of industrial application.

The term "industrial application" refers to capable of industrial application in relation to an invention means that the invention is capable of being made or used in an industry. One of the pre-requisite of invention is that it should be new i.e. the invention proposed to be patented has not been in the public domain or that it does not form part of the state of the art.

**Inventor.** Any person to whom this Policy is applicable, who creates, conceives, reduces to practice, authors, or otherwise makes a substantive intellectual contribution to the creation of IP and who meets the definition of 'Inventor', 'author' or 'breeder' as generally implied in the IP laws of India.

**Investigator.** Staff Members, Students and Visitors involved in the execution of Project / Scientific or Clinical Work as part of the Research Contract.

**Innovation.** is an Invention that has been implemented, or put to actual, practical use, that results in better products, processes, or services. Such Innovations result in new products, processes, or services that result in better solutions that meet new requirements, unarticulated needs, or existing market needs. The basic difference between an invention and an innovation is that the former is a laboratory creation, whereas an innovation is its actual application in the field.

**IP Disclosure Form.** The form provided in Annexure I to be completed by Inventors and submitted to IPMC to document their creation.

**IP Expenses.** All expenses incurred by the University in the management and

Commercialization of IP for which Gross IP Revenue has been received.

**IP Advisory Committee.** The body within the University, set up in terms of Article 4.1, which is responsible for overseeing the drafting, implementation, monitoring and evolution of the Policy, and for providing strategic oversight of the IPMC.

**IP Management Cell (IPMC).**The administrative unit established in terms of Article 4.2, responsible for day-to-day management of all IP-related activities of the University.

**Net IP Revenue.** Gross IP Revenue less IP Expenses.

**Policy.** This, Yenepoya (Deemed to be University) Intellectual Property Rights Policy.

**Project Expenses.** All expenses incurred by the University in the management and execution of Research Contract for which Gross non-IPR Revenue has been received.

**Public Disclosure.** The communication of information, relating to IP, to external parties. Public Disclosure includes, but is not limited to, disclosure in written or oral form; communication by email; posting on a web blog; disclosure in a news report, press release or interview; publication in a journal, abstract, poster, or report; presentation at a conference; examination of a thesis; demonstration of an Invention at a trade show; or the industrial application of an Invention.

**Public Domain.** The freely accessible public realm in which works that are not protected by IPRs, either because the rights have been forfeited or because the rights have been expired, are thereby held by the public at large and available for all to use without permission from the Inventor or owner.

**Research.** Any creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications. It comprises three activities: basic research, applied research and experimental development.

**Research Contract.** Any type of agreement between the University and an external party or research sponsor, concerning Research, which could result in IP being created at the University. This shall include, but is not limited to, all sponsorships, donorships and collaborations with the external party or research sponsor and can also be referred to as Contract R&D and or Contract Research.

**Research Project.** Any project that forms the basis of Research undertaken by the University and includes projects undertaken by a Student, under the supervision of a Staff Member or a Visitor, as part of a research degree program.

**Scholarly Works.** All copyright works which are the outputs of academic Staff Members, Students or Visitors, including Research, creative and other outputs in area(s) of his/her expertise. It does not include Course Materials and computer software and databases.

**Sponsor/ Funding Agency/ Industry.** These terms, used interchangeably in this IP Policy document, refer to the entity that funds the R&D work that is proposed to be carried out by the Institute. In addition, in the case of Collaborative R&D work carried out by the Institute and the Industry, the latter shall also make substantial inventive contributions, in tandem with the financial contributions made by it.

**Staff Member.** Any person who is under a contract of employment with the University including academic, research, technical, administrative and adjunct staff, whether full-time or part-time or on a temporary basis.

**Student.** Any student registered for an approved course at the University.

**Substantial Use.** Extensive use of the University's resources which include but are not limited to facilities, equipment, human resources or funds. Not included is routine use of libraries and/or office space or the IP has been written or developed in the personal (unpaid) time of the Inventor.

**Trade Secret.** Confidential information not publicly available that has commercial value because of its confidential nature, and which the owner has taken reasonable efforts to keep secret.

**Visitor.** Any person who is neither a Staff Member nor a Student of the University who engages in work at the University, including visiting professors, adjunct and conjoint professors, teachers, researchers, scholars and volunteers; and who concludes an Appointment agreement with the University.

### **ARTICLE 3- SCOPE OF THE POLICY**

**IP.** This Policy applies to all IP generated at the University, in particular by Staff Members, Students and Visitors.

**Background IP.** Upon commencing employment, enrolment or an Appointment, Staff Members, Students and Visitors must declare any existing IP they wish to exclude from the application of this Policy due to creation prior to their employment, enrolment or Appointment at the University.

**Applicability.** This Policy applies to all Staff Members, Students and Visitors who participate in a Research Project or produce Scholarly Works. Rights and obligations under this Policy shall survive any termination of employment, enrolment or Appointment at the University.

**Binding effect of the Policy.** This Policy constitutes an understanding that is binding on the University, Staff Members, Students and Visitors, once adopted by the Board of Management (BOM) of the University, on the following grounds:

**Staff Members.** The University shall ensure that the employment contract or other agreement establishing any type of employment relationship between the University and Staff Members includes a provision placing Staff Members under the scope of this Policy.

**Students participating in a Research Project.** The University shall ensure that Students participating in a Research Project sign an agreement before commencing the project, to the effect that they have read and will comply with the provisions of this Policy, according to Article 5.2.5.

**Visitors.** The University shall ensure that Visitors sign an Appointment agreement before commencing any activity at the University. Such agreement shall place the Visitor under the scope of this Policy and shall make reference to this Policy, a copy of which will be made available to the Visitor.

**Informed consent.** This Policy shall be included on the University's website. In addition, a reference to this Policy shall be made in the academic catalogues or their equivalent. Said reference shall be in sufficient detail to enable the full text of the Policy to be easily accessed.

## ARTICLE 4-GOVERNANCE AND OPERATION

### IP Advisory Committee

**Purpose.** The University shall establish an IP Advisory Committee to oversee the implementation and evolution of this Policy and provide strategic guidance to the IPMC (according to Article 4.2 below).

**Composition.** The IP Advisory Committee shall consist of members as identified by the Registrar and chaired by the Vice Chancellor or their designated other.

**Responsibilities.** The IP Advisory Committee is the ultimate decision making body in the determination of an IP management and Commercialization strategy for a particular IP.

**Meetings.** The IP Advisory Committee shall establish regular meetings and also be available for *ad hoc* meetings.

### The IP Management Cell (IPMC)

**Purpose.** The University has established an IP Management Cell(IPMC) to assist the University in managing and Commercializing its IP in a form that will most effectively promote its development and use for economic and social benefit.

**Responsibilities.** The responsibilities of the IPMC shall include, but are not limited to:

- a. Outreach/awareness to Inventors;
- b. Relationship management with Inventors;
- c. IP management;
- d. Technology marketing and IP contract negotiation;
- e. IP contract management; and
- f. IP costs and revenue distribution.

## **ARTICLE 5- OWNERSHIP OF IP AND RIGHTS OF USE**

### **IP Created by Staff Members**

**University ownership.** The University owns all IP created by a Staff Member:

- a. in the course and scope of his/her employment; or
- b. making Substantial Use of the University's resources.

**Staff Member ownership.** Staff Members will own/co-own the IP they have created when such IP:

- a. is outside the course and scope of their employment and without Substantial Use of the University's resources;
- b. Vests in Scholarly Works (see Article 5.5);
- c. Other IPRs, as required by national law, or for which the University cannot or does not wish to claim ownership and the University has communicated such in writing.

**IP emanating from Research Contracts.** Where there is no Substantial Use of the University's resources or if the Contract R&D Project is completely funded by the Sponsor/ Funding Agency/ Industry/ Collaborator, to cover all direct and indirect costs, as well as all operating costs and overheads for the independent(out-sourced) execution of the Contract R&D., the terms of the Research Contract will regulate ownership of IP created by Staff Members in the course of a Research Project that forms part of a Research Contract, as set out in Article 7.

**Appointment of Staff Members at another University.** It is the responsibility of each Staff Member that holds an honorary or other academic or research appointment at another University (Host University) to bring to the attention of the Host University, including its IPMC, his/her obligations in terms of this Policy, prior to the tenure at the Host University. To the extent that the Host University's IP Policy makes a claim on IP created by the Staff Member pursuant to such appointment, the Staff Member shall ensure that the Host University negotiates a suitable IP arrangement with the University.

### **IP Created by Students**

**Student ownership.** IP created by a Student in the course of study at the University (including theses, dissertations and other Scholarly Works) will be owned by the Student. This is in contrast to IP created by a Student in a Research Project, as per Article 5.2.3 below.

**Theses or dissertations.**

The Student must submit his/her final thesis or dissertation to the University repository. And the Student must grant a royalty-free license to the University to reproduce his/her thesis or dissertation and to distribute copies thereof to the public.

**University ownership.** IP emanating from a Student's Research Project shall be owned by the University in the following circumstances:

- a. if the IP is created by making Substantial Use of the University's resources (excluding supervision) and there is no re-imbursement agreement concluded between the University and the Student; or
- b. if the Research carried out by the Student forms part of the University's Research Projects.

**IP emanating from Research Contracts.** The terms of the Research Contract shall regulate the ownership of IP created by a Student in the course of such Research Contract, as set out in Article 8.

**University ownership responsibilities.** If the University is the owner of IP created by a Student, in terms of Article 5.2.3 or Article 5.2.4, and hence created in terms of a Research Project or Research Contract, respectively, the University shall:

- a. provide the Student with an explanation of the reasons for the assignment of IP rights to the University;
- b. advise the Student to seek independent advice regarding the assignment;
- c. obtain a deed of assignment from the Student for all IPRs emanating from the Student's Research Contract or Research Project, where relevant, in return for revenue sharing as provided for in Article 10; and
- d. withdraw the Student from the Research Project or Research Contract if a Student elects not to assign the relevant IPRs to the University.

### **IP Created by Visitors**

**University ownership.** Unless otherwise agreed to in writing by the University and the Visitor's home University prior to the tenure at the University, Visitors are required to assign to the University any IP:

- a. created in the course and scope of their Appointment at the University; or
- b. created by making Substantial Use of the University's resources.

**University IP.** On departure from the University, a Visitor must sign and submit to IPMC an IP Disclosure form disclosing any IP created, as per Article 5.3.1, whilst at the University.

### **Special Rules for Course Materials**

**University ownership.** The University will own the IP in Course Materials created by a Staff Member or a Visitor, with the exclusion of Course Material that is created from or for Open Educational Resources, in accordance with Article 5.6.1.

**Licensed by the University.** The University grants the Inventors of Course Materials a royalty-free, non-exclusive license to use the Course Materials created by them for teaching and Research purposes at the University.

### **Special Rules for Scholarly Works**

**Publication.** The University recognizes and endorses the rights of Staff Members, Students and Visitors to publish their Scholarly Works, provided that any Scholarly Work which may disclose any possible University IP shall first be cleared by IPMC after having an opportunity to protect such University IP according to Article 8.

**University repository.** Staff Members, Students and Visitors should endeavor to obtain publishers' permission to include published Scholarly Works in the University repository whether as a published edition or in pre-publication form.

**Licensed to the University.** Staff Members, Students and Visitors shall grant to the University a non-exclusive, royalty free license to use their Scholarly Works for the University's administrative, promotional, Research and teaching purposes.

### **Public Domain**

**Public Domain.** University IP forms part of the Public Domain in the following circumstances:

- a. if a Research Contract provides that the Research results be placed into the Public Domain; or
- b. if Staff Members or Visitors made use of resources licensed through Open Source or Creative Commons Licenses and the licensing conditions require release of derivatives into the Public Domain.

**Release into the public domain.** The University will release IP into the Public Domain in the following circumstances:

- a. where it is deemed to be in the public interest;
- b. if the IP has low commercial or other development potential and low prospects of fostering the development of new products or services; or
- c. if deemed necessary by the University.



## ARTICLE 6-PUBLICATION ,NON-DISCLOSURE AND TRADE SECRETS

- 6.1. **Right of publication.** The University encourages and supports the right of Inventors to decide if and when to publish their Research results, in accordance with Article 5.5 above.

**Non-disclosure for IP protection.** In conjunction with the right of publication, Inventors should be aware that premature Public Disclosure may result in loss of IP protection rights. Therefore, they are strongly encouraged to make all reasonable efforts to identify any protectable IP as early as possible, according to Article 8, and shall consult IPMC before making any Public Disclosure of potential University IP.

**Trade Secrets.** The University may designate certain confidential information as a Trade Secret, owned by the University. In that event, all Inventors will be obligated to maintain secrecy of the Trade Secret and to follow the direction for management of the Trade Secret by IPMC.

## ARTICLE 7-RESEARCH CONTRACTS

**Authority.** Staff Members, Students and Visitors shall not have the right to enter into a Research Contract with external parties on behalf of the University unless they are authorized to do so by an official representative of the University. Any substantial use of University resources by any external party, which includes but not limited to the use of University infrastructure and manpower, requires a formal Research Contract to be signed.

**Due diligence.** Persons acting for and on behalf of the University shall exercise all due diligence and consult IPMC when negotiating and signing contracts that may affect the University's IPRs.

**Ownership and rights to use.** Subject to any provisions in law to the contrary, ownership and rights to use shall be agreed upon with the external entity, in accordance with the guidelines outlined in the IP Policy of the University.

**Government rules.** Research Contracts shall comply with any applicable law and/or Government regulations and/or rules, which may be applicable to Research undertaken by the University, in particular, as far as it relates to the ownership of IP resulting from such Research.

**Approval.** Proposed Research Contract and other legal statements concerning the University's IPRs shall comply with the provisions of this Policy. Any variance from this Policy must be approved by the Vice Chancellor.

**Basic Principles.** The IP clauses in all Research Contracts shall be governed by the following basic principles:

**Concluded from the outset.** A Research Contract must be executed in writing and signed by the University and the external party(ies)/sponsor(s) prior to the commencement of any Research Project and, as appropriate and without limitation, must contain terms relating to ownership, management and use of IP arising from the Research Project as well as any Background IP.

**Background IP.** All University Background IP must be properly recorded and declared prior to the commencement of a Research Contract and belongs to the University. Similarly, Background IP of the external party/sponsor, belongs to such party or sponsor. Use of such Background IP requires express written permission.

**Foreground IP (IP arising from the Research Contract).** IP generated pursuant to a Research Contract by Staff Members, Students or Visitors shall be governed in terms of the above provisions relating to IP generated by these parties. The general rule is that such IP shall be owned by the University.

**Co-owned Foreground IP.**

- a. **Terms for co-ownership.** Co-ownership of IP generated pursuant to a Research Contract shall be in accordance with national legislative provisions, failing which, or as mutually agreed contractually. The University may consider joint ownership of the IP, with the corresponding Sponsor/ Funding Agency/ Industry in case of Collaborative R&D.
- b. **Costs for protecting and maintaining co-owned IP.** The costs for protecting and maintaining any IPRs shall be shared between the University and the external party(ies)/sponsor(s) in accordance with the percentage of IP ownership; or as mutually agreed contractually.

**Serendipitous IP.** Any IP created during the course of the Research Contract which falls outside of scope of the Research Contract shall be owned by the University or the external party(ies)/sponsor(s) which developed such IP, unless agreed contractually otherwise in the Research Contract.

**Right of first refusal to the IP.** The Research Contract may include provisions giving the external party(ies)/sponsors, a right of first refusal to Commercialize the IP emanating from the Research Contract, through a license or joint venture arrangement or assignment.

**Publication delay.** It is the strict policy of the University to allow Inventors freedom to publish their work. However, the University acknowledges that delays in publication for the purpose of initiating statutory protection

of the IP is often necessary. In this regard, the University will agree, on a case-by-case basis, to a contractual delay in publication by Inventors.

**Use of the IP for Research and teaching.** In instances, where the University IP is licensed exclusively or assigned as part of the Research Contract, all efforts should be made to secure a royalty-free license for use of the IP for on-going Research and teaching purposes.

**Contract Research Policy.** All Research Contracts must be executed and performed in compliance with the University's regulations and this IP Policy.

