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

Details of Members of Different Ethical Committees during the Year

YENEPOYA

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Program Name: PhD (Pre-PhD course)

Course Title: Research Methodology and Biostatistics including Research Publication and Ethics (RPE)

ATTESTED

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

RESEARCH METHODOLOGY

NOTE: The content given by UGC is Unit 3 and in bold

Total hours : 30 hours **Credits : 2**

Unit 1. Introduction to Research: General **(8 hours)**

- Definition, significance of research & importance
- Kinds and purposes of Research: Diagnostic, Descriptive, Exploratory, Explanatory
- Research approaches
- Criteria of good research
- Research process : components
- Types of Research: Quantitative, qualitative, basic and applied

General Topics

- Guidelines for Research ICMR, WHO, Nursing
- Research Ethics – Animal ethics; Human ethics
- Biosafety : Good Lab Practices,

Unit 2. Literature survey; Proposal writing **(4 hours)**

- Types of Literature search – use of library, books & journals – Medlines, internet, getting patents and article reprints as a source of literature survey
- Review of Literature– Identification and selection of research problems, formulation of Hypothesis
- Preparation of research proposal, synopsis.
- Research Proposal for grants- components
- IPR and patents

Unit 3. Research and Publication Ethics (RPE)

RPE 01: Philosophy and ethics **(2 hours)**

- **Introduction to philosophy: definition, nature and scope, concept, branches**
- **Ethics: definition, moral philosophy, nature of moral judgements and reactions**

RPE 02: Scientific Conduct **(4 hours)**

- **Ethics with respect to science and research**
- **Intellectual honesty and research integrity**
- **Scientific misconducts: Falsification, Fabrication and Plagiarism (FFP)**
- **Redundant publications: duplicate and overlapping publications, salami slicing**
- **Selective reporting and misrepresentation of data**

RPE 03: Publication Ethics **(3 hours)**

- **Publication ethics: definition, introduction and importance**
- **Best practices/standards setting initiatives and guidelines: COPE, WAME, etc.**
- **Conflicts of interest**
- **Publication misconduct: definition, concept, problems that lead to unethical**

behaviour and vice versa, types
- ❖ Violation of publication ethics, authorship and contributiorship
- ❖ Identification of publication misconduct, complaints and appeals
- ❖ Predatory publishers and journals

RPE 04: Open Access publishing (3 hours)
- ❖ Open access publications and initiatives
- ❖ SHERPA/RoMEO online resource to check publisher copyright & self - archiving policies
- ❖ Software tool to identify predatory publications developed by SPPU
- ❖ Journal finder/journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.

RPE 05: Publication Misconduct (4 hours)

A. Group discussions
- ❖ Subject specific ethical issues, FFP, authorship
- ❖ Conflicts of interest
- ❖ Complaints and appeals: examples and fraud from India and abroad

B. Software tools

Use of plagiarism software like Turnitin, urkund and other open source software tools

RPE 06: Databases and Research Metrics (3 hours)

A. Databases
- Indexing databases
- Citation databases: Web of Science, Scopus, etc.

B. Research Metrics
- Impact factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score
- Metrics: h-index, g index, i10 index, altmetrics

Recommended Books:

1. Ahuja R. Research Methods. Rawat Publications; 2001. 454 p.
2. Creswell JW. Research Design: Qualitative, Quantitative, and Mixed Methods Approaches. Erscheinungsort Nicht Ermittelbar: SAGE Publications Ltd.; 2013.
3. Denicolo P, Becker LM. Developing research proposals. Los Angeles: Sage; 2012.
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Program Name: PhD (Pre-PhD course work)

Course Title: Research Methodology and Biostatistics

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PRE-Ph.D EXAMINATION - PAPER I – SYLLABUS

RESEARCH METHODOLOGY & BIOSTATISTICS

SECTION A : RESEARCH METHODOLOGY (52 hours)

Unit 1. Introduction to Research: General (10 hours)

- Definition, need, process.
- Research objectives
- Research approaches
- Significance of research & importance of knowing how research is done
- Criteria of good research
- Types of Research: Pure, Applied and Action Research
- Kinds of Research: Diagnostic, Descriptive, Exploratory, Explanatory
- Research Ethics – Animal ethics; Human ethics
- Biosafety in research : microorganisms studies
- Scientific methods, components of scientific methods
- Research process
- Problem encountered by researchers in India;

Unit 2. Literature survey; Proposal writing (10 hours)

- Types of Literature search – use of library, books & journals – Medlines, internet, getting patents and article reprints as a source of literature survey
- Review of Literature– Formulation of Hypothesis
- Identification and selection of research problems, preparation of research proposal, synopsis.

Unit 3. Research Design; Study design (10 hours)

- Need for research design, Important concepts relating to design, Features of good design
- Research designs
- Basic principles of experimental design - Pre-experimental, CRD and Quasi-Experimental designs
- Types of research design: Historical design, Descriptive design, case control, cohort, cross sectional, longitudinal

Unit 4. Data Collection Techniques and Interpretation (10 hours)

- Collection of Data : Primary Data – Meaning
  Secondary data – Meaning – Relevances, limitations and cautions.
- Data Collection methods: Interview; Observation; Questionnaire
  Developing tools – Validity (internal & external), Reliability of the tools.
- Meaning of Interpretations; Techniques of Interpretation, Precautions in Interpretations, Data Processing; Coding, tabulations, classifications.

Unit 5. Research Reporting **(10 hours)**

Scientific Writing:

- ❖ Definition and kinds of scientific documents – research paper, review paper, book reviews, thesis, conference and project reports (for the scientific community and for funding agencies).