**Exceptions to the Policy.** In certain cases, it may be necessary and/or beneficial to the University to enter into a Research Contract that contains exceptions to the provisions of this Policy. Any such exceptions require prior, written approval from the Vice Chancellor.

#### **Sharing of Non-IP Revenue.**

**General.** In case University receives any non-IP related revenue and/or other returns, monetary or otherwise, through the execution of the Research Contracts, the investigator(s) executing such a project/work will be entitled to a portion of the revenue as detailed in 7.9.3. Staff Members, Students and Visitors (investigators) shall not have the right to raise invoices and/or collect revenues for the execution of Research Contracts.

**Calculation of revenues for distribution.** Calculation of Gross Non-IP Revenue, Project Expenses, and Net Non-IP Revenue shall be in accordance with the following rules:

**Calculation of Gross Non-IP Revenue.** "Gross Non-IP Revenue" is defined as *all revenue received by the University for Execution of Projects / Scientific or Clinical Work as part of the Research Contract before any cost recovery or deductions for the incurred Expenses* and includes, but is not limited to, consultation and evaluation fees received, and direct sale of products or services.

**Project Expenses.** "Project Expenses" is defined as *all expenses incurred by the University in the management and execution of Research Contract for which Gross non-IP Revenue has been received* and includes, but is not limited to, those expenses that relate to usage charges of the instruments and facilities, purchase of new equipment and consumables specifically for the execution of the particular Research Contract, institutional overheads and general administrative costs.

**Calculation of Net Non-IP Revenue.** The University shall maintain accurate and transparent documentation of Project Expenses incurred for a particular Research Contract and shall be entitled to cover all Project Expenses it has incurred, as set out in 7.9.2.2 above.

The “Net Non-IP Revenue” is calculated as the Gross non-IP Revenue less Project Expenses.

**Sharing of revenues – Investigator(s)**

**Standard Investigator’s share.**

80% of the Net non-IP Revenue will be allocated to the Investigator. Where there is more than one Investigator, the Investigators are entitled to an equal or *pro rata* share, based on contribution (as mutually agreeable between the University and the Investigators), except where there is a prior written agreement between all the Investigators to the contrary.

**Payment.** Payment to the Investigators will be made by the University on a periodic basis as agreed in writing, but no later than twelve months after receipt of the Gross non-IP Revenue by the University.

**Taxes.** The University may, if so obliged by national tax laws, make any applicable tax deductions before making payments to the Investigators.

**Entitlement.** The entitlement to an Investigator’s share of Net non-IP Revenue shall survive any resignation/termination of employment.

**Banking details.** The onus is upon each Investigator to ensure that the University has their current banking details for the purpose of revenue sharing. The University will keep the relevant revenue amounts in reserve for a maximum period of 2 (two) years after which all rights of Investigators to receive such payments will be forfeited. If the University pays an amount into an incorrect account as a result of information supplied to it being outdated or incorrect, the University will not have any further obligation or liability in respect of such payment, which will be deemed to have been duly and properly made.

**Sharing of revenues – University.** The University’s share of Net non- IP Revenue is distributed internally as follows:

10% towards development of research infrastructure; 10% towards maintenance of research facilities and equipment.
--

## ARTICLE 8-DETERMINATIONS BY THE IPMC

### Responsibility to Disclose IP

**Recording.** Inventors shall keep appropriate records of their Research in accordance with the University's applicable policy procedures and make reasonable efforts to ensure that only those individuals within the University who have a need to have access to such records for the performance of their duties are granted such access.

**IP Disclosure.** Where an Inventor identifies potential IP resulting from his/her Research or that of his/her team, he/she shall disclose such potential IP to IPMC promptly by means of an IP Disclosure Form.

**Complete disclosure.** Inventors must provide to IPMC such full, complete and accurate information as IPMC may reasonably require enabling it to sufficiently assess the technical and related features and functions, ownership, commercial potential and IP protection that might be applicable to such IP. Upon complete disclosure, the IP Disclosure will be registered and assigned a reference number and IPMC will share this reference number with the Inventors to signify that the IP Disclosure has been formally received by the University.

### Inventorship and Ownership

**Inventorship.** Inventors shall, upon request, sign the appropriate legal documents provided by IPMC that attest to Inventorship. Where there is more than one Inventor, and there is a dispute as to the contribution to Inventorship, IPMC shall in consultation with the Inventors, assist in the determination of the percentage IP Inventorship, failing which it shall be assumed that there was an equal undivided contribution.

8.2.2 **Ownership.** Once Inventorship has been determined, the Inventors shall be required to formally assign any right, title or interest they may have in that IP to the University in the form of a contract that specifies the rights that will accrue to the Inventor(s) and the University and the obligations they will have to assist the University with the Commercialization of that IP. Article 9.3 will apply.

### Determination as to IP Protection and Commercialization

**Evaluation and recommendation.** IPMC will analyze the information disclosed in the IP Disclosure within usually 30-60 days of formal receipt. The analysis will include: whether or not the subject matter is protectable as IP; an assessment of economic viability or marketability; and determination of any rights of external parties, such as a funder or collaborator. After evaluation, IPMC will prepare a

preliminary report with findings that enable the University to decide if it will proceed with IP protection and Commercialization. IPMC shall share the preliminary report with the Inventor(s) and seek their input.

**Decision to protect/Commercialize.** The University will decide, as soon as reasonably practicable, whether or not it wishes to protect and/or Commercialize the IP. IPMC will use all reasonable efforts to notify the Inventor(s) of the University's decision within usually 60-90 days of formal receipt of the IP Disclosure. IPMC will also make a determination in relation to the validity of any claim made by a Staff Member, a Visitor or a Student that they are the true Inventor(s) of that IP and in relation to their rights under this Policy.

#### **University Elects not to Protect /Commercialize the IP**

**IP abandoned or not Commercialized.** The University reserves the right not to protect or Commercialize IP that it owns if after consultation with the Inventors:

- a. there is no reasonable prospect of commercial success;
- b. it is not deemed to be in the best interest of the University; or
- c. it is not deemed to be in the public interest.

**8.4.2 Transfer of Ownership.** In the event the University decides not to pursue IP protection and/or Commercialization, it will take steps to return said IPRs to the Inventor(s), contingent on any other superseding contract rights of external party(ies)/sponsor(s).

**Written notification.** If the University is unable to or decides not to protect or Commercialize the University IP, it should notify the relevant Inventor(s) of its decision in writing and in a timely manner.

**No prejudice to IP protection.** The Inventor(s) should receive the written notification in a timely manner that enables the relevant Inventor(s) to take any formal steps to ensure the protection of IP, should they so desire.

**Assignment.** If the Inventor elects to take assignment of the IP, the University shall ensure that a deed of assignment is executed without delay.

**Terms and conditions.** If the University assigns IPRs to the Inventor in terms of this Article

8.4.5, the assignment may be subject to one or more of the following terms and conditions:

- a. that upon Commercialization, the University be compensated for any expenditure it may have incurred in connection with the protection and/or Commercialization of such IP; and/or
- b. that the University be granted a non-exclusive, royalty-free license to use the IP for Research and teaching purposes.

## ARTICLE 9-COMMERCIALIZATION OF IP

**Determination of the Commercialization Strategy.** Within usually 8-12 months of the decision to protect or Commercialize the IP under Article 8.3.2, the University will determine, with input from the Inventors, the most appropriate Commercialization strategy.

**Assistance to IPMC.** Inventors of IP which has been selected for IP protection and Commercialization by the University must provide IPMC with all reasonable support in the assessment, protection (including preventing premature disclosure and execution of any documents including deeds of assignment and deeds attesting to Inventorship), and Commercialization of the IP.

**Sovereignty and Cooperation.** The University shall have the sole discretion regarding the Commercialization of IP owned by it. Notwithstanding, the University will ensure that reasonable efforts are made to keep the Inventors informed and, where appropriate, involved in the Commercialization of the IP to which they contributed. The Commercialization of University IP will be planned, executed, and monitored by IPMC.

**Commercialization Pathways.** Modes of IP Commercialization may include:

- a. license, either exclusive or non-exclusive, and variations thereof;
- b. assignment (sale) for lump sum fees or
- c. assignment (sale) to Inventor led company against equity and IP Expenses (as per 10.2.2.2);
- d. formation of a Commercialization Entity/ Startup to which the IP is licensed or assigned in terms of this Policy;
- e. non-profit use or donation;
- f. joint ventures;
- g. royalty free access on humanitarian or other grounds; or
- h. various combinations of the above.

**Guidelines.** Regardless of the mode of IP Commercialization, the transaction will be executed in a contract which:

- a. protects the interests of the University, its Staff Members, Students and Visitors;
- b. retains rights for the University to use the IP for educational and research purposes;
- c. assures that the IP will be utilized in a manner which will serve the public good;
- d. assures that the IP will be developed and brought to the marketplace as useful goods and services; and
- e. prohibits its use in any illegal or unethical manner.

The University will endeavor to Commercialize IP in a manner that encourages and fosters entrepreneurship by Staff Members and others and which supports Commercialization Entities.

## **ARTICLE 10-INCENTIVES AND DISTRIBUTION OF REVENUES**

### **The University's Incentive Structure**

**Purpose and scope.** The University, in the interest of promoting knowledge transfer, will give due consideration to incentives to researchers to foster Research that has socio-economic impact; such incentives may be financial or non-financial. An Inventor/Enabler may receive incentives from each IP they created/enabled which is Commercialized.

### **Sharing of Revenues**

**General.** The University will award Inventors/Enablers in the sharing of monetary benefits that may accrue to the University from the Commercialization of University IP.

**Calculation of revenues for distribution.** Calculation of Gross IP Revenue, IP Expenses, and Net IP Revenue shall be in accordance with the following rules:

**Calculation of Gross IP Revenue.** "Gross IP Revenue" is defined in Article 2 as "*all revenue received by the University for Commercialization of University IP before any cost recovery or deductions for IP Expenses*" and includes, but is not limited to, outright sale of IP, option payments received, license fees received, evaluation fees received, upfront and milestone payments received, royalty payments received, share of profits received, dividends received, shares/stake received, commissions, income through disposal of equity, and direct sale of products or services.

**IP Expenses.** "IP Expenses" is defined in Article 2 as "*all expenses incurred by the University in the management of IP for which Gross IP Revenue has been received*" and includes, but is not limited to, those expenses that relate to (i) the University's expenses incurred by payment to external entities for securing, maintaining and enforcing IP protection, such as patenting and litigation expenses; (ii) costs incurred by the University in the licensing/assignment of IP, including marketing costs, contract negotiation and drafting costs; but not including staff time or general administrative costs.

**Calculation of Net IP Revenue.** IPMC shall maintain accurate and transparent documentation of IP Expenses incurred for a particular IP and shall be entitled to cover all IP Expenses it has incurred, as set out in



10.2.2.2 above. The “Net IP Revenue” is calculated as the Gross IP Revenue less IP Expenses.

**Co-owned IP.** Where the IP is co-owned by the University and an outside organization, the Gross IP Revenue received by the University will be shared in accordance with a pre-determined formula as per a contractual arrangement. Thereafter, the Gross IP Revenue received by the University and the Net IP Revenue will be determined, and revenues will be shared in accordance with section 10.2.3.1 and 10.2.3.2 below.

#### **Sharing of revenues – Inventors/Enablers**

##### **Standard Inventor’s share.**

80% of the Net IP Revenue will be allocated to the Inventor. Where there is more than one Inventor, the Inventors are entitled to an equal or *pro rata* share, based on contribution (as mutually agreeable between the University and the Inventors), except where there is a prior written agreement between all the Inventors to the contrary.

##### **Standard Enabler’s share.**

The University may elect to set aside 10% of the Net IP Revenue for an Enabler. Where there is more than one Enabler, the Enablers are entitled to an equal or *pro rata* share, based on practical contribution, except where there is a prior written agreement between the Enablers and the Inventor(s)/University to the contrary. Where there is no identified enabler, this share will belong to the University.

**Disputes.** In the event of a dispute or uncertainty regarding the Inventors’/Enablers’ share of the Gross or Net IP Revenue from a specific IP, the issue shall be brought for resolution to the IP Advisory Committee in which case the decision of the IPMC shall be final and binding.

**Payment.** Payment to the Inventors/Enablers will be made by the University on a periodic basis as agreed in writing, but no later than twelve months after receipt of the Gross IP Revenue by the University.

**Taxes.** The University may, if so obliged by national tax laws, make any applicable tax deductions before making payments to the Inventors/Enablers.

**Entitlement.** Inventors/Enablers and their heirs will be entitled to IP revenue sharing for as long as the University receives Gross IP Revenues from Commercialization of the University IP. The entitlement to a Inventor’s/Enabler’s share of Net IP Revenue shall survive any resignation/termination of employment.

**Banking details.** The onus is upon each Inventor/Enabler to ensure that the University has their current banking details for the purpose of revenue sharing. The University will keep the relevant IP revenue amounts in reserve for a maximum period of 3 (three) years after which all rights of Inventors/Enablers to receive such payments will be forfeited. If the University pays an amount into an incorrect account as a result of information supplied to it being outdated or incorrect, the University will not have any further obligation or liability in respect of such payment, which will be deemed to have been duly and properly made.

**Sharing of revenues – University.** The University’s share of Net IP Revenue is distributed internally as follows:

<p>In case of allocation of Enabler’s Share 5% to IPMC; 5% to University overheads.</p> <p>In case of no identifiable Enablers 10% to IPMC; 10% to University overheads.</p>
--

**Other Incentives**

**General.** As a default position, the University will refrain from accepting non- monetary benefits for the Commercialization of its IP or from offering incentives other than revenue sharing, unless they are in addition to the revenue sharing as per 10.2.3.1 and 10.2.3.2, as appropriate. The University will thus give consideration, on a case-by-case basis, to the provision of other incentives, where monetary benefits (revenues) are not available or where the Inventor/Enabler elects to choose other benefits *in lieu of* revenue sharing, which may only be realized in due course. Other incentives will include, but are not limited to, the incentives described in Article 10.3.2. – 10.3.4.

**Growth, development and acknowledgement.** A framework for growth and development of the Inventor/Enabler in their professional and personal capacity shall be developed including (i) recognition of IP generation and Commercialization performance in appraisal procedures; and (ii) opportunities for enterprise development or capacity development through, for example, specific training opportunities, sabbaticals, and local and international exchanges in their relevant Research field or in their area of interest.

**Research funds.** The University will actively, through its IPMC, promote, source and/or facilitate collaborative arrangements with industry partners to secure funding for further Research for the Inventors/Enablers.

### **Inventor/Enabler receiving shares in a Commercialization Entity or other licensee.**

In the case where an Inventor/Enabler is granted equity in a Commercialization Entity that licenses the University IP which the Inventor/Enabler has created, such Inventor's/Enabler's portion will be adjusted accordingly, taking into account the shares held in the company by the Inventor/ Enabler. All other Inventors/Enablers will be rewarded in accordance with the formula in Article 10.2.3.1 or 10.2.3.2.

Where the University, either directly or indirectly, receives shares in a licensee company, which company may be a Commercialization Entity, as consideration for an IP license, the University,

- may hold, either directly or indirectly, all the shares until liquidation, at which time the income will be considered Gross IP Revenue and the Inventors/Enablers will receive their share according to the revenue sharing formula in Article 10.2.3.1 or 10.2.3.2.
- Or take steps such that the Inventors/Enablers will be issued their licensee company shares in the revenue sharing proportions, at the time the shares are issued to the University by the licensee.

Notwithstanding the benefit sharing in respect of shares in terms of this Article 10.3.4, the Inventors/Enablers will still be entitled to their share of any other revenues under the IP license.

### **Contact Details**

**Contact details.** The onus is upon each Inventor/Enabler to ensure that the University is in receipt of their current address details for the purpose of revenue sharing. Unless contrary to law, should the University be unable to locate the Inventors/Enablers through reasonable efforts, in order to effect payment of the revenue share amount, and a period of two years has passed since an initial attempt, then the portion owed to that Inventor/Enabler or his/her heirs will be paid to the University's central fund to be used to support Research and innovation activities.

## ARTICLE 11-IP PORTFOLIO MAINTENANCE

**Recording and monitoring.** IPMC shall maintain records of the University's IP in an appropriate form and in sufficient detail. It shall monitor the deadlines for the payment obligations related to the maintenance or annuity fees of protected IP, and shall, within a reasonable time, inform the person or department designated to make such payments.

**Accounting.** IPMC shall maintain income/expense accounting records on each IP so that revenue sharing allocations can be calculated.

## ARTICLE 12- DISPUTE

**Violation.** Breach of the provisions of this Policy shall be dealt with under the normal procedures of the University, and in accordance with the relevant provisions of laws and regulations in force.

### **Dispute Resolution.**

Any internal disputes or questions of interpretation arising under this Policy must in the first instance be referred to IPMC for consideration and mediation by the IP Advisory Committee.

If the matter cannot be resolved by the IPMC and IP Advisory Committee within two months, then the dispute or question of interpretation must be referred to the Vice Chancellor for mediation.

The Vice Chancellor may at their sole discretion refer the matter to University's Executive Committee and/or an independent committee for arbitration as final arbiter of any disputed issues or for final determination.

**Appeal.** Individuals covered by this Policy shall have the right to appeal the application of any aspect of this Policy to the IP Advisory Committee.

## ARTICLE 13- AMENDMENT

**Revision.** This Policy may be amended at any time by a decision of the IP Advisory Committee. In this case:

- a. all IPR disclosed on or *after* the effective date of such amendment shall be governed by the Policy as amended; and
- b. all IPR disclosed *prior* to the effective date of the amendment shall be governed by the Policy prior to such amendment, provided that the provisions of the Policy (as amended) shall apply to all IPR licensed or otherwise Commercialized on or after the effective date of any such amendment regardless of when the IP is disclosed.





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

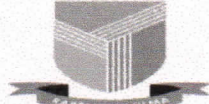
Recognized under Sec 3(A) of the UGC Act 1956

Accredited by NAAC with 'A' Grade

# **Code of Research Ethics**







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

University Road, Deralakatte, Mangaluru – 575 018

No. Y/REG/PA/BOM-53/Notification/005/2021

Date: 31.03.2021

## **NOTIFICATION**

**Sub: Code of Research Ethics - reg.**

**Ref: 53<sup>rd</sup> meeting of the BoM held on 23.03.2021 – Agenda 6.**

.....

As discussed under Agenda 6 of the 53<sup>rd</sup> Board of Management Online meeting held on 23<sup>rd</sup> March 2021, it was resolved to approve the Code of Research Ethics and the same is being notified with effect from 31<sup>st</sup> March 2021.

*ks somayaji*

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

**Encl:**  
Code of Research Ethics

To:  
Centre for Ethics.



## **Table of contents**

<b>1. Preamble</b>	<b>58</b>
<b>2. Scope and definitions</b>	<b>58</b>
<b>3. Codes of ethics for researchers</b>	<b>60</b>
<b>A. Human biomedical and healthcare research</b>	
<b>B. Research involving animals</b>	
<b>4. Code of ethics for Ethics Committees</b>	<b>63</b>

**Code of Research Ethics**  
**Yenepoya (Deemed to be University)**

**Preamble:** With the growth of the University and rapid recognition on the global scene, Yenepoya deemed to be University perceives the need to revise and strengthen its Institutional Code of Research Integrity and Publication Ethics to match global standards and yet weave the local cultural flavour into the fabric of professional conduct.

Yenepoya deemed to be University stands by the principles enshrined in this code and encourages and supports all its faculty members, employees and students to conduct research as prescribed.

**Scope and definitions:** This code shall apply to all the following stakeholders and activities in Yenepoya deemed to be University:

**1. Research:**

Any scientific activity undertaken to answer a specific research question, that is conducted systematically and within the existing regulations, utilizing human participants, patients, biological samples, data, animals with the objective of generating new knowledge, or adding to the body of existing knowledge, or disseminating such information as gathered in the course of healthcare or research.

**2. Researcher:**

- a. Any appropriately qualified, trained and experienced person conducting research on human participants, patients, biological samples, data, animals in Yenepoya deemed to be University, its constituent colleges, centres and the community it serves.
- b. Teacher: Any employee of Yenepoya deemed to be University who is engaged in research (includes all types of teachers such as full-time, part-

time, adjunct, additional, temporary, permanent, contractual and honorary/emeritus.

- c. Student: Any learner, with bonafide credentials (admitted provisionally or otherwise), to any course approved by the Academic Council, and offered by any of the constituent units/centres of Yenepoya deemed to be University, including and up to the point of receiving the degree/diploma, in the convocation.
- d. Research Scholar/ Assistant/ Fellow: Any person appointed in the Yenepoya deemed to be University or its constituent units for conducting research

**3. Patient and Research participant:**

- a. Any person irrespective of caste, religion, gender or social status, visiting the outpatient department of the hospitals in the University, or being seen by any healthcare provider for health reasons (including in the villages, primary health centres, community, etc) or admitted to the wards of any of the teaching hospitals coming under the ambit of the University for reasons of health care (including their attendant caregivers) and or research.
- b. Any animal bred, used or sacrificed for the purpose of research

**4. Biological sample:**

- a. Human Biological Sample: Any tissue, fluid, cells, body part, specimen taken from a patient, a research participant, a cadaver or any animal for the purpose of conducting research, or in the course of healthcare, taken for diagnosis or therapy or follow-up
- b. Other biological samples: Any tissue, fluid, cells, body part, specimen taken from a non-human source for the purpose of research.

**5. Ethics committee:**

A committee constituted by the Yenepoya deemed to be University as per the bye laws and existing regulations, whose main objective is to discuss and

deliberate on the ethical issues arising out of biomedical and healthcare research protocols on human participants or biological samples and give ethical approval for the same and ensure the safety of research participants throughout the course of the research study.

**6. Animal ethics committee:**

A committee constituted by the Yenepoya deemed to be University as per existing regulations, whose main objective is to discuss and deliberate on the ethical issues arising out of research protocols on animals give ethical clearance for the same.

**7. Scientific review board:**

A board constituted by the Yenepoya deemed to be University or its constituent units whose main objective is to discuss and deliberate on the scientific issues arising out of research protocols approve the same.

**8. Institutional Stem Cell Research Committee:**

A committee constituted by the Yenepoya deemed to be University or its constituent unit as per the existing regulations, whose main objective is to discuss and deliberate on the scientific issues arising out of research protocols involving stem cells and approve the same.

**The code of ethics for research:**

**A. Human biomedical and healthcare research:**

1. Research involving human participants, directly or indirectly, must be conducted in accordance with the Indian Council of Medical Research's ethical guidelines, and Indian Good Clinical Practice guidelines, as applicable from time to time
2. Research involving human participants - directly or indirectly - must comply with the regulations in force from time to time
3. Research involving human participants - directly or indirectly - must be pre-approved by the Ethics Committee and must be conducted as per the approved protocol

4. During the conception, design and implementation of the research protocol, and during the dissemination of the results of research, participants' safety should be of prime importance and researcher should not compromise the participants' safety in the interest of science.
5. Researchers must comply with the post-approval requirements of the Ethics Committees within the broad framework of the regulations, guidelines and the Standard Operating Procedure (SOP) Manual of the Ethics Committees.
6. Research on stem cells must be conducted only after due permissions of the concerned stem cell research review committees (national, wherever applicable and institutional) and the Ethics Committee.
7. Research protocols must be submitted for approval from the respective Scientific Review Board(s) and other scientific review boards as applicable (eg. stem cells research)
8. Researchers must be qualified, trained and have experience in the subject in which they are conducting the research.
9. Researcher must undergo the requisite training in the field of research methodology, biostatistics and research ethics
10. Research should be conducted with integrity, keeping in mind accountability and transparency and with total responsibility
11. Research on human participants conducted outside the University must have requisite permissions from the concerned authorities
12. Human tissue samples/data shared with researchers or laboratories outside the University for the purpose of research must be done only after requisite permissions are obtained as per the current regulations and guidelines
13. Human tissues/samples/data/records obtained in the course of healthcare should not be subjected to research without approval of the Ethics Committee and wherever required, with the informed consent of the patients.

14. Manuscripts sent for publication must be checked for plagiarism and must not have more than permissible amount of similarities, within the framework of the University policy
15. Publications arising out of the research conducted in the Yenepoya deemed to be University must duly acknowledge the affiliation to the University
16. Authors listed in the manuscripts for publication must satisfy the criteria for authorship by the International Committee of Medical Journal Editors (ICMJE) and the Committee on Publication Ethics (COPE) and author placements should be decided at the time of protocol writing.
17. Research related documents must be kept confidential and stored for a period of time as per applicable regulations and guidelines from time to time.
18. Researchers and authors must declare conflicts of interest (financial and non-financial) as and when it arises and within the scope of the regulations and guidelines.
19. Yenepoya deemed to be University is committed to protecting the environment and strongly encourages all researchers to reduce the burden on the ecosystems through responsible use of biological tissues/samples and proper disposal.

**B. Research involving animals:**

1. Research involving animals must be conducted in accordance with the Central Government's Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)
2. Research involving animals - directly or indirectly - must be pre-approved by the Institutional Animal Ethics Committee of the University and must be conducted as per the approved protocol
3. Yenepoya deemed to be University is committed to the protection and welfare of animals and requires its researchers to only conduct necessary research (with no other alternative model) keeping in mind the principles of reduce, reuse, recycle and rehabilitate.



**Code of ethics for Ethics Committees:**

1. The code of ethics is applicable to both human and animal ethics committees
2. The Ethics Committees must review, approve the research protocols keeping in mind the protection of the participants
3. The Ethics committees must maintain the highest standard for review and post-approval activities
4. The Ethics Committee must monitor the study until its completion
5. The Ethics Committees must follow the applicable guidelines and regulations applicable from time to time
6. The Ethics Committees must review and approve protocols in an independent manner adhering to the Standard operating procedures





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# Publication





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

University Road, Deralakatte, Mangaluru – 575 018

No. Y/REG/PA/BOM-53/Notification/004/2021

Date: 31.03.2021


## **NOTIFICATION**

**Sub: Publication Policy – Proposal from YRC - reg.**

**Ref: 53<sup>rd</sup> meeting of the BoM held on 23.03.2021 – Agenda 5.**

.....

As discussed under Agenda 5 of the 53<sup>rd</sup> Board of Management Online meeting held on 23<sup>rd</sup> March 2021, it was resolved to approve the Publication Policy and the same is being notified with effect from 31<sup>st</sup> March 2021.

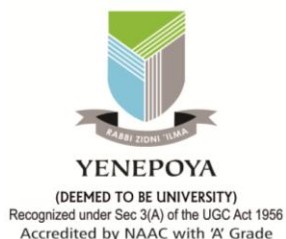
  
Dr. Gangadhara Somayaji K.S.  
Registrar

Registrar  
YENEPOYA  
(Deemed to be University)

**Encl:**  
Publication Policy.

To:  
Dy. Director, YRC



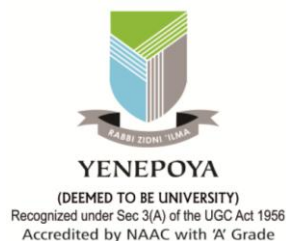


## **Yeneponya (Deemed to be University)**

### **Publication Policy**

#### **Table of Contents**

<b>1. Preamble</b>	<b>70</b>
<b>2. Scope</b>	<b>70</b>
<b>3. Authorship</b>	<b>71</b>
<b>4. Acknowledgement of Non-Author Contributions</b>	<b>71</b>
<b>5. Quality of Research / Advisory on Journals for Publication</b>	<b>72</b>
<b>6. Regulatory Approvals</b>	<b>73</b>
<b>7. Avoid Authorship Disputes</b>	<b>73</b>
<b>8. Dispute Resolution in Authorship</b>	<b>74</b>
<b>9. Conflict of interest and disclosure of funding support</b>	<b>75</b>
<b>10. Claiming for article processing charge (APC)</b>	<b>75</b>



## Publication Policy

### 1. Preamble:

The Yenepoya (Deemed to be University) is committed to generate quality publications across various disciplines and departments. The university encourages generation of publications/articles when data collected from sources such as field surveys, experimental studies, etc. are deemed sufficient for preparation of manuscripts for submission in peer reviewed journals of international repute. The university is committed to adhering to scientific integrity and maintaining highest ethical standards towards the generation of data for publication. The university publications policy provides a mechanism to credit authors who have substantially contributed towards the completion of the study. The policy also addresses the issues related to conflict of interest among authors and penalties associated with violations of the policy. The policy outlines an uncompromising resolve to prevent plagiarism to maintain academic integrity. With an ambition to generate data focussed towards enhancement of knowledge, improving societal outlook, guiding policy changes, addressing societal and environmental issues, and improving healthcare, the university streamlines measures for generating data and publications while maintaining highest ethical standards.

### 2. Scope:

Academic integrity and moral and ethical conducts are essential while reporting research outcomes that have ramifications for the research community and for society at large. The Yenepoya (Deemed to be University) publications policy defines standards that must be maintained while reporting data intended for publication. The policy aims to protect the interests of all the stakeholders. The policy promotes enhancement of the quality of academic publications. The policy also elaborates on intellectual property rights associated with research publications.



### **3. Authorship:**

#### **Criteria for authorship**

Designating authorship should be based on significant inputs given by the person in designing and interpreting the study. The order of authorship should be based on the individuals' contributions to the work and drafting of the manuscript. Based on the suggestions of the International Committee of Medical Journal Editors, the university recommends the following guidelines for publications in the field of biomedical sciences. These authorship criteria should be strictly followed. A person can be included as an author if he/she fulfils the following:

- a. The authorship should be a balance of contribution towards generating the hypothesis, designing the workflow, data acquisition, analysis, or interpretation and writing of the manuscript.
- b. Take consent of all the authors for the publication and their contribution is free from plagiarism.
- c. The order of authors must be directly proportional to the contribution towards the research work.
- d. All authors must take public responsibility for the content of their paper. Disclosure of individual's contributions is a must in multidisciplinary research.
- e. Drafting the manuscript and / or revising it critically for important intellectual content.
- f. Final approval of the version to be published.

### **4. Acknowledgement of Non-Author Contributions:**

- a. Contributions which do not meet the above criteria should be acknowledged as non-author contributions. Examples of such contributions include providing financial resources (but not contributing as per above criteria), equipment / consumables / reagents / writing assistance, technical editing, language editing, proofreading, general supervision, expert statistical advice, caring of patients, etc. Such contributions by themselves do not qualify for authorship.

- b. Explicit written approval must be obtained from individuals who are being acknowledged in publications.
- c. All funding sources should be acknowledged.

## 5. Quality of Research and Publication:

- a. The research carried out in the university should be having originality abiding the university plagiarism policies, and good quality adhering to highest standards of good laboratory practices and ethics.
- b. Plagiarism in research shall be unacceptable and discouraged at all levels.
- c. In order to recognize the research contribution by the research fraternity, publications in UGC's approved journals and journals indexed in PubMed /Scopus/Web of Science is mandatory.
- d. The University recommends publishing in UGC approved journals listed in <https://www.ugc.ac.in/journallist/>. Only such publications shall be considered for career progression, increments, and for incentives.
- e. The University may revise such policy as deemed necessary in future based on the applicable regulatory and research framework.
- f. Predatory journals and pseudo-journals: These journals do not meet scholarly standards of publications. Such journals have increased in the recent past for financial benefits and most often are not peer reviewed. Hence the university strongly condemns publishing in such journals. Faculty and students are advised to be informed of such journals and practices, and to avoid publishing/supporting them in any way.
- g. Open Access Journals: Open access journals are scholarly journals that are available online free of any direct cost to the readers. However, such an online "free access" model is increasingly being adopted by unscrupulous predatory and pseudo-journal publishers. The following recommendation is made for evaluating legitimacy and "safety" of Open Access Journals. Check with the Directory of Open Access Journals (DOAJ) accessible at <https://doaj.org/>. DOAJ is a website maintained by a non-profit organization that lists Open Access Journals that meet basic publishing quality standards by exercising peer review or editorial quality control. This can be used a "whitelist".