- ❖ Publication – role of author, guide, co-authors.
- ❖ Components of a research paper – the IMRAD system, title, authors and addresses, abstract, acknowledgements, references, tables and illustrations.
- ❖ Structure, style and contents; Style manuals (Chicago, Harvard, Vancuvour, APA, MLA); Citation styles: Footnotes, references; Evaluation of research
- ❖ Dealing with publishers – submission of manuscript, ordering reprints.
- ❖ Current trends in LIS research (Advanced countries, Less-Advanced countries and Global)

Report writing

- ❖ Significance of Report writing; Different steps in Report writing; Mechanics and precuations of writing research reports; Layout of the Research project; Types of reports and Oral presentation
- ❖ Oral and poster presentation of research papers in conferences/symposia; Preparation of abstracts.
- ❖ Preparation and submission of research project proposals to funding agencies.
- ❖ Structure of Thesis and Content – Preparing Abstracts.

Collaborators & Funding **(2 hours)**

- ❖ Classification of Institutes
- ❖ Collaborations and collaborators
- ❖ Funding for research
- ❖ Computers in research

Recommended Books:

- ❖ How to Write and Publish a Scientific Paper? ; Robert A. Day, Barbara Gastel ; 6th edition; Cambridge : Cambridge University ; 2006.
- ❖ Research Methodology Methods and Techniques; C.R. Kothari ; 2nd edition ; New Age International ; 1990 (published in 2009).
- ❖ Research Methodology Methods and Statistical Techniques ; Santosh Gupta ; New Delhi : Deep & Deep Publications ; 2000.
- ❖ Research Methodology ; Indrayan

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Program Name: M.Sc. Research Ethics

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YENEPOYA UNIVERSITY – FOGARTY INTERNATIONAL CENTER RESEARCH ETHICS MASTERS' PROGRAM FOR INDIA

Curriculum blue print

S No	Module	Specific Learning Objectives	Content
SEMESTER ONE			
Week 1	Introduction	Icebreaking and group forming Orientation Mentoring Journals -Describing course objectives and overview - Know the origins of modern bioethics - Locate the importance of bioethics in the backdrop of the history of research	Introduction to modern bioethics Historical development of bioethics
Weeks 2/3	Moral reasoning and ethical theory	Describe the ethical theories Know what is moral reasoning and how it influences our choices	Utilitarianism Deontology Virtue theory Care ethics Justice theory Moral reasoning using Milgram experiment, Stanford prison experiment and others
Weeks 4/5/6	Biomedical ethics	Know what is respect for person Understand the philosophical underpinnings of respect of person Describe the process of informed consent Know the various types of informed consent Know what is beneficence	Ethics principles: Dignity and respect for person Informed consent Beneficence Non-maleficence Justice (including ethics of HIV and Ebola –

		Know what is non- maleficence Know what is justice and its various types	stigma/discrimination) Criticism of the four principles approach
Week 7	Moral Theories – Indian perspectives	Know about different schools of moral philosophy in Indian culture Understand approaches to ethical issues in systems of Indian medicine Understand similarities and differences in theory and practice of health care ethics between Indian and Western approaches	Hindu, Islamic, Buddhist and other Indian moral approaches with a focus on ethical issues in health, medical practice and research
Week 8	Historical aspects of Research ethics	Background and key debates	World War 2 Nazi and Japanese experiments Nuremburg Code, Tuskeegee, Henry Beecher, Maurice Papworth, Belmont, Guatemala Tropical Medicine, 10/90 split International health research
Weeks 9/10	Introduction to research methods	Know about collection analysis of qualitative and quantitative data Choose appropriate methods for specific research studies Skills to collect and analyze qualitative and quantitative data Identify key issues in research	Overview of basic epidemiology, biostatistics, qualitative and quantitative methods, research design and research methodology
Weeks 11/12	Critical appraisal	Able to identify specific research objectives, study design and methods used in the study under review Able to assess the fitness of the study design and methods Able to interpret findings presented in the study Able to critically evaluate the discussions and conclusions of the study	Appraisal methods for different types of research (with use of itemized checklist, systematic review checklist) Parametric and non- parametric tests
Weeks 13/14	Human Rights, Public Health, and Medical	Know the process of policy making Understand how	International and local

	Law	legislation, regulation and advocacy influence public health policies Identify moral and ethical problems in public health research	law as it applies to health and health research, public health policies
Week 15	International guidelines and laws relating to research	Be cognizant with the international laws, regulations and guidelines relevant to research	Food & Drug Act Nuremberg Code International code of medical ethics Declaration of Helsinki 45 CFR 46 including subparts B and C (pregnant women and prisoners) Belmont report,CIOMS WHO guidelines for ethics committees
SECOND SEMESTER			
Week 1:	Synopsis completion week	To complete the synopsis and submit to University as per university timeline	Adding finer details and finishing touches and completing final check list for the completion of the synopsis
Week 2:	Ethics of Indian systems of medicine Clinical trial designs	Know the different Indian systems of medicine prevalent in India Know the regulations that govern the practice of these systems Describe ethical issues in research in these systems of medicine Be familiar with the commonly used clinical trial designs	Introduction to AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy) Concept of positive health and wellness Regulations and laws regarding practice and research of AYUSH Ethical issues thereof Phases of CTs Randomization FIH studies
Week 3:	Ethics of storage of body parts, tissues and biobanks	Describe the utility of biobanks Know when to use stored samples Identify and address the ethical issues in storage, retrieval and usage of stored tissues	Models of biobanks, functioning of biobanks, ethical and legal issues of stored tissues Global and local variations, data safety, privacy and confidentiality
Week 4:	Responsible Conduct of Research – 2	Know importance of maintaining good records and data	Undertaking the practice of scientific research with integrity

		Know how to handle data and data sharing Define conflict of interest (CoI) Know how to avoid CoI Define medical errors & negligence, Error reporting Describe the various aspects of research misconduct Define plagiarism (revision) Describe the various authorship issues (revision)	with special attention handling misconduct, conflict of interest, collaborative research, research misconduct and handling, publication ethics
Weeks 5/6/7:	Research Ethics – Indian laws & regulations Week 5: Schedule Y (Drugs & Cosmetics Act) Week 6: ICMR guidelines - 1 Week 7: ICMR guidelines – 2	Understand the importance of adhering to ethical principles in health care research Know the key issues in health care research Familiarize with the laws and guidelines relating to research ethics (Drugs and cosmetics act; Indian Council of Medical Research ethical guidelines;	Drugs and Cosmetics Act with amendments (focusing on Schedule Y) ICMR guidelines 1 (Risk-benefit assessment; Informed consent process; privacy/ confidentiality) ICMR guidelines 2 (compensation; post-trial access; conflict of interest; vulnerability)
Week 8:	Disaster research ethics Health Technology Assessment	Differentiate types of disasters Classify disasters Describe methods of mitigation Assess gaps in disaster research and the ethical issues thereof Be familiar with the process of health technology assessment for new devices, implants, diagnostic procedures	Ethical issues in disaster, and research in disaster Impact of disasters on children and female population Development of guidelines Health Technology Assessment
Week 9:	Environment Ethics	Know the interrelatedness of ecosystems Describe the theories related to environmental ethics Describe the ethical challenges in environment-related research	Integrity, accountability, conflict resolution, communication skills, leadership, responsible global citizenship
Week 10:	Genetic technology	Know the basics of molecular biology, recombinant DNA and human genetics	Ethics of genetic technology, the background, use in therapy and enhancements.

		Identify and address the ethical issues in body enhancements	Introduction to somatic and germ cell therapy Status of research in stem cell therapy
Week 11:	Animal Ethics Mid-semester revision	Be familiar with the laws and guidelines relating to the use of animals in research Revise all the topics covered so far Downtime to complete assignments	Committee for the purpose of control and supervision of experiments on animals (CPCSEA) guidelines
Week 12:	Communities and Vulnerability Practicum	Determine criteria for participation in health care research by vulnerable populations Understand sensitivity to priorities and needs by vulnerable population Skills to facilitate informed consent of vulnerable participants in health care research Know about and develop skills related to participatory research	Field visits and placements On-site lectures
Week 13	Public Health Ethics	Know the applications of ethics in the field of public health implementation and policy	Ethical issues in specific public health situations (vaccine trials, vaccine policies, research in public health)
Weeks 14-15:	Research Unit 2	Extensive library search and compilation of review of literature Refining of the objectives	Developing questionnaire or other relevant tool Validating and pilot testing of the tool (as and when necessary)
SEMESTER THREE			
week 1		-	Preparation for exam
week 2		-	Revision class
week 3	Application of research ethics in social science research	History of social sciences, philosophy of social sciences, research ethics controversies and	Evolution of guidelines and governance mechanism in social sciences research
week 4	Applied research ethics in HIV medicine	Ethical issues in HIV research, Indian context	

week 5	Quantitative research basics	Introduction to research methods in health and allied themes, Research designs and methods	Literature Review Methods, Mixed Methods approach, Qualitative research methodologies
week 6	Practicing Ethics in Research and Innovation	Practicing ethics in research and innovation, Technology assessment & health technology assessment, Anticipatory technology ethics, Value sensitive design, Paternalism, Justice Theory	The ethical matrix, Ethics canvas, Nanomedicine, Nudging, Artificial intelligence
week 7	Roles and responsibilities of ethics committee		
week 8	Medicolegal aspects and public Health	Human rights AI	Human rights and Ebola virus outbreak. AI, Brain computer interphases Ethics of Deep Brain Stimulation Studies, Ethical issues of Biometric registration
week 9	Community based research ethics	Overview of Public Health, Reflections on Success Stories of Public Health Interventions, Advocacy, Legislation & Public Health,	Community Engagement, Community Based Participatory Research, National Health Policy and Sustainable development goals
week 10	Research progress review and presentation	-	
week 11	Application of research ethics in policy-making	Review of Public Health Research, Status of primary health care in India, Epidemiology and research, Health policy and systems research, Implementation research, Research on big data	Understanding the application of research ethics in policy making in various contexts including big data, epidemiology, healthcare
week 12	Implementing informed consent in research	Research Involving Children and Adolescents, Ethical Issues in CHIM (Human Challenge) Studies, Erosion of Informed Consent, Cluster Randomized Trials and Implementation Research, Deception in Social and Behavioral Research	Informed consent Assent Electronic consent
week	EC scope. Mandate	Ethical review process	Understanding the process in

13/14/15/16	and SOP construction	Post approval processes-1 Post approval processes-2	ethical review, approval and post-approval monitoring
SEMESTER FOUR			
Weeks 1-16	Project work	Data collection Analysis Statistical tests Report writing s	Submission to the Centre for Ethics

Director
Centre for Ethics
Yenepoya University

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Program Name: M.Sc. Bioscience

Course Title: Research Methodology

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Course Name: RESEARCH METHODOLOGY Credits: 3 (42 hours)

Course code: FS02BS-3C1

CO 1	Introductory understanding of research methodology, its significance and scientific methods used in research
CO 2	Basic understanding on how to define a Research Problem
CO 3	Understand Ethical and regulatory bodies and their role in shaping Research
CO 4	Learn about Intellectual Property Rights and their issues in Research

Unit 1: Introduction to Research Methodology

14 hrs

Definition of Research and objectives, General Characteristics of Research; Types of Research, Research Approach: Qualitative and Quantitative; Significance of Research, Research and Scientific Methods. Important Research designs: Experimental (randomized, non-randomized, single blind and double blind) and observational (cross-sectional, prospective, retrospective and case control).

Unit 2: Defining the Research Problem

14 hrs

Concept and Identification of Research problem, Understanding lacunae in research, Defining a research problem, Literature review, types of research articles, Search tools (Databases, Pubmed, Google Scholar, Keyword search), Basis of systematic review (filtering criteria). Research Questions and Hypothesis: Basis and characteristics for good hypothesis.

Unit 3: Ethical and regulatory aspects in Research

14 hrs

ICMR guidelines: National ethical guidelines For biomedical and health research Involving human participants. Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. CPCSEA guidelines for use of animals in research. Central Drugs Standard Control Organization (CDSCO). National Guidelines For Stem Cell Research (ICMR and DBT). DBT guidelines for biosafety. GLP guidelines (OECD)

Unit 4: IPR (Intellectual Property Rights) issues in Research

14 hrs

Patent, designs, trademarks: IPR- intellectual property rights and patent law, commercialization, trade related aspects of intellectual property rights (TRIPS). Inventions and patentskey differences. Understanding the inventorship, ownership and rights, royalty. Novelty, inventive step and industrial applicability. Introduction to patent specifications; provisional and complete specifications. Patent filling procedure, Patent granting organizations, Geographical indications in patent. Copy right and Plagiarism. Start-up and entrepreneurship.