(Refer to Laine, C. & Winker, M. A. (2017). Identifying predatory or pseudo-journals. *Biochemia Medica*, 27(2), 285–291. <http://doi.org/10.11613/BM.2017.031> and similar resources)

## **6. Regulatory Approvals:**

In order to promote high scientific and ethical standards, and facilitate the intellectual property in professional education, clinical research, and community, any research work and subsequent publication has to follow the following regulatory bodies, as applicable.

- a. The research study shall abide by the university's policy on intellectual property rights.
- b. As per university policy approval of research studies by institutional relevant Scientific Review Board (SRB), Institutional Research Ethics Review Board and Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)
- c. Approval of research studies by the Institutional Bio-Safety Committee (IBSC): A research study pertaining to risk or cause any damage to the human/flora/fauna or environment maybe initiated only after obtaining direct written approval from the IBSC.
- d. Approval of research studies by the Institute Committee for Stem Cell Research (ICSCR): A research study on stem cells maybe initiated only after obtaining direct written approval from the ICSCR.
- e. Approval of research studies by the National Biodiversity Authority (NBA): A research study on the human/flora/fauna extinct population subjects to require direct written approval from the National Biodiversity Authority.

## **7. Avoid Authorship Disputes**

The following strategies will be useful to avoid circumstances that may lead to an authorship dispute:

- a. Discuss Proactively: There should be initial deliberations of who will be an author and the possible order of all authors. The condition for authorship should be discussed in advance of writing the manuscript, and prior to starting the research work, if possible. Each author should have an awareness of the nature of work, which merits authorship, with the information that, as the research work evolves, the author position may change. Every author should also have an awareness of who among all authors will have the prime responsibility to write, submit, and revise the work required for a manuscript. This can be having paramount importance, during the execution and publication of collaborative projects.
- b. To avoid disputes over attribution of academic credit, it is helpful to decide authorship during the conception of the study. Planning of a research project should identify

contributors as those who will become authors and those who will be acknowledged. In due course, additional authors can be added as per contribution.

- c. **Be Consistent:** The exactness of authorship and the order of authorship should be accurate, both within the research group as well as the norms for the field.
- d. **Realization of the Rules:** All authors should be sensible about the institutional as well as specific journal policies regarding authorship. All Yenepoya (Deemed to be University) authors should review and follow the institution's policy for authorship on scientific and scholarly publications.

## **8. Dispute Resolution in Authorship**

Naturally, the authors should initially attempt to solve differences in opinion within the research group. However, when you are a research scholar, resolving authorship issues can be generally difficult. Possibly, discuss the problem with the research supervisors or anyone equivalent. Initially, try to solve the problem within the research group, and if the authorship dispute still persists, it may benefit to discuss the argument with a senior researcher outside of the group, who can evaluate the issue. If the issue is not resolved, seek the help from the department HOD, and if not finalized still, the lead author may discuss with the research integrity committee/ department HOD and Dean who will have the final authority in resolving the authorship issues. The solution of an authorship issue that do not signify a desecration of the authorship policy must be solved at the department level. The authorship problems frequently rise over who should or should not be included as an author and the order in which authors should appear in the paper. The guidelines for these common areas of disagreement are as follows:

- a. **Inappropriate Application of Authorship Criteria:** The decision as to who should be listed as an author can often become a source of conflict. Yenepoya (Deemed to be University)'s Publications Policy provides criteria that, an individual should meet in order to be listed as an author.
- b. **Prior to the preparation of the manuscript, authors must refer to the criteria for authorship outlined above.** Failure to agree to this criterion while providing an authorship, for example: unequal application of authorship criteria, granting of authorship to undeserving individuals, and/or omitting individuals who deserve authorship, are serious concerns and may be considered as research misconduct.
- c. **Authorship order as they appear in the manuscript:** Authors should attempt to resolve issues regarding author order among themselves. If matter fails to be resolved in this manner, Yenepoya (Deemed to be University)'s Publications Policy suggests that the authors request mediation from senior members such as the research integrity

committee or head of the department and by the Dean. In cases that cannot be resolved, the lead author will consult the Chair or Dean to finalize the author arrangement. The complaints about authorship arrangement do not create research misconduct.

- d. Acknowledgements: All individuals that have contributed to the work, but do not meet the criteria for authorship, should be recognized in the acknowledgements section. This typically includes those who provide: (i). Financial support, (ii). Technical skill, (iii) Statistical advice, etc.

## **9. Conflict of interest and disclosure of funding support**

- a. Authors should explicitly disclose relevant information that give rise to conflict of interests among authors. The conflicts may arise out of potential financial, non-financial, personal or other sources. If no information needs to be declared, the authors must declare a no conflict of interest statement.
- b. Authors must disclose all relevant financial sources that funded the study. The financial sources along with the grant numbers and a brief description of the role of the funder must be acknowledged in the manuscript.

## **10. Claiming for article processing charge (APC)**

- a. Authors can claim for article processing charges for publishing in open access articles in top 5% journals of a specific subject category.
- b. Both lead/first author and corresponding author should be from Yenepoya (Deemed to be University). In case of shared first/ and corresponding author, appropriate portion of total amount shall be given and the remaining should be from the collaborating partners.
- c. Authors are encouraged to request for APC waiver wherever possible.
- d. Prior permission from the University should be taken for claiming the article processing charges with appropriate supporting documents.





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# Plagiarism





Ref: No. Y/REG/ACA/Circular/2018

20.09.2018

**CIRCULAR-17(1)/Plagiarism/2018**

Sub: Policy of Plagiarism

Ref: 1. This office circular No. YU/REG/ACA/Plagiarism/2018 dtd. 17.05.2018  
2. Decision of the 43<sup>rd</sup> Board of Management held on 11.08.2018, vide agenda - 12

\*\*\*\*\*

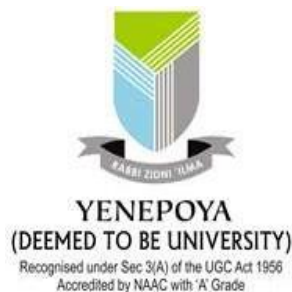
The committee for prevention of plagiarism, Yenepeya (Deemed to be) University has formulated on policy for prevention of plagiarism based on UGC guidelines. The same is to be circulated to all the students, research scholars and faculty members of Yenepeya (Deemed to be) University. The policy will come into effect immediately.

  
**(Dr. G. Shreekumar Menon)**  
**Registrar**  
mj

Copy to:

1. The Principals of the Constituent Colleges
  2. All the Centers Heads
  3. Academic Section
- } for information and circulation among the staff & students working under them

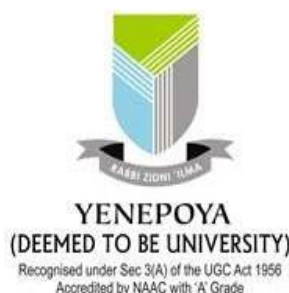




## **POLICY FOR PREVENTION OF PLAGIARISM**

### **Table of contents**

<b>1. Preamble</b>	<b>82</b>
<b>2. Short title, application and commencement</b>	<b>82</b>
<b>3. Definitions</b>	<b>82</b>
<b>4. Awareness Programmes and Trainings</b>	<b>83</b>
<b>5. Steps for Curbing Plagiarism</b>	<b>83</b>
<b>6. Similarity checks for exclusion from Plagiarism</b>	<b>84</b>
<b>7. Zero Tolerance Policy in core area</b>	<b>85</b>
<b>8. Levels of Plagiarism in non-core areas</b>	<b>85</b>
<b>9. Detection/Reporting/Handling of Plagiarism</b>	<b>85</b>
<b>10. Penalties</b>	<b>85</b>



## **POLICY FOR PREVENTION OF PLAGIARISM**

### **1. Preamble**

Yenepoya (Deemed to be University) has state-of the art facilities to support high quality research in interdisciplinary/ multidisciplinary areas to meet the contemporary challenges. The focus is to generate new knowledge towards national development through quality research integrated with highest ethical standards.

Yenepoya (Deemed to be University) has taken all steps to maintain highest ethical standards and academic discipline among the faculty, research scholars and students.

As per the recommendations of University Grants Commission (UGC) Yenepoya (Deemed To Be University) formulated a policy on plagiarism in line with UGC (Promotion of Academic Integrity and Prevention of plagiarism in Higher Education Institutions) Regulations, 2017.

The Policy will provide guidelines to establish the mechanism to ensure academic integrity & prevention of plagiarism as per the act 2017.

### **2. Short title, application and commencement**

- a. The policy is called as “Yenepoya (Deemed to be University) Policy on Plagiarism”.
- b. Policy shall apply to the students, researchers, faculty and staff of all constituent colleges under Yenepoya (Deemed to be University).
- c. This Policy shall come into force from the date of their notification by Yenepoya (Deemed to be University).

### **3. Definitions**

- a. ‘Academic Misconduct Panel’ shall mean the body constituted to investigate allegations of plagiarism as described in UGC regulations - clause 11.
- b. ‘Academic Integrity’ is the intellectual honesty in processing, performing and reporting any activity, which leads to the creation of intellectual property.

- c. Author includes a student or a faculty or a researcher or staff of Yenepoya (Deemed to be University) who claims to be creator of the work under consideration;
- d. Information means data, message, text, images, sound, voice, codes computer programs, software and database or micro film or computer generated micro fiche.
- e. Notification means a notification issued by Registrar Yenepoya (Deemed to be University).
- f. Plagiarism means an act of academic dishonesty and a breach of ethics. It involves using someone else's work as one's own. It also includes data plagiarism and self-plagiarism.

#### **4. Awareness Programmes and Trainings**

- a. Yenepoya (Deemed to be University) shall instruct students, faculty and staff about proper attribution, seeking permission of the author wherever necessary, acknowledgement of source compatible with the needs and specificities of disciplines and in accordance with rules and regulations governing the source.
- b. Sensitization seminars/ awareness programmes will be conducted on responsible conduct of research, project work, assignment, thesis, dissertation, promotion of academic integrity and ethics in education for students, faculty and other members of academic staff.
- c. Yenepoya (deemed to be University) shall include the cardinal principles of academic integrity in the curricula of Undergraduate (UG)/Postgraduate (PG)/PG Diploma as a compulsory course work.
- d. Committee for prevention of plagiarism has been constituted and institution has subscribed for [www.checkforplag.com](http://www.checkforplag.com)

#### **5. Steps for Curbing Plagiarism**

- a. All researchers shall be provided with access to the plagiarism check software.
- b. Every student, researcher, faculty and staff of all constituent colleges under Yenepoya (Deemed to be University) submitting a thesis, dissertation, term papers, reports, manuscripts for publication or any other research document shall submit an undertaking that the document has been prepared by him or her and the document is his/her original work and free of any plagiarism.
- c. Each submission should have the report generated by the anti-plagiarism software and counter signed by the concerned researcher; head of the department/guide/co-guide and respective center in charge for research and PhD scholars. In case of dissertations the document should be certified by the Deans of the constituent colleges.

- d. The PhD Center of Yenepoya (Deemed to be University ) shall submit to INFLIBNET soft copies of, M.Phil, Ph.D. Dissertation/Thesis carried out in its various departments after the award of degrees for hosting in the digital repository under the “Shodh Ganga e-repository: program”.
- e. The Chief Librarian of Yenepoya (Deemed to be University) shall create Institutional Repository on institute website which shall include dissertation/thesis/paper/publication and other in-house publications.
- f. Each researcher should maintain the copy of plagiarism check. In case of students, a copy of plagiarism check should be maintained in the office of the respective guides.

## **6. Similarity checks for exclusion from Plagiarism**

The similarity checks for Plagiarism shall exclude the following:

- a. All quoted work either falling under public domain or reproduced with all necessary permission and/or attribution
- b. All references, bibliography, table of content, preface and acknowledgements.
- c. All small similarities of minor nature
- d. All generic terms, laws, standard symbols and standard equation

Researcher may choose to “exclude” certain parts of the document from checking for similarities based on above mentioned exclusion points. The checker software lists out all such exclusion performed in the final printout. It is the responsibility of the researcher and guide (as applicable) to acknowledge each of the exclusions and give a brief reason in writing for each of the exclusions and sign them.

### **Who should countersign the similarity exclusion statement of researcher/guide (As applicable)?**

- a. In case of dissertations, it should be countersigned by the respective Heads of the department and Deans of the constituent colleges.
- b. In case of Ph.D. thesis, it should be countersigned by Deputy Director, Center for PhD Program.
- c. In case of research scholars it should be countersigned by Deputy Director, Yenepoya Research Center.
- d. In case of any research done by faculty and students other than dissertation/thesis it should be countersigned by The Deans of the constituent colleges.
- e. For research done by Deans or University centre in-charge, a three member committee of senior faculty members constituted by University will countersign the document.

## **7. Zero Tolerance Policy in core area:**

The core work carried by the student, faculty, staff and researcher shall be based on original ideas and shall be covered by Zero Tolerance Policy on Plagiarism. In case plagiarism is established in the core work claimed, then Plagiarism Disciplinary Authority of the Yenepoya (Deemed to Be University) shall impose maximum penalty.

The core work shall include abstract, summary, hypothesis, observations, results, conclusions and recommendations.

## **8. Levels of Plagiarism in non-core areas**

For all other (non-core) cases, plagiarism would be quantified into following levels in ascending order of severity for the purpose of its definition:

- a. Similarities up to 10%-excluded
- b. Level 1: Similarities above 10 % to 40%
- c. Level 2: Similarities above 40% to 60%
- d. Level 3: Similarities above 60%

**Similarity is permitted for non-core areas of all type of documents up to 10% only.**

## **9. Detection/Reporting/Handling of Plagiarism**

If any member of the academic community suspects with appropriate proof that a case of plagiarism has happened in any document, he or she shall report it to the Registrar, Yenepoya Deemed to be University. Upon receipts of such a complaint or allegation the Registrar shall refer the case to Academic Misconduct Panel of Yenepoya Deemed to be University who in turn shall submit a report to the Plagiarism Disciplinary Authority constituted by Yenepoya (Deemed to be University).

The authority of Yenepoya (Deemed to be University) can also take suo moto notice of an act of plagiarism and initiate proceedings under these regulations. Similarly proceedings can also be initiated by the Yenepoya Deemed to be University on the basis of the findings of an examiner.

## **10. Penalties**

Penalties in the cases of plagiarism shall be imposed on students pursuing studies at the level of PG, Masters, M.Phil, Ph.D and faculty only after academic misconduct on the part of the offender has been established without doubt, when all avenues of appeal have been

exhausted and individual in question has been provided enough opportunity to defend himself or herself in a fair or transparent manner.

Since act of plagiarism, witting or unwitting, is potentially detrimental to the academic credibility and social reputation of the individual concerned, all proceedings of investigations and imposition of penalties shall be conducted in camera so as to prevent encrustation of stigma and slur upon individual concerned.

**a. Penalties for students:**

Plagiarism Disciplinary Authority of Yenepoya (Deemed to be University), based on recommendations of the Academic Misconduct Panel, shall impose penalty considering the severity of the Plagiarism.

- I. Level 1: Similarities above 10% to 40%-**such student shall not be given any mark and/or credit for the plagiarized script and shall be asked to submit a revised script within a stipulated time period not exceeding six months.
- II. Level 2: Similarities above 40% to 60%-** such student shall not be given any mark and/or credit for the plagiarized script and shall be asked to submit a revised script after a time period of one year but not exceeding eighteen months.
- III. Level 3: Similarities above 60%-** such student shall not be given any mark and/or credit for the plagiarized script and his/her registration for that course to be cancelled.

**Note 1:** Penalty on repeated plagiarism-such students shall be punished for the plagiarism of one level higher than the previous level committed by him/her. In cases where plagiarism of highest level is committed then the punishment for the same shall be operative.

**Note 2:** Penalty in case where the degree/credit has already been obtained-If plagiarism is provided on a date later than the date of award of degree or credit as the case may be, then his/her degree or credit shall be put in abeyance for a decision by the AMP and PDA.