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3. Sinha, S.C. and Dhiman, A.K. (2002). Research Methodology. Volume 2. Ess Publications.
4. Trochim, W.M.K. (2005). Research Methods: the concise knowledge base, Atomic Dog Publishing.
5. Fink, A. (2009). Conducting Research Literature Reviews: From the Internet to Paper. Sage Publications.
6. Day, R.A. (1992). How to Write and Publish a Scientific Paper, Cambridge University Press.
7. Coley, S.M. and Scheinberg, C. A. (1990). "Proposal Writing", Sage Publications.
8. Leedy, P.D. and Ormrod, J.E. (2004) Practical Research: Planning and Design, Prentice Hall.
9. Kargad, P. (2018). How to Patent an Idea in India: From Idea to Granted Patent in Quickest Time, Saving Costs and Making Money with Your Patented Invention; A Step by ... Rights (Intellectual Property in India) (1st Ed.).
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Program Name: MPT

Course Title: Research Methodology & Ethics

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University Road, Deralakatte
Mangalore - 575 018, Karnataka

	Limitations & Delimitations, Variables. • Hypothesis- formation & testing				
5	**Sampling** • Sampling technique • Population, sample • Sample size & determination of sample size • Sampling methods • Sampling error	3		Long essay Short essay	12 8
6	**Data collection and analysis** • Data sources, technique of data collection, tools • Reliability & validity • Process of data collection • Pilot study- method, need	3		Long essay Short essay	12 8
7	**Interpretation & presentation of data** • Qualitative & quantitative analysis • Graphical representation of data • Conclusion & discussion	3		Long essay Short answer	12 5
8	**Writing a dissertation, research paper**	2		Long essay	12
9	Critical **appraisal of research**	2		Short essay	8
10	**Presentation and publication of research- steps and process**	2		Long essay	12
11	**Autonomy and individual responsibility consent** ➢ **Autonomy and individual responsibility (1 hrs)** • Levels and notions of autonomy • Responsibility: its different aspects and dual nature • Autonomy and patients right to self-determination in treatment • The patient's right to refuse • Special measures for protecting the rights and interests of socially and mentally disables patients • Patient responsibilities ➢ **Consent (2 hrs)** • Purpose of the principle of consent (prior, free & informed consent) • What is express consent? • The patient's right to refuse • Consent of subjects of scientific research • Compare the provisions for consent in scientific	3		Short essay	8

	research with those for medical interventions • Consent by individual, group and community • Exceptional circumstances for the application of the principle of consent • Persons without the capacity to consent ❖ Criteria for capacity to consent ❖ Categories of persons without the capacity to consent ❖ How to obtain consent in health care practice for the special categories?				
Ethics					
1	• Medical ethics versus medical law – (Definition - Goal – Scope) • Introduction to Code of conduct	1		Short answer	5
2	Basic principles of Bio ethics & ICMR guidelines	2		Short essay	5
3	Malpractice and negligence	1		Short essay	5
4	Animal ethics	1		Short essay	5
5	Medico legal aspects of medical records – Medico legal case and type- Records and document related to MLC - ownership of medical records - Confidentiality Privilege communication - Release of medical information - Unauthorized disclosure - retention of medical records - other various aspects.	1		Short essay	5
5	Professional Indemnity insurance policy	1		Short answer	5
6	Development of standardized protocol to avoid near miss or sentinel events	1			
7	Medical diagnosis versus physiotherapy diagnosis.	1		Short answer	5
8	Code of ethics for physiotherapists (IAP & WCPT)	1		Short answer	5
Title: Biostatistics					
1	**Introduction** • Types of variables • Measurement scales • Frequency distribution • Tabulation & graphical presentation of data	4		Long essay	12

2	**Measures of central tendency** • Mean • Median • Mode	2		Long essay	12
3	**Measures of variability** • Range • Interquartile range • SD • Coefficient of variation	3		Long essay	12
4	• Sample distribution & error • Normal distribution, • Skewness and Kurtosis	3		Long essay	12
5	**Correlation** • Meaning • Types of correlation • Scatter diagram • Karl Pearsons correlation • Spearman rank correlation	2		Short essay	8
6	**Statistical significance** • Basic concepts of hypothesis testing • Parametric tests- 't' tests -paired & unpaired One-way ANOVA • Nonparametric tests: Chi-square test, Mann Whitney U test, 'Z'test, Wilcoxon's signed rank test	4		Short essay	8
7	**Computer application for statistical analysis**	2		Short essay	8

Question pattern (60 marks)
Part A : Research methodology & Ethics 35 marks
Part B : Bio statistics 25 marks

Recommended books:

1. Fundamentals of Biostatistics; Rastogi Veer Bala
2. Teaching Health Statistics; Lwanga SK and Cho-Yook Tye
3. Twenty lessons and seminar outlines, World Health Organization ,Geneva.
4. Mahajan's Methods in Biostatistics for medical students and research workers. 8th Edition, Khanal Arun Bhadra Jaypee brothers Medical Publishers, New Delhi;.
5. Research Methodology: Methods and Techniques. Kothari CR.
6. Physical Theraphy Ethics Gabard Donald L

YENEPOYA

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

Program Name: M.Sc. Nursing

Course Title: Nursing Research and Biostatistics

ATTESTED

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

NURSING RESEARCH AND BIOSTATISTICS

Placement : I Year

Hours of Instruction
Theory : 150
Practical : 100
Total : 250

Part-A : Nursing Research

Theory : 100
Practical : 50
Total : 150

Course Description

This course is designed to assist the students to acquire an understanding of the research methodology and statistical methods as a basis for identifying research problem, planning and implementing a research plan. It will further enable the students to evaluate research studies and utilize research findings to improve quality of nursing practice, education and management.

Objectives

At the end of the course, the students will be able to,

1. define basic research terms and concepts
2. review literature utilizing various sources
3. describe research methodology
4. develop a research proposal
5. conduct a research study
6. communicate research findings
7. utilize research findings
8. critically evaluate nursing research studies
9. write scientific paper for publication

Units	Hours		Course Content
	Theory	Practical	
I	10		**Introduction** • Basic research terminologies • Historical Evolution of research in nursing • Methods acquiring knowledge ▪ problem solving and scientific method • Research definition, characteristics, purposes, kinds /types of research • Scope of nursing research ▪ areas, problems, characteristics in nursing, health and social research • Concept of evidence based practice • Ethics in research • Overview of research process

Units	Hours		Course Content
	Theory	Practical	
II	5	5	**Review of Literature** • Importance, purposes, sources, criteria for selection of resources and steps in reviewing literature
III	10	5	**Research problem** • Identification of research problem • Formulation of problem statement and research objectives • Definition - conceptual / operational • Assumptions and delimitations • Identification of variables • Hypothesis ▪ Definition ▪ Formulation and types
IV	12		**Research approach & designs** • Types of research approaches • Types of research designs ▪ Quantitative research designs: experimental and non experimental ▪ Qualitative research designs: ▪ Phenomenology, Grounded theory, Ethnography and case study. • Mixed research designs
V	4	7	**Developing & presenting a research proposal**
VI	5	5	**Developing theoretical/conceptual framework** • Theories ▪ Nature ▪ Characteristics ▪ Purpose and uses ▪ Using, testing and developing conceptual framework ▪ Models and theories
VII	6		**Sampling** • Population and sample • Factors influencing sampling • Sampling techniques • Sample size • Probability and sampling error • Problems of sampling
VIII	20	10	**Tools and methods of data collection** • Concepts of data collection • Data sources, methods/techniques quantitative and qualitative

Units	Hours		Course Content
	Theory	Practical	
			• Tools for data collection ▪ Types ▪ Characteristics and their development • Validity and reliability of tools • Procedure for data collection
IX	5		**Implementing research plan** • Pilot Study • Review research plan (design) • Planning for data collection • Administration of tool /interventions • Collection of data
X	10	10	**Analysis and interpretation of data** • Plan for data analysis quantitative and qualitative • Preparing data for computer analysis and presentation • Statistical analysis • Interpretation of data • Conclusion and generalizations • Summary and discussion
XI	10		**Reporting and utilizing research findings** • Communication of research results ▪ Oral and written • Writing research report ▪ Purposes ▪ Methods and style - Vancouver, American Psychological Association(APA) ▪ Campbell etc • Writing scientific articles for publication ▪ Purposes &Style ▪ Purposes &Style
XII	3	8	**Critical analysis of research reports and articles**

Activities

- Annotated Bibliography of research reports and articles
- Review of literature of selected topic and reporting
- Formulation of problem statement, objective and hypothesis
- Developing theoretical/conceptual framework
- Preparation of a sample research tool
- Analysis and interpretation of given data
- Developing and presenting research proposal
- Journal club presentation
- Critical evaluation of selected research studies
- Writing a scientific paper

Method of Teaching

- Lecture-cum-discussion
- Seminar/Presentations
- Project
- Class room exercises
- Journal club

Methods of Evaluation

- Quiz, Tests (Term)
- Assignments/Term paper
- Presentations
- Project work

YENEPOYA

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

Program Name: BPT

Course Title: Research Methodology

ATTESTED

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l. Hemiballism,
m. Psychiatric disorders,
n. Malformations of the nervous system,
o. Carotid artery stenosis,
p. Arteriovenous malformations,
q. Spina bifida

9. Applied Yoga in neurological conditions – Rationale of Yoga and Physiotherapy, Therapeutic benefits of Yoga.

PRACTICAL

Practical shall be conducted for all the relevant topics discussed in theory in the following forms:

1. Bedside case presentations and case discussions
2. Lab sessions consisting of evaluation and assessment methods on student models, treatment techniques and practice sessions.

Recommended books:

1. Tidy's physiotherapy.
2. Cash's Textbook of Neurology for Physiotherapists
3. Neurological Rehabilitation by D Umphred
4. Physical Rehabilitation Assessment and Treament – O'Sullivan Schmitz
5. Elements of Pediatric Physiotherapy-Eckersley
6. Title: Occupational Therapy for Physical Dysfunction - Authors: Mary Vining Radomski, Catherine A. Trombly Latham. Lippincott Williams & Wilkins.
7. DeJong's The Neurologic Examination, Authors: Campbell, William W.
8. Pediatric Physical Therapy. Authors: Jan Stephen Tecklin. Lippincott Williams & Wilkins

BIOSTATISTICS (Section –A) & RESEARCH METHODOLOGY (Section B)

Course description: This course provides basic knowledge in selected important topics in biostatistics. This course introduces the students to the types of data, data collection, tabulation, analysis and interpretation of data using suitable statistical tools. This course helps the student to understand the course on Evidence based practice also in their project work in 8th semester.

Seventh Semester (37-42 months)				
Course code & Titles	**Hours**			**Weekly class hours**
	Theory	**Practical**	**Total**	
AP01PT 702- Biostatistics **AP01PT 702-** Research Methodology	60	-	60	4

BIOSTATISTICS

(Section- A)

1. Introduction: Meaning, definition, characteristics of statistics., Importance of the study of statistics, Branches of statistics, Statistics and health science including physiotherapy, Parameters and Estimates, Descriptive and inferential statistics, Variables and their types, Measurement scales.
2. Tabulation of Data: Basic principles of graphical representation, Types of diagrams – histograms, frequency polygons, smooth frequency polygon, cumulative frequency curve, Normal probability curve.
3. Measure of Central Tendency: Need for measures of central Tendency, Definition and calculation of mean – ungrouped and grouped, Meaning, interpretation and calculation of median ungrouped and grouped., Meaning and calculation of mode, Comparison of the mean, median and mode, Guidelines for the use of various measures of central tendency.
4. Probability and Standard Distributions: Meaning of probability of standard distribution, the binominal distribution, the normal distribution, Divergence from normality – skewness, kurtosis.
5. Sampling techniques: Need for sampling - Criteria for good samples, Application of sampling in community, Procedures of sampling and sampling designs errors, Sampling variation and tests of significance.
6. Analysis of variance & covariance: Analysis of variance (ANOVA), what is ANOVA? Basic principle of ANOVA, ANOVA technique, Analysis of Co variance (ANACOVA).
7. Format of scientific documents. (Structure of protocols, formats reporting in scientific journals, systematic reviews and meta-analysis).