**b. Penalties for faculty, staff, researcher of HEI**

- I. Level: Similarities above 10% to 40%-**Shall be asked to withdraw manuscript submitted for publication and shall not be allowed to publish any work for a minimum period of one year
- II. Level 2: Similarities above 40% to 60%-** Shall be asked to withdraw manuscript submitted for publication and shall not be allowed to publish any work for a minimum period of two years and shall be denied a right to one annual increment and shall not be allowed to be a supervisor to any UG, PG, Master's, M.Phil. , Ph.D. student/scholar for a period of two years.
- III. Level 3: Similarities above 60%-** Shall be asked to withdraw manuscript submitted for publication and shall not be allowed to publish any work for a minimum period of three years and shall be denied a right to two successive



annual increments and shall not be allowed to be supervisor to any UG, PG, Master's, M.Phil. , PhD. Student/scholar for a period of three years.

**Note 1:** Enhanced penalty on repeated plagiarism-Shall be punished for the plagiarism of one level higher than the lower level committed by him/her. In case where plagiarism of higher level is committed then the punishment for the same shall be operative. In case level 3 offence is repeated then the concerned person shall be dismissed.

**Note 2:** Penalty in case where the benefit or credit has already been obtained-If plagiarism is proved on a date later than the date of benefit or credit obtained as the case may be then his/her benefit or credit shall be put in abeyance for a period decided by the AMP and PDA on recommendation of the AMP.

**Note 3:** If there is any complaint of plagiarism against the Head of the Yenepoya (Deemed to Be University), a suitable action, in line with these regulations, will be taken by the Competent Authority/Governing Board/Governing Council as the title may be.





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# **Guidelines for Incentives on Research and Publications**





**YENEPOYA**

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

University Road, Deralakatte, Mangaluru – 575 018

No.YU/REG/PA/BOM-45/Not/2019

Date: 20.02.2019

### **NOTIFICATION - 8**

**Sub: Revised guidelines for claiming incentives for research & Publications – reg.**

**Ref: Proceedings of 45<sup>th</sup> meeting of the Board of Management held on 9<sup>th</sup> February 2019 – Agenda 16.**

.....

Pursuant to the decision of the **Board of Management** at its meeting held on 9<sup>th</sup> February 2019, vide Agenda 16, **approved** the revised guidelines (copy enclosed) for claiming incentives for research & publications & is hereby notified.

Registrar  
Yenepoya (Deemed to be University)

To:  
Deputy Director, YRC

Cc to:  
Finance Officer  
Academics





**Guidelines for Claiming Research Incentives**

Sl. No.	Criterion	Incentive Points			
<b>A</b>	<b>Research Paper Publication in Journals</b>				
<p>The points allotted are the maximum per paper/project/conference. All the authors will share the points for joint works.            Sharing of the points for joint publications is as follows:  <b>More than 3 authors:</b> The first and the corresponding authors shall share equally 60% of the total points and the others shall share 40% equally;  <b>Two authors:</b> Equal sharing;  <b>Three authors:</b> The first and corresponding authors shall share equally 70% of the total points and remaining 30% for the other author.            Journal Impact Factor means the most recent Impact factor provided in Journal Citation Reports (JCR)</p>					
	<b>Article type</b>	<b>Original Research</b>	<b>Case Reports</b>	<b>Review</b>	<b>Other</b>
1	Papers with impact factor > 10	35	20	25	15
2	Papers with impact factor >5	25	15	20	10
3	Papers with impact factor 1-5	20	10	15	8
4	Papers with impact factor <1	15	8	10	6
5	Scopus listed/Medline indexed journals	10	5	6	4
6	Journals indexed in Indian Citation Index (ICI), Index Copernicus, Embase, Excerpta Medica, Index Medicus	4	2	2	1
7	All other Journals	2	1	1	0.5
<b>B</b>	<b>Books/Chapters in books</b> (Multiple authors/editors, points are shared equally)				
	<b>Book type</b>	<b>Author</b>	<b>Editor</b>	<b>Chapter author</b>	
1	Text/Reference books published by international publishers with ISBN	20	15	10	
2	Text/ Reference books by national level publishers with ISBN	15	12	6	
3	Editing of the Proceedings of Seminar/Symposia/Conference/Workshops (Abstract books excluded)	International	National	State	
		20	15	10	
<b>C</b>	<b>Research Projects</b> <b>(Extramural Research Grants)</b>	<b>Grant &lt; Rs. 5 Lakhs</b>	<b>Grant Rs. 5-15Lakhs</b>	<b>Grant Rs. 15-50 Lakhs</b>	<b>Grant &gt; Rs. 50 Lakhs</b>



1	Sanctioned Projects (Principal Investigator & Co-investigator shall share the points in 7:3 ratio)	10	25 + 1 point/lakh above 5 lakhs	35 + 1 point/lakh above 15 lakhs-to a max 50 points	50 + 2 point/lakh above 50 lakhs
2	Ongoing Consultancy Projects (In case of joint venture points are to be shared in 7:3 ratio)				
<b>D</b>	<b>Research Guidance</b> (Guide & Co-guide shall share the points in 7:3 ratio)				
1	Ph.D. (Degree awarded only)		7		
2	PG dissertations accepted under ICMR thesis support		7		
3	ICMR-STC projects (UG-level)		5		
<b>E</b>	<b>Paper presentation in Conferences/Symposia</b>	<b>International</b>	<b>National</b>	<b>Regional/ State-level</b>	
1	Paper presentation (Oral/poster) Presenting author only)	3	2	1	
2	Best Paper/Poster award	7	5	2.5	
3	Participation in Conference as Resource person (invited/key note etc)	4	3	2	
<b>F</b>	<b>Awards/Recognition from Professional Body/Government Body</b>	<b>International</b>		<b>National</b>	
		8		5	

**Conditions for claiming:**

1. Weightage points and incentives:

Sl.No.	Weightage Points	Incentive
1	Minimum points to claim 10	Rs. 10,000
2	11-20 points	Rs. 11,000 + Rs. 750 per point above 10 points
3	21-50 points	Rs. 20,000 + Rs. 1000 per point above 21 points
4	>51 points	Rs. 60000 + Rs. 1000 per point above 50 points

2. Minimum points needed for claim is 10 points from the publications or other attributes with affiliation to Yenepoya University,
3. All claims must be calculated for the output between from January to December.
4. All the claims must be supported by copies of the relevant documents. Claims without appropriate documents shall not be considered.
5. Decision of the expert committee will be final and incentive amount is subject to the approval of the finance committee.





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# **Standard Operating Procedures**





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# **National Ethical Guidelines for Biomedical and Health Research Involving Human Participants**





No. YU/REG/Not/Oct 2017

Office of the Registrar  
University Road  
Deralakatte  
Mangalore - 575018  
Ph: 0824-2204667/68/69  
Fax: 0824-2203943  
Date: 15.10.2017

### **NOTIFICATION**

**Sub: University commitment on ICMR Ethical Guidelines 2017.**

.....

Yenepoya (Deemed to be University) stands committed to the comprehensive application of Indian Council of Medical Research's National Ethical Guidelines for biomedical and health research involving human participants 2017 for all research conducted in any of the constituent Units, Departments and Centers of Yenepoya (Deemed to be University) including community-based studies. The guidelines are also applicable to the Ethics Committees reviewing and approving the protocols.

*B.T. N. [Signature]*  
**REGISTRAR**  
Registrar *f/c*  
Yenepoya University  
University Road, Deralakatte  
Mangalore - 575018



# NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS



INDIAN COUNCIL OF MEDICAL RESEARCH  
2017

# **NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS**



**INDIAN COUNCIL OF MEDICAL RESEARCH  
2017**



Compiled & Edited by:

**Dr. Roli Mathur**

Head, ICMR Bioethics Unit

NCDIR, Bengaluru

Published by:

**Director-General**

Indian Council of Medical Research

New Delhi 110 029

[www.icmr.nic.in](http://www.icmr.nic.in)

**ISBN: 978-81-910091-94**

**October, 2017**

**Price: ₹ 500.00**

© Copyright Indian Council of Medical Research

The use of content from this book is permitted for all non-commercial purposes giving full acknowledgement to ICMR which shall not be held liable for any damages whatsoever as a result of the use or application of the contents of this document. ICMR reserves the right to update and change the contents without notice and accepts no liability for any errors or omissions in this regard. Care has been taken to present the information accurately, however the reader is urged to check latest notifications/rules/regulations by GOI from time to time.

***Design and layout:***

The cover page drawing depicts the sections of this document.

Tejeswini Padma, Kalyani Thakur, Rajib K Hazam and Monesh B Vishwakarma

## TABLE OF CONTENTS

<b>Message from Hon'ble Union Minister for Health and Family Welfare, Government of India</b>	<b>ix</b>
<b>Foreword by DG ICMR and Secretary DHR</b>	<b>x</b>
<b>Message from President, Medical Council of India</b>	<b>xi</b>
<b>Preface by Chairperson, Central Ethics Committee on Human Research</b>	<b>xii</b>
<b>Message from Chairperson, Advisory Group</b>	<b>xiii</b>
<b>Acknowledgement</b>	<b>xiv</b>
<b>Introduction</b>	<b>1</b>
Scope	2
<b>Section 1 Statement of general principles</b>	<b>3</b>
1.1 General principles	3
<b>Section 2 General ethical issues</b>	<b>5</b>
2.1 Benefit-risk assessment	5
2.2 Informed consent process	5
2.3 Privacy and confidentiality	7
2.4 Distributive justice	8
2.5 Payment for participation	8
2.6 Compensation for research related harm	8
2.7 Ancillary care	10
2.8 Conflict of interest	10
2.9 Selection of vulnerable and special groups as research participants	10
2.10 Community engagement	11
2.11 Post research access and benefit sharing	12
<b>Section 3 Responsible conduct of research</b>	<b>133.1</b>
Values of research	13
3.2 Policies	14
3.3 Planning and conducting research - specific issues	15

3.4	Reviewing and reporting research	17
3.5	Responsible authorship and publication	18
3.6	Research misconduct and policies for handling misconduct	19
3.7	Registration with Clinical Trials Registry- India	20
3.8	Collaborative research	21
<b>Section 4</b>	<b>Ethical review procedures</b>	<b>25</b>
4.1	Terms of reference for ethics committees (EC)	25
4.2	Special situations	26
4.3	Composition of an EC	27
4.4	Terms of reference for EC members	31
4.5	Criteria for selection of EC members	32
4.6	Training	32
4.7	Roles and responsibilities of EC	33
4.8	Submission and review procedures	34
4.9	Full committee meeting	41
4.10	Review of multicentric research	43
4.11	Continuing review	45
4.12	Site monitoring	45
4.13	Record keeping and archiving	46
4.14	Administration and management	47
4.15	Registration and accreditation of ECs	48
<b>Section 5</b>	<b>Informed consent process</b>	<b>49</b>
5.1	Requisites	49
5.2	Essential information for prospective research participants	49
5.3	Responsibility of researchers	51
5.4	Documentation of informed consent process	52
5.5	Electronic consent	53
5.6	Specific issues in clinical trials	53
5.7	Waiver of consent	53
5.8	Re-consent or fresh consent	54

5.9	Procedures after the consent process	54
5.10	Special situations	55
5.11	Consent for studies using deception	55
<b>Section 6</b>	<b>Vulnerability</b>	<b>56</b>
6.1	Principles of research among vulnerable populations	56
6.2	Additional safeguards/protection mechanisms	57
6.3	Obligations/duties of stakeholders	58
6.4	Women in special situations	60
6.5	Children	61
6.6	Research involving sexual minorities and sex workers	64
6.7	Research among tribal population	65
6.8	Research involving individuals with mental illness or cognitively impaired/affected individuals	65
6.9	Individuals who have diminished autonomy due to dependency or being under a hierarchical system	67
6.10	Patients who are terminally ill	67
6.11	Other vulnerable groups	68
<b>Section 7</b>	<b>Clinical trials of drugs and other interventions</b>	<b>69</b>
7.1	General guidelines	69
7.2	Clinical drug/vaccine development	71
7.3	Bioavailability/bioequivalence study	75
7.4	Ethical implications of study designs	76
7.5	Multicentric trials	77
7.6	Phytopharmaceutical drugs	78
7.7	Device trials	78
7.8	Biologicals and biosimilars	80
7.9	Clinical trials with stem cells	80
7.10	Surgical interventions	81
7.11	Community trials (public health interventions)	82
7.12	Clinical trials of interventions in HIV/AIDS	82

7.13	Clinical trials on traditional systems of medicine	83
7.14	Trials of diagnostic agents	84
7.15	Radioactive materials and X-rays	85
7.16	Investigator initiated clinical trials	86
7.17	Clinical trials on contraceptives	87
7.18	Pregnancy and clinical trials	88
7.19	Clinical trials in oncology	89
7.20	Clinical trials of products using any new technology	90
7.21	Synthetic biology	91
<b>Section 8</b>	<b>Public health research</b>	<b>93</b>
8.1	Principles of public health research ethics	93
8.2	Ethical issues of epidemiological and public health research study designs	96
8.3	Use of administrative and other data sources for research	100
8.4	Informed consent	100
8.5	Role of EC	102
8.6	Protecting participants and communities	103
8.7	Stakeholders in public health research	103
<b>Section 9</b>	<b>Social and behavioural sciences research for health</b>	<b>104</b>
9.1	Some key features	104
9.2	Addressing the ethical challenges	105
<b>Section 10</b>	<b>Human genetics testing and research</b>	<b>112</b>
10.1	General issues	112
10.2	Genetic counselling	113
10.3	Privacy and confidentiality	113
10.4	Informed consent	114
10.5	Culturally sensitive issues	115
10.6	Storage of samples for future genetic research	116
10.7	Results of genetic testing	116
10.8	Publication aspects	116

10.9	Commercialization and COI	117
10.10	Role of the team in genetic testing and research	117
10.11	Quality standards of the laboratory	117
10.12	Misuse of genetic technology	118
10.13	Genetic diagnosis/testing and screening	118
10.14	Gene therapy	122
10.15	Use of newer technologies	123
10.16	Research on human embryos	125
10.17	Foetal autopsy	126
<b>Section 11</b>	<b>Biological materials, biobanking and datasets</b>	<b>127</b>
11.1	Biobanking	127
11.2	Storage of biospecimens and data with their personal identifiers	128
11.3	Ethical issues related to donors	130
11.4	Ethical issues related to research	132
11.5	Biological material/data in forensic departments of laboratories	134
11.6	Governance of biobank/biorepository	135
11.7	Special issues related to datasets	135
11.8	Contingency plan	136
<b>Section 12</b>	<b>Research during humanitarian emergencies and disasters</b>	<b>137</b>
12.1	Pre-emptive research preparation for humanitarian emergency	138
12.2	Informed consent requirements	138
12.3	Risk-minimization and equitable distribution of benefits and risks	139
12.4	Privacy and confidentiality	139
12.5	Ethics review procedures	140
12.6	Post research benefit	140
12.7	Special considerations	140

12.8	Continuation of ongoing research when a humanitarian emergency occurs	141
12.9	International participation in research	141
	<b>List of references</b>	<b>143</b>
	<b>Suggested further reading</b>	<b>146</b>
	<b>Abbreviations and acronyms</b>	<b>150</b>
	<b>Glossary</b>	<b>152</b>
<b>Annex 1</b>	<b>Standard operating procedures</b>	<b>160</b>
<b>Annex 2</b>	<b>List of members of committees involved in revision of guidelines (2015-2017)</b>	<b>161</b>
	A. Members of Central Ethics Committee on Human Research	161
	B. Chairpersons of Sub-Committees and Members of Advisory Group	162
	C. Members of Sub-Committees/Invited Experts	162
	D. Members – National Consultation, ICMR, New Delhi	164
	E. Members – Regional Consultation, NCDIR, Bengaluru	167
	F. Secretariat	170
	G. Admin and Finance	170

**For more details:**

**[https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)**





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# **Standard Operating Procedure Manual for Yenepoya Ethics Committee-1**





**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

Recognised under Sec. 3(A) of the UGC Act 1956

Accredited by NAAC with 'A' Grade

YU/REG/ACA/YEC-1/SOP/2019

03.10.2019

## **NOTIFICATION**

Sub: Yenepoya Ethics Committee-1 Standard Operating Procedure Manual (SOPM)

\*\*\*\*\*

The Standard Operating Procedure Manual of the Yenepoya Ethics Committee -1, Yenepoya (Deemed to be University), Mangalore, version 3 (referred to in short as YEC-1 SOP/v3) is hereby notified with effect from 03 October 2019. These SOPs (all twenty six chapters listed below) are in accordance with the current national guidelines. The same shall be made available to all researchers on the Yenepoya (deemed to be University) website to take note of and comply.

No.	SOP Code	Title of the SOP
1	SOP01/v3	Preparation of Standard Operating Procedures for YEC-1
2	SOP02/v3	Constitution of YEC-1: selection, roles and responsibilities of the YEC-1 members
3	SOP3A/v3	Handling conflict of interest among ethics committee members
4	SOP3B/v3	Maintenance of Confidentiality
5	SOP04/v3	Selection and responsibilities of independent consultants
6	SOP05/v3	Procedure for allowing guest/observer to YEC-1 or attend meeting
7	SOP06/v3	Management of submission of protocol and protocol-related documents
8	SOP07/v3	Categorization of protocols for review
9	SOP7A/v3	Full Review of Protocols
10	SOP7B/v3	Expedited Review of Protocols
11	SOP7C/v3	Exemption of protocols from review
12	SOP08v3	Agenda, preparation, meeting procedures and recording of minutes



**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

13	SOP9A/v3	Review of resubmitted protocols and related documents
14	SOP9B/v3	Amendment of Protocols and protocol-related documents: Review
15	SOP10/v3	Periodic and Continuing Review of Protocols
16	SOP11/v3	Protocol Deviations and Protocol Violations: Review and Management
17	SOP12/v3	Adverse Events (AE) Reports: Review and Management
18	SOP13/v3	Review of study completion reports
19	SOP14/v3	Management of termination/suspension/discontinuation of a research protocol
20	SOP15/v3	Waiver of informed consent
21	SOP16/v3	Site Monitoring Visit and audit of protocols
22	SOP17/v3	Dealing with participant requests, queries and/or complaints to YEC-1
23	SOP18/v3	Maintenance, archival, retrieval and disposal of protocol and protocol-related documents
24	SOP19/v3	Protocols involving vulnerable populations: Review and management
25	SOP20/v3	Preparing for audit/inspection of YEC-1
26	SOP21/v3	YEC-1 Members: Training, Assessment and Feedback



*Kesomayah*  
3/10

**(DR. GANGADHARA SOMAYAJI K.S.)**

**REGISTRAR**

Yenepoya (Deemed to be University)  
University Road, Deralakatte  
Mangalore 575 018

Copy to:

1. Secretary, YEC-1
2. Dy. Director, IT Section –for uploading the notification on the website.
3. File Copy





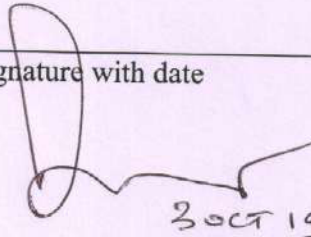
YENEPOYA  
(DEEMED TO BE UNIVERSITY)  
Recognized under Sec 3(A) of the UGC Act 1956  
Accredited by NAAC with 'A' Grade

**Title:** Preparation of Standard Operating procedures for YEC-1

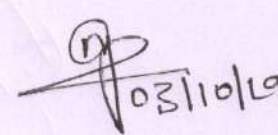
**SOP Code:** SOP01/v3

**Effective Date:** 03/10/2019

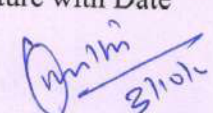
**Prepared by:**

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with date  3 OCT 19
--	---

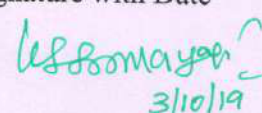
**Reviewed by:**

Dr. Nagapati Bhat Member, YEC-1 SOP Subcommittee	Signature with Date  03/10/19
---	---

**Approved by:**

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date  3/10/19
---------------------------------------	--

**Notified by:**

Registrar, Yenepoya deemed to be University	Signature with Date  3/10/19
--	--

## Table of Contents:

Sl.No.	Contents	Page No.
1	Purpose	117
2	Scope	117
3	Responsibility	117
4	Detailed instructions on the structure of the SOPs	119
5	Detailed instructions on the preparation and implementation of the SOPs	121
6	Annexures	125
7	Flowchart	127

## **1. Purpose:**

- 1.1. The purpose of this Standard Operating Procedure (SOP) is to define the process for drafting, reviewing, distributing and amending SOPs of Yenepoya Ethics Committee - 1 (YEC-1).
- 1.2. The SOPs shall provide clear, unambiguous instructions so that all the activities of the committee are conducted in a standardized, orderly, fair and transparent manner, in accordance with Indian regulations and relevant, national and international ethical guidelines.

## **2. Scope:**

- 2.1. This SOP covers the procedures of drafting, reviewing, distributing and amending all the SOPs of YEC-1.

## **3. Responsibilities:**

### **3.1. The Chairperson will:**

- 3.1.1. Nominate SOP subcommittee(s) to formulate new SOP(s) or to revise/amend existing SOP(s)
- 3.1.2. Approve the SOP(s)
- 3.1.3. Sign and date the approved SOP(s)

### **3.2. The Registrar, Yenepoya deemed to be University will**

- 3.2.1. Notify the SOP subcommittee
- 3.2.2. Notify the SOP (s) approved by the Chairperson.
- 3.2.3. Ensure that the SOPs are widely made available to all researchers, on the webpage of YEC-1.

### **3.3. The Member-Secretary will**

- 3.3.1. Assist the Chairperson to formulate the SOP subcommittee(s)
- 3.3.2. Coordinate activities of drafting, reviewing, distributing and amending SOP(s)
- 3.3.3. Ensure that all the YEC-1 members and involved administrative staff of YEC-1 have access to the SOP(s)
- 3.3.4. Ensure that all YEC-1 members and involved staff are working according to current version of SOP(s)
- 3.3.5. Maintain an up-to-date distribution list for each SOP(s) distributed to

the YEC-1 members

**3.4. The Secretarial staff will**

- 3.4.1. Assist the Member-Secretary in the coordination of the SOP subcommittee activities

**3.5. SOP subcommittee members will**

- 3.5.1. Assess the request(s) for SOP(s) revision in consultation with the Secretariat, Member-Secretary and Chairperson
- 3.5.2. Formulate and/or revise/amend SOP(s) by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the YEC-1.
- 3.5.3. Propose new/modified SOP(s) as needed (vide supra)
- 3.5.4. Draft the SOP(s) in consultation with the YEC-1 members and involved administrative staff of YEC-1
- 3.5.5. Review the draft SOP(s)
- 3.5.6. Submit the draft for approval to Chairperson & Yenepoya deemed to be University (YU) authorities

**3.6. The YEC-1 members will**

- 3.6.1. Receive, sign and date the approved SOP(s) when they receive it
- 3.6.2. Maintain a personal file of all the current SOP(s) received
- 3.6.3. Return all the older versions of the SOP(s) that are in their possession
- 3.6.4. Familiarize themselves with the content of the SOPs
- 3.6.5. Maintain adherence to the guidelines in the SOPs and
- 3.6.6. Constantly refer to these SOPs while conducting ethical review of protocols



#### 4. Detailed instructions on the structure of the SOPs:

##### 4.1. General SOP structure

4.1.1. Each SOP will be prepared according to the standard template given in

Ann01/SOP01/v3.1 will consist of

- 4.1.1.1. Title
  - 4.1.1.2. SOP Number
  - 4.1.1.3. Details of SOP preparation and approval
  - 4.1.1.4. Table of contents: *The headings and page numbers*
  - 4.1.1.5. Purpose of the SOP: *Summarize and explain the objectives of the SOP.*
  - 4.1.1.6. **Scope:** *State the range of activities that the SOP applies to.*
  - 4.1.1.7. **Definitions, if any:** *Define terms relevant to the SOP for easy understanding of the procedures*
  - 4.1.1.8. **Responsibilities:** *Refers to person(s) assigned to perform the activities involved in the SOP*
  - 4.1.1.9. **Detailed instructions:** *Describes the procedures step by step in short and clear sentences in numbered bullets*
  - 4.1.1.10. **Reference to other SOPs:** *List of all other SOPs referred to in the current SOP.*
  - 4.1.1.11. **Annexures:** *Forms or templates or letters to capture information pertaining to the SOP instructions numbered serially*
  - 4.1.1.12. **Abbreviations:** *List of abbreviations used in the SOP manual for easy reference*
  - 4.1.1.13. **Flowchart:** *Simplified representation of the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*
- 4.1.2. Each page of the SOP will bear a header which will consist of
- 4.1.2.1. The YU logo
  - 4.1.2.2. YEC-1 name
  - 4.1.2.3. Brief title of the SOP

4.1.2.4. SOP number/version

4.1.2.5. Effective date (*dd/mm/yyyy*).

4.1.3. Each page will have a footer that will bear the page number as page p of q (total) pages.

#### **4.2. Naming the SOPs:**

4.2.1. Each function/activity of the YEC-1 will have a separate SOP

4.2.2. All the SOPs together will be called the SOP Manual

4.2.3. Each SOP chapter will be given a title that is self-explanatory and easily understood.

4.2.4. Each SOP will be given a unique code in the format SOP<sub>xx</sub>/v<sub>y</sub> where:

4.2.4.1. SOP refers to “xx” will be a two-digit number assigned specifically to each activity-based SOP

4.2.4.2. “v” refers to version of the SOP

4.2.4.3. “y” a number identifying the version.

4.2.5. Thus the first SOP of the current version would be SOP01/v3

#### **4.3. Annexures for the SOP:**

4.3.1. Each SOP may have annexures which are forms or templates to be used by YEC-1 members, Principal Investigators (PI) or other stakeholders.

4.3.2. Each annexure will be given a unique code number with the format Ann“pp”/SOP“xx”/v“y”. “Ann” refers to annexure form, “pp” is a two-digit number, in serial order for the various annexures, and “xx”/v“y” refers to the SOP number and its version. For example, Ann01/SOP01/v3 means annexure form/template number 1 from SOP01/v3.

## **5. Detailed instructions on the preparation and implementation of the SOPs**

### **5.1. Revision of current SOP chapter or need for a new SOP chapter:**

- 5.1.1. The YEC-1 will review the SOPs at least once in every 3 years.
- 5.1.2. Revision of SOP may also be done after an audit/ inspection/ accreditation of YEC-1 as suggested/ recommended by them
- 5.1.3. Revision of SOPs may also be required with changes in the regulations governing the Ethics Committees or changes in the guidelines on research on human participants
- 5.1.4. Revision of SOPs may also be considered in the background of advancement in scientific research methodologies
- 5.1.5. Apart from these, any member of the YEC-1 or Secretariat who feels the requirement of a revision or notices an inconsistency/discrepancy /has any suggestions on how to improve the existing SOP(s) or requests to design an entirely new SOP can put forth a formal request to the YEC-1 Chairperson either as an email/letter/verbal request in a meeting.

### **5.2. Initiating the action on revision of current SOP/preparation of a new SOP chapter:**

- 5.2.1. Once need for revision is discussed in the YEC-1 meeting
- 5.2.2. The Chairperson approves the need for revision if the majority of members agree to the request
- 5.2.3. The Chairperson will nominate SOP subcommittee(s) to initiate the action

### **5.3. Appointment of the SOP subcommittee(s):**

- 5.3.1. The Chairperson will nominate members to the SOP subcommittee(s) consisting of the Member-Secretary, two or more members of YEC-1, and based on inputs from Member-Secretary two or more members from YU (optional), who have a thorough understanding of the ethical review process.
- 5.3.2. The Chairperson will request the Registrar to notify the subcommittee

5.3.3. The Registrar will notify the subcommittee

**5.4. Drafting of the SOPs:**

5.4.1. The SOP subcommittee will assign the various SOP drafts to different members.

5.4.2. The SOP subcommittee members will prepare the new SOP or make changes in the current SOP based on the requirement

5.4.3. The SOP subcommittee members will keep the current regulatory guidelines and the local rules and regulations while drafting the SOPs

**5.5. Review of the draft SOP:**

5.5.1. The draft SOP written by one or more members of the SOP subcommittee will be reviewed by another member(s) of the SOP subcommittee.

5.5.2. The Member-Secretary will include it in the agenda of the subsequent YEC-1 meeting for review by other YEC-1 members

5.5.3. The suggestions that are agreed upon by the members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.

**5.6. Approval of the SOPs:**

5.6.1. The SOP draft will be approved by the YEC-1 members in the YEC-1 meeting

5.6.2. The authors and the reviewers will sign and date the SOPs

5.6.3. The Chairperson will approve the SOPs and sign and date the SOPs

5.6.4. The extract of the relevant resolution of the YEC-1 meeting minutes will be attached to the SOP as an annexure (Ann“xx”/SOP “yy”/v“z”). In the case of this SOP, this annexure will be Ann03/SOP01/v3.

**5.7. Notification of the SOPs:**

5.7.1. Once the SOPs are approved by the YEC-1 members and the YEC-1 Chairperson, they are forwarded to the Registrar, YU

5.7.2. The SOPs are then notified by the Registrar, YU.

**5.8. Effective date of the SOPs:**

- 5.8.1. The authors, reviewers and the Chairperson will sign and date the SOP on the first page of the SOP document.
- 5.8.2. The date of approval signed by the Chairman will be declared as the effective date from which the SOP will be implemented.
- 5.8.3. The same page will also bear the signature of the Registrar, YU as having accepted the document for notification.

**5.9. Supersession of previous SOP(s):**

- 5.9.1. If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form appended as an annexure (Ann02/SOP01/v3) along with description of the main change(s).

**5.10. Distribution of SOPs**

- 5.10.1. The approved SOP(s) will be distributed to the YEC-1 members and a log will be maintained as per the annexure (Ann“xx”/SOP“yy”/v“z”). In this case, it will be Ann 04/SOP 01/v3.
- 5.10.2. When the revised version is distributed, all the YEC-1 members will be requested to destroy their earlier version.
- 5.10.3. The SOPs are also uploaded to the YEC-1 website for easy access to stakeholders including the YEC-1 members, researchers, sponsors, Independent consultants, auditors, and others.

**5.11. Filing of SOPs:**

- 5.11.1. One complete original set of current SOP will be filed in the SOP Master file, by the YEC-1 Secretariat in the YEC-1 office *and marked as the controlled copy as per the SOP20/v3*
- 5.11.2. *An additional ‘uncontrolled’ copy is kept available in the YEC-1 for easy access*
- 5.11.3. One copy of the earlier version will be filed in the file entitled ‘Past SOPs of the YEC-1’ by the YEC-1 Secretariat in the YEC-1 office, in the Master File.