RESEARCH METHODOLOGY

(Section-B)

1. Introduction to Research methodology: Meaning of research, objectives of research, Motivation in research, Types of research & research approaches, Research methods vs methodology, Criteria for good research, Problems encountered by researchers in India.
2. Research problem: Statement of research problem., Statement of purpose and objectives of research problem, Necessity of defining the problem
3. Research design: Meaning of research design, Need for research design, Features for good design, Different research designs, Basic principles of research design
4. Sampling Design: Criteria for selecting sampling procedure, Implications for sample design, steps in sampling design, characteristics of good sample design, Different types of sample design
5. Measurement & scaling techniques: Measurement in research- Measurement scales, sources of error in measurement, Technique of developing measurement tools, Meaning of scaling, its classification. Important scaling techniques.
6. Methods of data collection: collection of primary data, collection data through questionnaires & schedules, Difference between questionnaires & schedules.

7. Sampling fundamentals need for sampling & some fundamental definitions, important sampling distributions.
8. Processing & analysis of data: Processing operations, problems in processing, Types of analysis, Statistics in research, Measures of central tendency, Dispersion, Asymmetry, relationship.
9. Testing of hypothesis: What is hypothesis? Basic concepts concerning testing of hypothesis, Procedure of hypothesis testing, measuring the power of hypothesis test, Tests of hypothesis, limitations of the tests of hypothesis
10. Computer technology: Introduction to Computers, computer application in research, computers & researcher.

Recommended Textbooks:

1. Elements of Health Statistics: Rao.N.S.N
2. An introduction of Biostatistics: Sunder Rao.P.S.S.
3. Methods in Bio-Statistics 6thEdn. 1997: B.K. Mahajan
4. Biostatistics : A manual of Statistics Methods: K. Visweswara Rao
5. Elementary Statistics 1stEdn, 1990. in Medical Workers: Inderbir Singh
6. Statistics in Psychology and education: Great and Henry
7. An Introduction to Gupta C.B. Statistical Methods, 1972: Ram Prasad & Sons
8. Basic Statistics, 3rd Edn..: Simpsory G. Kaftha. P
9. Research; Principles and Methods: L Denise F. Poli & Hungler
10. Fundamentals of Research, 4thEdn.: David J. fox

HEALTH PROMOTION, FITNESS AND WELLNESS

course description: This course includes discussion on health risks, screening, and assessment considering epidemiological principles. Risk reduction strategies for primary and secondary prevention, including programs for special populations are covered.

Seventh Semester (37-42 months)				
Course code & Titles	**Hours**			**Weekly class hours**
	Theory	**Practical**	**Total**	
AP01PT 704- Health Promotion and Fitness	15	30	45	3

1. Prevention practice: a holistic perspective for physiotherapy
    a. Defining Health
    b. Predictions of Health Care
    c. Comparing Holistic Medicine and Conventional Medicine
    d. Distinguishing Three Types of Prevention Practice.

2. Healthy People
    a. Definition of healthy people

YENEPOYA

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

Program Name: B.Sc Nursing

Course Title: Introduction to Nursing Research & Statistics (Second Year)

ATTESTED

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Mangalore - 575 018, Karnataka

INTRODUCTION TO NURSING RESEARCH AND STATISTICS

Placement : Second Year

Theory - 45 hrs.
Practical - 120 hrs.

COURSE DESCRIPTION

The course is designed to assist the students to develop an understanding of basic concepts of research and statistics, use the findings of nursing research in nursing practice, apply the knowledge in conducting projects and solve problems related to nursing using scientific methods.

OBJECTIVES

At the end of the course, the student will be able to,

1. define the terms and concepts of nursing research.
2. identify needs and scope of nursing research.
3. identify and define a research problem.
4. locate and list sources of literature for a specific study.
5. describe different research approaches, methods of data collection and sampling techniques with a special reference to survey method.
6. develop tool for data collection.
7. enumerate steps of data analysis and present data summary in tabular form.
8. use descriptive and correlational statistics in data analysis.
9. conduct a personal or group research project.

COURSE CONTENTS

A. INTRODUCTION TO RESEARCH METHODOLOGY

Unit	Hours	Learning Objectives	Content	Teaching Learning Activities	Assessment Methods
I	5	• Define the terms and concepts of nursing research.	**Research and research process** • Steps of scientific methods • Definition of research • Need for nursing research • Characteristics of good research • Research Process • Ethics in research	• Lecture cum discussion. • Narrate steps of research process followed from examples of published studies.	• Short answer • Objective Type • Essay type
II	5	• Identify and define a research problem • Locate and list sources of literature for a specific study	**Research problem and literature review** • Statement of research problem, • Statement of purpose and objectives. • Formulation of hypotheses • Definition of research terms. • Review of literature	• Lecture cum discussion. • Exercise on writing statement of problem, objectives • Reviewing one research report/ article • Each student selects a research problem	• Short answer • Objective Type • Proposal development