**5.12. Training of YEC-1 members and secretariat:**

- 5.12.1. The Member-Secretary will discuss the approved SOP(s) with the involved administrative staff of the EC and instruct them to implement it accordingly.
- 5.12.2. The Member-Secretary will organize training of the YEC-1 members on a regular basis so as to train them with the SOPs. as in SOP21/v3

**5.13. Implementation of SOPs:**

- 5.13.1. The approved SOP(s) will be implemented from the effective date.
- 5.13.2. All procedures including forms, templates, procedures and timelines will be adhered to by all the YEC-1 members including the Independent consultants and the Secretariat.
- 5.13.3. Any challenges faced in the implementation of the SOPs is brought to the notice of the Member-Secretary/ Chairperson who in turn will plan an action for better implementation and smooth functioning of the YEC-1

**6. Annexures:**

- 6.1. Ann01/SOP01/v3 - Template for SOPs
- 6.2. Ann02/SOP01/v3 - Documentation of History of the SOPs
- 6.3. Ann03/SOP01/v3 - Log of the YEC-1 members receiving SOPs

**Annexure 1: Ann01/SOP01/v3**

**Template for Standard Operating Procedures**

Logo of institution	YEC-1	SOP Code: SOP xx/vy
Title of the SOP	<b>Effective date:</b> aa/bb/cccc	
<b>Title:</b> Title which is self-explanatory and easily understood		
SOP Code: SOP xx/vy		
Effective date: aa/bb/cccc		
<b>Prepared by :</b> xxxxxxxxxx	<b>Signature with date</b> -----	
<b>Reviewed by:</b> xxxxxxxxxx	<b>Signature with date</b> -----	
<b>Approved by:</b> xxxxxxxxxx	<b>Signature with date</b> -----	
<b>Notified by:</b> xxxxxxxxxx	<b>Signature with date</b> -----	
<b>Table of Contents:</b>		
1. <b>Purpose:</b> Summarizes and explain the objectives of the SOP.		
2. <b>Scope:</b> States the range of activities that the SOP applies to.		
3. <b>Responsibility:</b> Refers to person(s) assigned to perform the activities involved in the SOP		
4. <b>Detailed instructions:</b> Describes procedures step by step in short and clear sentences in numbered bullets		
5. <b>Annexure:</b> Forms to capture information pertaining to the SOP instructions		
. <b>Flow chart:</b> Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity		

**Annexure 2: Ann02/SOP01/V3**

**Documentation of History of the SOPs**

**Details of superseded SOP**

<b>Name of the subcommittee convenor</b>	<b>Version</b>	<b>Effective date (dd-mm-yyyy)</b>	<b>Describe the main change(s)</b>

**Details of current SOP**

<b>Name of the SOP subcommittee convenor</b>	<b>Version</b>	<b>Effective date (dd-mm-yyyy)</b>	<b>Describe the main change(s)</b>

**Annexure 3: Ann03/SOP01/v3**

**Log of the YEC-1 members receiving SOPs**

<b>No.</b>	<b>Name of Recipients</b>	<b>Designation</b>	<b>SOP code number</b>	<b>Hard/soft copy</b>	<b>Signature</b>	<b>Date</b>



### 8. Flow Chart



**For more details:**

<http://www.ethics.edu.in/eth-com.html>



**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# **Standard Operating Procedure Manual for Yenepoya Ethics Committee-2**





**YENEPOYA**  
(DEEMED TO BE UNIVERSITY)

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

YU/REG/ACA/YEC-2/208

22.09.2018

### **NOTIFICATION – 26/2018**

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

\*\*\*\*\*

The Standard Operating Procedure Manual of the Yenepoya Ethics Committee-2, Yenepoya(Deemed to be University) Mangalore, is hereby notified. These SOPs (all twenty two chapters listed below) are in accordance with the Indian Council of Medical Research's National Ethical guidelines for Biomedical and Health Research involving Human Participants (2017) and Central Council of Research in Ayurvedic Science and the Schedule Y of the Drugs and Cosmetics Act, 1940. The same shall be made available to all researchers on the Yenepoya (Deemed to be University) website to take note of and comply.

#### **List of SOPs of the YEC -2**

<b>No</b>	<b>Title of the Standard Operating Procedures (SOPs)</b>	<b>SOP No.</b>
1	Preparation of Standard Operating Procedures for Yenepoya Ethics Committee - 2	SOP01/v1
2	Constitution of Yenepoya Ethics Committee (YEC -2), Selection, Roles and Responsibilities of Members of the Yenepoya Ethics Committee - 2	SOP02/v1
3	Handling Conflict of Interest among Ethics Committee Members in Yenepoya Ethics Committee - 2	SOP03/v1
4	Selection and Responsibilities of Independent Consultants in Yenepoya Ethics Committee - 2	SOP04/v1
5	Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee – 2 or attend Yenepoya Ethics Committee - 2 meeting	SOP05/v1
6	Management of Submission of Research Study Protocol and Study Related Documents in Yenepoya Ethics Committee - 2	SOP06/v1
7	Categorization of new research protocols for initial review in Yenepoya Ethics Committee - 2	SOP07/v1
7A	Initial Full Review of Research Study Protocols in Yenepoya Ethics Committee - 2	SOP7A/v1
7B	Expedited Review of Research Study Protocols in Yenepoya Ethics Committee - 2	SOP7B/v1
7C	Exemption from Ethics Review of Research Study Protocols in Yenepoya Ethics Committee - 2	SOP7C/v1
8	Agenda Preparation, Meeting Procedures and Recording of Minutes	SOP08/v1
9	Review of resubmitted and Amended Protocol, Protocol-related Documents in Yenepoya Ethics Committee - 2	SOP09/v1

University Road, Deralakatte, Mangaluru - 575 018.

T : +91 824 220 6000 E : reachus@yenepoya.edu.in www.yenepoya.edu.in



**YENEPOYA**  
(DEEMED TO BE UNIVERSITY)

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

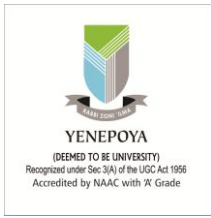
10	Continuing Review of Study Protocols in Yenepoya Ethics Committee - 2	SOP10/v1
11	Review of Protocol Deviations / Violations in Yenepoya Ethics Committee - 2	SOP11/v1
12	Review of Serious Adverse Events (SAE) Reports in Yenepoya Ethics Committee - 2	SOP12/v1
13	Review of Study Completion Reports in Yenepoya Ethics Committee - 2	SOP13/v1
14	Management of Premature Termination / Suspension / Discontinuation of the Study in Yenepoya Ethics Committee - 2	SOP14/v1
15	Waiver of Written/Verbal Informed Consent in Yenepoya Ethics Committee - 2	SOP15/v1
16	Site Monitoring and Post-Monitoring Activities in Yenepoya Ethics Committee - 2	SOP16/v1
17	Dealing with Participants' Requests and/or Complaints in Yenepoya Ethics Committee - 2	SOP17/v1
18	Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents in Yenepoya Ethics Committee - 2	SOP18/v1
19	Reviewing Proposals involving Vulnerable Populations in Yenepoya Ethics Committee - 2	SOP19/v1
20	Preparing for Yenepoya Ethics Committee - 2 Audit/ Inspection	SOP20/v1
21	Training and Assessment of Ethics Committee Members in Yenepoya Ethics Committee - 2	SOP21/v1
22	Special consideration for Clinical trials in Ayurveda, Siddha, Unani, Yoga and Naturopathy protocol submission in Yenepoya Ethics Committee - 2	SOP22/v1

  
**(Dr. G. Shreekumar Menon)**  
**REGISTRAR**

Copy to:

1. Member Secretary, YUEC - 2
2. Dy. Director, IT Section – for uploading the notification on the website
3. Academic Section ,





**YENEPOYA ETHICS COMMITTEE 2** **YEC2/SOP01/v1**  
**PREPARATION OF STANDARD OPERATING PROCEDURE** **14/06/2018**

**Title: Preparation of Standard Operating Procedures for Yenepoya Ethics  
Committee 2**

**SOP Code: YEC2/SOP01/v1**

**Effective Date:**

**Prepared by:**

Dr. Smitha SOP Team Member, YEC 2	Signature with date
--------------------------------------	---------------------

**Reviewed by:**

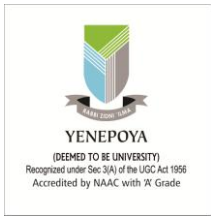
Dr. H.Hari Kishore Bhat Member Secretary , YEC 2	Signature with Date
---	---------------------

**Approved by:**

Dr. Vijaya Hegde Chairperson, YEC 2	Signature with Date
--	---------------------

**Notified by:**

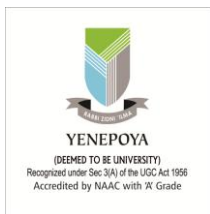
Registrar, Yenepoya (Deemed to be university) Vide Notification No. YU/REG/ACA/YEC-2/208 dated 22.09.2018	Signature with Date
---	---------------------



**Table of Contents:**

Sl.No	Contents	Page No.
1.	Purpose	135
2.	Scope	135
3.	Responsibility	135
4.	Detailed Instructions	136
5.	Annexures	140
6.	Flowchart	145





## **1. Purpose**

The purpose of this Standard Operating Procedure (SOP) is to define the process for drafting, reviewing, distributing and amending SOPs of Yenepoya Ethics Committee 2 (YEC 2). The SOPs provide clear, unambiguous instructions so that all the activities of the committee are conducted in an orderly, fair and transparent manner, in accordance with Indian regulations and relevant, national and international ethical guidelines.

## **2. Scope**

This SOP covers the procedures of drafting, reviewing, distributing and amending the SOPs of YEC 2.

## **3. Responsibilities**

### **3.1 Role of the Chairperson, YEC 2**

It is the responsibility of the Chairperson, YEC 2 to

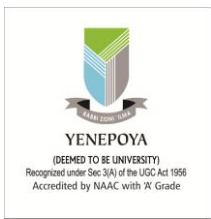
- Nominate SOP team(s) to formulate new SOP(s) or to revise/amend existing SOP(s)
- Approve the SOP(s)
- Sign and date the approved SOP(s)

**Note:** *The SOP team(s) shall be notified by the University under a notification from the office of the Registrar, Yenepoya (Deemed to be University). The SOP(s) approved by the Chairperson shall be notified by the office of the Registrar, Yenepoya (Deemed to be University). The latter shall ensure that these are widely made available to all researchers, on the University website.*

### **3.2 Role of the Secretariat, YEC 2**

The Secretariat, YEC 2, will assist the Chairperson to

- Formulate an SOP Team(s)
- Co-ordinate activities of drafting, reviewing, distributing and amending SOP(s)
- Ensure that all the YEC 2 members and involved administrative staff of YEC 2 have access to the SOP(s)
- Ensure that all YEC 2 members and involved staff are working according to current



version of SOP(s)

- Maintain an up-to-date distribution list for each SOP(s) distributed to the YEC 2 members

### **3.3 Responsibilities of the YEC 2 SOP team**

The YEC 2 SOP team will

- Assess the request(s) for SOP(s) revision in consultation with the Secretariat, Member-Secretary and Chairperson
- Formulate and/or revise/amend SOP(s) by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the YEC 2.
- Propose new/modified SOP(s) as needed (vide supra)
- Draft the SOP(s) in consultation with the YEC 2 members and involved administrative staff of YEC 2
- Review the draft SOP(s)
- Submit the draft for approval to Chairperson & University authorities

### **3.4 Responsibilities of YEC 2 members and involved administrative staff of YEC 2**

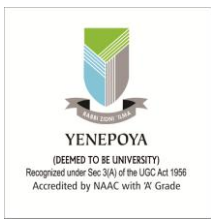
The YEC 2 members and involved administrative staff of YEC 2 will

- Sign and date the approved SOP(s) when they receive it
- Maintain a personal file of all the current SOP(s) received
- Destroy all the old versions of the SOP(s) that are in their possession
- Familiarize themselves with the content of the SOPs and
- Maintain adherence to the guidelines in the SOPs

## **4. Detailed instructions**

### **4.1 Identification of the need for new or amendment of current SOP**

- 4.1.1 Any member of the YEC 2 or Secretariat who would feel the requirement of a revision or notices an inconsistency/discrepancy /has any suggestions on how to improve the existing SOP(s) or requests to design an entirely new SOP can



put forth a formal request to the YEC 2 Chairperson either as an email/letter/verbal request in a meeting.

4.1.2 Once this request is approved by the Chairperson, the Secretary will inform all the YEC 2 members at a regular YEC 2 meeting.

4.1.3 If the majority of members agree to the request, appropriate SOP team(s) will be nominated by the Chairperson and designated the task to proceed with the revision process/ formulation process of the SOP, with due approval from YenePOYA (Deemed to be University).

4.1.4 If majority of YEC 2 members do not agree, no further action will be taken and the Member-Secretary will inform the member of the YEC 2 or Secretariat who made the request for modification of the SOP(s).

#### **4.2 Appointment of the SOP Team(s)**

The Chairperson will nominate members to the SOP Team(s) consisting of the Member-Secretary, two or more members of YEC 2, and based on inputs from Member-Secretary, two or more members from YenePOYA (Deemed to be University), who have a thorough understanding of the ethical review process.

#### **4.3 Listing all relevant procedures**

The SOP team will write down step-by-step all the procedures of the YEC 2 that are to be standardized in the form of an SOP. Each procedure will then be organized, structured and named.

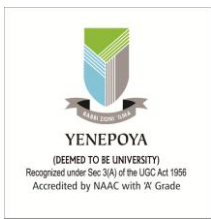
#### **4.4 Drafting of the new SOP**

The SOP team will identify one or more designated members and assign the various SOP drafts to them.

#### **4.5 Versions for the SOPs**

4.5.1 Each SOP should be given a number and a title that is self-explanatory and easily understood.

4.5.2 A unique code number with the format YEC2/SOP xx/vy will be assigned to each



SOP item by the Secretariat. “xx” will be a two-digit number assigned specifically to each activity-based SOP. “v” refers to version SOP and “y”, a number identifying the version. Thus the first SOP of the current version would be YEC2/SOP01/v1.

#### **4.6 Annexures for the SOP**

Each SOP may have Annexures which are forms or templates to be used by YEC 2 members, Principal Investigators (PI) or other stakeholders. Each annexure will be given a unique code number with the format YEC2/Ann“pp”/SOP“xx”/v“y”. “Ann” refers to annexure form, “pp” is a two-digit number, in serial order for the various Annexures, and “xx”/v“y” refers to the SOP number and its version. For example YEC2/Ann01/SOP01/v1 means annexure form/template number 1 from YEC2/SOP01/v1. YEC2 represents ‘Yenepoya Ethics Committee 2’

#### **4.7 General SOP structure**

4.7.1 Each SOP will be prepared according to the standard template given in YEC2/Ann01/SOP01/v1.

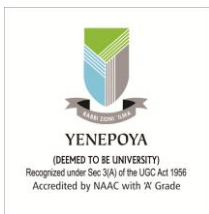
4.7.2 Each page of the SOP will bear a header. The Institutional logo will be in the left margin of the header, the ethics committee name and title of the SOP will be in the centre of the header, and the SOP number/version and effective date (*dd/mm/yyyy*) i.e. the date of approval of the SOP by the Chairperson, will be on the right margin of the header.

4.7.3 There will be a footer that will bear the page number as page p of q (total) pages.

#### **4.8 Review of the draft SOP**

4.8.1 The draft SOP written by one or more members of the SOP team will be reviewed by another member(s) of the SOP team. The reviewer will sign with date of review.

4.8.2 After incorporating the suggestions put forth by the SOP reviewer(s), a copy of the revised draft SOP will be sent to the Member-Secretary, with a request to bring it up in the agenda of the next YEC 2 meeting for formal approval from the YEC 2 members, before forwarding it to the Office of the Registrar for notification.



#### **4.9 Supersession of previous SOP(s)**

If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form appended as an annexure (YEC2/Ann02/SOP01/v1) along with description of the main change(s).

#### **4.10 Preparation and submission final draft**

4.10.1 The SOP Team will submit the reviewed SOP to the YEC 2 Members who will review it in the meeting.

4.10.2 The suggestions that are agreed upon by the members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.

4.10.3 The extract of the relevant resolution of the YEC 2 meeting minutes will be attached to the SOP as an annexure (YEC2/Ann“xx”/SOP “yy”/v“z”). In the case of this SOP, this annexure will be YEC2/Ann03/SOP01/v1.

#### **4.11 Approval of the new/revised/amended SOP(s)**

4.11.1 The authors, reviewers and the Chairperson will sign and date the SOP on the first page of the SOP document. The date of approval signed by the Chairman will be declared as the effective date from which the SOP will be implemented.

4.11.2 The same page will also bear the signature of the Registrar, Yenepoya (Deemed to be University) as having accepted the document for notification.

#### **4.12 Dissolution of the SOP team**

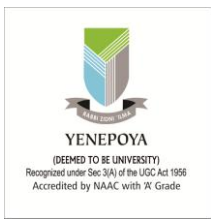
The SOP team(s) would stand automatically dissolved once the YEC 2 takes final decision regarding the SOP(s) and the Registrar notifies the new SOP(s).

#### **4.13 Implementation, distribution and filing of SOPs**

4.13.1 The approved SOP(s) will be implemented from the effective date.

4.13.2 The Member-Secretary will discuss the approved SOP(s) with the involved administrative staff of the EC and instruct them to implement it accordingly.

4.13.3 The approved SOP(s) will be distributed to the YEC 2 members and a log will be

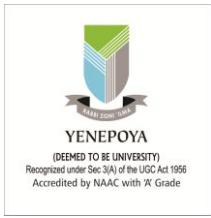


maintained as per the annexure (YEC2/Ann“xx”/SOP“yy”/v“z”). In this case, it will be YEC2/Ann 04/SOP 01/v1.

- 4.13.4 One complete original set of current SOP will be filed in the SOP Master file, by the YEC 2 Secretariat in the YEC 2 office.
- 4.13.5 When the revised version is distributed, all the YEC 2 members will be requested to destroy their earlier version. Only one copy of the earlier version will be filed in the file entitled ‘Past SOPs of the YEC 2’ by the YEC 2 Secretariat in the YEC 2 office, in the Master File.
- 4.13.6 The YEC 2 members and Secretariat will review the SOPs at least once in every 3 years.

## **5. Annexures**

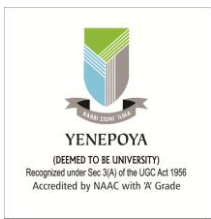
- 5.1 YEC2/Ann01/SOP01/V1 - Template for SOPs
- 5.2 YEC2/Ann02/SOP01/V1 - Documentation of History of the SOPs
- 5.3 YEC2/Ann03/SOP01/V1 - Extract of the relevant resolution
- 5.4 YEC2/Ann04/SOP01/V1 - Log of the YEC 2 members receiving SOPs
- 5.5 YEC2/Ann05/SOP01/V1 - List of SOPs of the YEC 2



**Annexure 1: YEC2/Ann01/SOP01/V1**

**Template for Standard Operating Procedures**

Logo of institution	YEC 2	SOP	Code:
YEC2/SOP xx/vy			
Title of the SOP		<b>Effective date:</b> aa/bb/cccc	
<b>Title:</b> Title which is self-explanatory and easily understood			
<b>SOP Code:</b> YEC2/SOP xx/vy			
<b>Effective date:</b> aa/bb/cccc			
<b>Prepared by :</b> xxxxxxxxx		<b>Signature with date</b> -----	
<b>Reviewed by:</b> xxxxxxxxx		<b>Signature with date</b> -----	
<b>Approved by:</b> xxxxxxxxx		<b>Signature with date</b> -----	
<b>Notified by:</b> xxxxxxxxxxx		<b>Signature with date</b> -----	
<b>Table of Contents:</b>			
1. <b>Purpose:</b> Summarizes and explains the objectives of the procedure.			
2. <b>Scope:</b> States the range of activities that the SOP applies to.			
3. <b>Responsibility:</b> Refers to person(s) assigned to perform the activities involved in the SOP			
4. <b>Detailed instructions:</b> Describes procedures step by step in short and clear sentences			
5. <b>Annexure:</b> Forms to capture information pertaining to the SOP instructions			



6. **Flow chart:** *Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)

**Annexure 2: YEC2/Ann02/SOP01/V1**  
**Documentation of History of the SOPs**

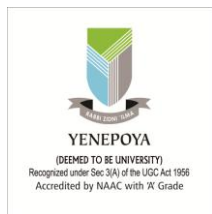
**Details of superseded SOP**

**Annexure 3: YEC2/Ann03/SOP01/V1**  
**Extract of the relevant resolution of the minutes of the YEC 2 meeting**  
*Attach the extract of the relevant resolution of the YEC 2 meeting.*

**Annexure 4: YEC2/Ann04/SOP01/V1**  
**Log of the YEC 2 members receiving SOPs**

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date



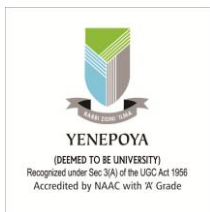


**YENEPOYA ETHICS COMMITTEE 2** **YEC2/SOP01/v1**  
**PREPARATION OF STANDARD OPERATING PROCEDURE** **14/06/2018**

**Annexure 5: YEC2/Ann05/SOP 01/V1**

**List of SOPs of the YEC 2**

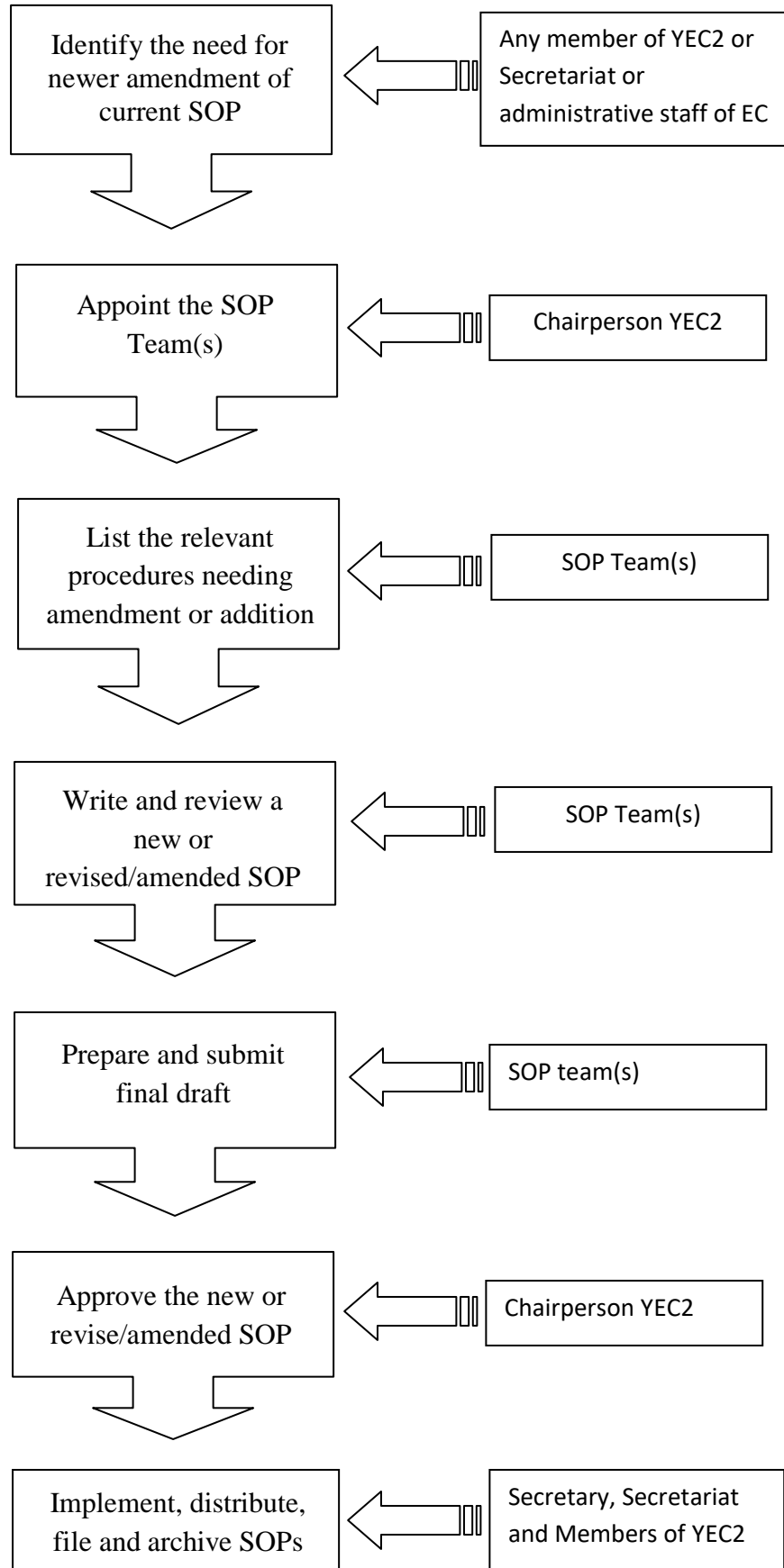
<b>No</b>	<b>Title of the Standard Operating Procedures (SOPs)</b>	<b>SOP No.</b>
1	<i>Preparation of Standard Operating Procedures for Yenepoya Ethics Committee 2</i>	YEC2/SOP01
2	<i>Constitution of Yenepoya Ethics Committee (YEC 2), Selection, Roles and Responsibilities of Members of the YEC 2</i>	YEC2/SOP02
3	<i>Handling Conflict of Interest among Ethics Committee Members</i>	YEC2/SOP03
4	<i>Selection and Responsibilities of Independent Consultants</i>	YEC2/SOP04
5	<i>Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee 2 or attend YEC 2 meeting</i>	YEC2/SOP05
6	<i>Management of Submission of Research Study Protocol and Study Related Documents</i>	YEC2/SOP06
7	<i>Categorization of Submitted Protocols for Ethics Review</i>	YEC2/SOP07
7A	<i>Initial Full Review of Research Study Protocols</i>	YEC2/SOP7A
7B	<i>Expedited Review of Research Study Protocols</i>	YEC2/SOP7B
7C	<i>Exemption from Ethics Review of Research Study Protocols</i>	YEC2/SOP7C
8	<i>Agenda Preparation, Meeting Procedures and Recording of Minutes</i>	YEC2/SOP08
9	<i>Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol</i>	YEC2/SOP09
10	<i>Continuing Review of Study Protocols</i>	YEC2/SOP10
11	<i>Review of Protocol Deviations / Violations</i>	YEC2/SOP11



**YENEPOYA ETHICS COMMITTEE 2** **YEC2/SOP01/v1**  
**PREPARATION OF STANDARD OPERATING PROCEDURE** **14/06/2018**

12	<i>Review of Serious Adverse Events (SAE) Reports</i>	YEC2/SOP12
13	<i>Review of Study Completion Reports</i>	YEC2/SOP13
14	<i>Management of Premature Termination / Suspension / Discontinuation of the Study</i>	YEC2/SOP14
15	<i>Request for Waiver of Written Informed Consent and Waiver of Consent</i>	YEC2/SOP15
16	<i>Site Monitoring and Post-Monitoring Activities</i>	YEC2/SOP16
17	<i>Dealing with Participants Requests and Complaints Coming to Ethics Committee</i>	YEC2/SOP17
18	<i>Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents</i>	YEC2/SOP18
19	<i>Reviewing Proposals involving Vulnerable Populations</i>	YEC2/SOP19
20	<i>Preparing for Ethics Committee Audit/ Inspection</i>	YEC2/SOP20
21	<i>Training and Assessment of Ethics Committee Members</i>	YEC2/SOP21

**6. Flow Chart**



**For more details:**

<https://www.yenepoya.edu.in/academics-centres/yenepoya-ethics-committee-2>



**YENEPOZA**

(DEEMED TO BE UNIVERSITY)

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

Accredited by NAAC with 'A' Grade

# **New Drugs and Clinical Trials Rules 2019**





University Road, Deralakatte, Mangaluru – 575 018

.....  
No. Y/REG/Notification/2019

Date: 10.06.2019

### **NOTIFICATION**

**Sub: University commitment on New Drugs & Clinical Trials Rules 2019.**

.....

Yenepoya (Deemed to be University) stands committed to comprehensive application of New Drugs and Clinical Trials Rules 2019 for all clinical trials conducted in any of the constituent Units, Departments and Centers of Yenepoya (Deemed to be University) including community based studies. The Rules are also applicable to the ethics committees reviewing and approving the protocols.

**REGISTRAR**

**Registrar  
YENEPOYA  
(Deemed to be University)**







# भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)

PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं. 200]

नई दिल्ली, मंगलवार, मार्च 19, 2019/फाल्गुन 28, 1940

No. 200]

NEW DELHI, TUESDAY, MARCH 19, 2019/ PHALGUNA 28, 1940

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 19 मार्च, 2019

**सा.का.नि. 227(अ).**—औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 की उप-धारा (1) और धारा 33 की उप-धारा (1) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, भारत के राजपत्र, असाधारण, भाग II, खंड 3, उप-खंड (i), में अधिसूचना संख्या सा.का.नि. 104 (अ), तारीख 1 फरवरी, 2018 द्वारा, औषधि तकनीकी सलाहकार बोर्ड के परामर्श के पश्चात केंद्रीय सरकार, नई औषधि और नैदानिक परीक्षण नियम, 2018 के प्रारूप को प्रकाशित किया गया था, प्रभावित होने वाले सभी व्यक्तियों से पैंतालीस दिनों की अवधि समाप्त होने से पहले आपत्तियां और सुझाव आमंत्रित किए गए हैं, जब उक्त अधिसूचना वाले उक्त राजपत्र की प्रतियां जनता को उपलब्ध कराई गई थी;

**और,** उक्त अधिसूचना वाली राजपत्र की प्रतियां 7 फरवरी, 2018 को जनता के लिए उपलब्ध करा दी गई थीं;

**और,** उक्त प्रारूप अधिसूचना के उत्तर में प्राप्त सभी आपत्तियों और सुझावों पर केंद्रीय सरकार द्वारा समयक रूप से विचार किया गया है;

**और,** माननीय उच्चतम न्यायालय ने रिट याचिका सं. 79/2012 (पीआईएल-डब्ल्यू) के साथ रिट याचिका (एस) (सिविल) नं. 33/2012 स्वास्थ्य अधिकार मंच, इंदौर और अन्य बनाम भारत संघ और अन्य के साथ-साथ पाया कि नई नैदानिक परीक्षण नियमों को तत्काल अंतिम रूप दिया जाएगा

अब, केंद्रीय सरकार, औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 और धारा 33 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, ने औषधि तकनीकी सलाहकार बोर्ड के साथ परामर्श करने के पश्चात निम्नलिखित नियम बनाती है, अर्थात:-

**MINISTRY OF HEALTH AND FAMILY WELFARE****(Department of Health and Family Welfare)****NOTIFICATION**

New Delhi, the 19th March, 2019

**G.S.R.227(E)** .— **WHEREAS** the draft of the New Drugs and Clinical Trials Rules, 2018 was published, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i) *vide* notification number G.S.R. 104(E), dated the 1<sup>st</sup> February, 2018, by the Central Government, after consultation with the Drugs Technical Advisory Board, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

**AND WHEREAS**, copies of the Official Gazette containing the said notification were made available to the public on the 7<sup>th</sup> February, 2018;

**AND WHEREAS**, all objections and suggestions received in response to the said draft notification have been duly considered by the Central Government;

**AND WHEREAS**, the Hon'ble Supreme Court of India in Writ Petition(s) (Civil) No (s). 33/2012 Swathaya Adhikar Manch, Indore and another Versus Union of India and others with W.P.(C) No. 79/2012 (PIL-W), *inter alia*, observed that new clinical trial rules shall be finalised urgently;

**NOW, THEREFORE**, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules, namely:—

**CHAPTER I****PRELIMINARY**

**1. Short title, commencement and applicability.**— (1) These rules may be called the New Drugs and Clinical Trials Rules, 2019.

(2) They shall come in to force from the date of their publication in the Official Gazette, except Chapter IV which shall come in to force after one hundred and eighty days.

(3) They shall apply to all new drugs, investigational new drugs for human use, clinical trial, bioequivalence study, bioavailability study and Ethics Committee.

**2. Definitions.**— (1) In these rules, unless the context otherwise requires,—

- (a) “academic clinical trial” means a clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the Central Licencing Authority or regulatory authority of any country for marketing or commercial purpose;
- (b) “Act” means the Drugs and Cosmetics Act, 1940 (23 of 1940);
- (c) “active pharmaceutical ingredient” means any substance which can be used in a pharmaceutical formulation with the intention to provide pharmacological activity; or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease; or to have direct effect in restoring, correcting or modifying physiological functions in human beings or animals;
- (d) “adverse event” means any untoward medical occurrence (including a symptom or disease or an abnormal laboratory finding) during treatment with an investigational drug or a pharmaceutical product in a patient or a trial subject that does not necessarily have a relationship with the treatment being given;
- (e) “bioavailability study” means a study to assess the rate and extent to which the drug is absorbed from a pharmaceutical formulation and becomes available in the systemic circulation or availability of the drug at the site of action;

**For more details:**

[https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/NewDrugs\\_CTRules\\_2019.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf)







**REGISTRAR**  
**YENEPOYA (DEEMED TO BE UNIVERSITY)**  
**UNIVERSITY ROAD, DERALAKATTE MANGALORE-575018**  
**PHONE NO 0824-2204668, 0824-2203943**  
**EMAIL: [registrar@yenepoya.edu.in](mailto:registrar@yenepoya.edu.in)**  
**Copyright © all rights reserved**