Unit	Hours	Learning Objectives	Content	Teaching Learning Activities	Assessment Methods
III	3	• Describe the research approaches and designs	**Research approaches and designs** • Research approaches : historical, survey and experimental. • Qualitative and quantitative designs	• Lecture cum discussion. • Explain types of research approaches used from examples of published and unpublished research studies with rationale	• Short answer • Objective type • Essay type
IV	8	• Explain the sampling process • Describe the methods of data collection • Developing and standardizing an instrument	**Sampling and data collection** • Sampling • Sampling techniques and methods of data collection. • Instruments; questionnaire, interview, • Observation schedule, records, measurements. • Reliability and validity of instruments. • Pilot study • Data collection procedure	• Lecture cum discussion. • Prepare the tool in respect to the selected research problem.	• Short answer • Objective type • Essay type
V	3	• Enumerate steps of data analysis and present data summary in tabular form	**Analysis of data** • Tabulation, • Classification and summarization, • Presentation, • Interpretation of data	• Lecture cum discussion. • Preparation of sample tables	• Short answer • Objective type • Essay type
VI	3	• Describe the methods of communicating research findings.	**Communication of research findings** • Writing Report ▪ Organizing materials for writing ▪ Format of the report ▪ Use of computers.	• Lecture cum discussion. • Writing group research project & presentation	• Short answer • Objective type • Assessment of group research Project

B. INTRODUCITON TO STATISTICS

Unit	Hours	Learning Objectives	Content	Teaching Learning Activities	Assessment Methods
VII	10	• Explain the use of statistics, scales of measurement and graphical presentation of data	**Descriptive statistics** • Definition, uses of statistics • Scales of Measurement • Frequency Distribution and graphical presentation of data • Measures of central tendency - mean, median and mode • Measures of variability : range, standard deviation, • Introduction to normal probability • Inferential Statistics • Chi square	• Lecture cum discussion. • Practice on graphical Presentations • Practice on computation of measures of central tendency, variability	• Short answer • Objective type
VIII	3	• Describe the methods of correlation	**Correlation** • Computation by rank difference methods • Uses of correlation co-efficient.	• Lecture cum discussion. • Practice on computation of correlation	• Short answer • Objective type
IX	2	• Discuss biostatistics	**Biostatistics** • Crude rates and standardized rates, ratio and estimation of the trends	• Lecture cum discussion.	• Short answer • Objective type
X	3	• Describe the use of computers in nursing	**Introduction to computers in nursing** • Introduction to computer & disk- operating system • Introduction to word processing • Introduction to data base • Windows applications, word, excel, power point, multimedia • Use of statistical packages • Introduction to internet & use of electronic mail • Computer aided teaching & testing	• Lecture cum discussion. • Practice on computers using data base, windows and statistical packages	• Short answer • Objective type

PRACTICUM

Students will conduct research project in small groups in selected areas of nursing and submit report. (Group studies include studying of existing health practices, improved practices of nursing (procedures), health records, patient records and survey of nursing literature).

References :

1. Polit DF, & Beck CT. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Walter Kluwer, Lippincott Williams & Wilkins. 7th edition
2. Polit DF, & Beck CT. Principles and methods. Lippincott Williams & Wilkins. 7th edition
3. **Polit**, DF, & Beck CT.Nursing Research; Generating and assessing evidence for Nursing Practice. Walter Kluwer, Lippincott Williams & Wilkins. 8th edition
4. Sharma SK. Nursing research & Statistics. Elsevier 3rd edition,.
5. Kaur S, Singh A. Simplified nursing research and statistics for undergraduates. CBS. 1st edition,
6. Clement N. Textbook on Nursing Research & Statistics, EMMESS, 1st edition
7. Nursing Research Society of India, Nursing Research & Statistics, Pearson
8. Mahajan BK. Methods in Biostatistics. Jaypee, 6th edition.

YENEPOYA

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

Program Name: B.Sc. Nursing

Course Title: Nursing Research & Biostatistics
(Third Year)

ATTESTED

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

Nursing Research and Statistics

Placement : Third Year

Theory : 45 hours
Practical : 45 hours

Course Description : The course is designed to enable students to develop an understanding of basic concepts of research, research process and statistics and to enable them to conduct/participate in need based research studies in various settings. Further the students will be able to utilize the research findings to provide quality-nursing care. The hours for practical will be utilized for conducting individual or group research project.

Unit	Hours	Learning Objectives	Content	Teaching Learning Activities	Assessment Methods
I	4	• Describe the concept of research, terms, need and areas of research in nursing. • Explain the steps of research process.	**Research and research process** • Introduction and need for nursing research. • Definition of Research & nursing research. • Steps of scientific method. • Characteristics of good research. • Steps of research process – overview	• Lecture cum discussion. • Narrate steps of research process followed from examples of published Studies.	• Essay type • Short answers • Objective type
II	3	• Identify and state the research problem, objectives, hypothesis, assumption and variables	**Research Problem/Question** • Identification of problem area &Problem statement. • Stating objectives of the research problem • Writing Objectives • Hypothesis , Assumption , Variables • Proposal development	• Lecture cum discussion. • Exercise on writing statement of problem and objectives. • Each student selects a research problem	• Essay type • Short answer • Objective type
III	3	• Review the related literature	**Review of Literature** • Location • Sources • Online search: CINHAL,COCHRANE • Purposes • Method of Review • Writing the Review Of Literature • Writing of Bibliography	• Lecture cum discussion • Exercise on reviewing one research report/ article for a selected research Problem.	• Essay type • Short answer • Objective type
IV	4	• Describe the research approaches and designs	**Research approaches and designs** • Historical, survey and experimental • Qualitative and Quantitative designs	• Lecture Discussion • Explain types of research approaches	• Essay type • Short answer • Objective type

Unit	Hours	Learning Objectives	Content and teaching learning activity	Teaching Learning Activities	Assessment Methods
				used from examples of published and unpublished research studies with rationale.	
V	8	• Explain the sampling process • Describe the methods of data collection, developing and standardizing an instrument	**Sampling and data collection** • Definition of population, sample, sampling criteria, factors influencing sampling process, types of sampling techniques. • Data - Why, What, From, Whom, When, Where to collect • Data collection Methods and Instruments ▪ Methods of data collection ▪ Questionnaire, interview ▪ Observation, record analysis and measurement. ▪ Types of instrument ▪ Validity & Reliability of the instrument ▪ Pilot Study ▪ Data collection procedure	• Lecture cum Discussion • Prepare the tool in respect to the selected research Problem.	• Essay type • Short answer • Objective type
VI	4	• Analysis, interpret and sum-marize the research data	**Analysis of data :** • Compilation, Tabulation, classification, summarization, presentation, interpretation of data	• Lecture cum discussion • Preparation of sample tables	• Essay type • Short answer • Objective type
VII	15	• Explain the uses of statistics, scales of measure-ment and graphical presentation of data • Describe the measures of central	**Introduction to statistics** • Definition, use of statistics, scales of measurement • Frequency distribution and graphical presentation of data • Mean, Median, Mode, standard deviation • Normal probability and tests of significance • Coefficient of correlation	• Lecture cum discussion • Practice on graphical presentations • Practice on computation of measures of central tendency, variability & correlation	• Essay type • Short answer • Objective type

Unit	Hours	Learning Objectives	Content and teaching learning activity	Teaching Learning Activities	Assessment Methods
		tendency and variability and methods of correlation	• Inferential statistics and types. • Statistical packages and its application		
VIII	4	• Communi-cate and utilize the research findings.	**Communication and utilization of Research** • Communication of research findings ▪ Verbal report ▪ Writing research report ▪ Writing scientific article/paper ▪ Critical review of published research ▪ Utilization of research Findings	• Lecture cum discussion • Writing group research project & presentation	• Essay type • Short answer • Objective type • Assessment of group research Project

INERNSHIP

HOURS	DURATION IN WEEKS	ACTIVITIES TO BE COMPLETED
45 hours	1 week	Project to be completed, report to be submitted to the university and publish the research findings

References :

1. Polit DF, & Beck CT. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Walter Kluwer, Lippincott Williams & Wilkins. 7th edition
2. Polit DF, & Beck CT. Principles and methods. Lippincott Williams & Wilkins. 7th edition
3. **Polit**, DF, & Beck CT.Nursing Research; Generating and assessing evidence for Nursing Practice. Walter Kluwer, Lippincott Williams & Wilkins. 8th edition
4. Sharma SK. Nursing research & Statistics. Elsevier 3rd edition,.
5. Kaur S, Singh A. Simplified nursing research and statistics for undergraduates. CBS. 1st edition,
6. Clement N. Textbook on Nursing Research & Statistics, EMMESS, 1st edition
7. Nursing Research Society of India, Nursing Research & Statistics, Pearson
8. Mahajan BK. Methods in Biostatistics. Jaypee, 6th edition.

YENEPOYA

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

Program Name: B. Pharm.

Course Title: Biostatistics and Research Methodology

ATTESTED

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BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Objectives : Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

Course content :

Unit-I **10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

Unit-II **10 Hours**

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples **Probability:**Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II t ype, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference

Unit-III **10 Hours**

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

YENEPOYA

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Accredited by NAAC with 'A' Grade

Program Name: BAMS

Course Title: Research Methodology & Medical Statistics

ATTESTED

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CENTRAL COUNCIL OF INDIAN MEDICINE
NEW DELHI

SYLLABUS OF AYURVEDACHARYA (BAMS) COURSE

INDEX

4TH PROFESSIONAL

ATTESTED

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4.5 Research methodology and Medical statistics

Total Marks 50 (Part A-30 and Part B- 20)

PART – A –Research Methodology

1. Brief historical background of research in Ayurved and contemporary medical science Evidences of researches in ayurvedic classics
2. Etymology, definitions and synonyms (Anveshana, Gaveshana, Prayeshana, Anusandhan and Shodha) of the word Research
3. Research in Ayurved - Scope, need, importance, utility
4. Types of Research (familiarization of the terms)
    a) Pure and Applied
    b) Qualitative , Quantitative and Mixed
    Observational and interventional.
5. Research process (Importance of each steps in brief)
    a. Selection of the topic
    b. Review of the literature
    c. Formulation of Hypothesis
    d. Aims and Objectives
    e. Materials and methods
    f. Observations and results
    g. Methods of communication of Research
6. Research tools – Role of the pramanas as research tools
7. The concept and importance of ethics in research
8. Concept of Evidenvce Based Medicine and Scientific Writing
9. Importance of IT in data mining and important research data portalsconcerned with Ayurved and contemporary medical science (DHARA , PubMed, Ayush Research Portal, Bioinformatics Center, Research Management Informatic System etc.)

Part – B Medical-Statistics

1. Definition, scope and importance of the Medical statistics
2. Common statistical terms and notations
    a. Population
    b. Sample
    c. Data
    d. Variable
    e. Normal distribution
3. Collection and Presentation of data
    a. Tabular
    b. Graphical
    c. Diagrammatical
4. Measures of location
    a. Average
    b. Percentile

    Measures of Central Tendency
    a. Arithmetic mean
    b. Median

c. Mode

5. Variability and its measurement
   a. Range
   b. Standard deviation
   c. Standard error
6. Introduction to probability and test of significance
7. Parametric and non parametric tests
8. Introduction to commonly used statistical soft-wares.

Reference books for Research methodology :

1. Dawson, Catherine, 2002, Practical Research Methods, New Delhi, UBS Publishers' Distributors
2. Kothari, C.R.,1985, Research Methodology-Methods and Techniques, New Delhi, Wiley Eastern Limited.
3. Kumar, Ranjit, 2005, Research Methodology-A Step-by-Step Guide for Beginners, (2nd.ed), Singapore, Pearson Education
4. Students guide to research methodology – Undergraduates. Alexandria Medical Students Association.
5. Health research methodology. A guide for training in research methods. 2nd edition. Manila, World Health Organization Regional Office for the Western Pacific, 2001.

Reference Books for statistics :

1. Health research methodology. A guide for training in research methods. 2nd edition. Manila, World Health Organization Regional Office for the Western Pacific, 2001.
2. Statistical methods in medical research. P.Armitage (Ed) Oxoford Blackwell
3. Statistical methods . Snedecor GW and Cochran, WG
4. Altman, D. G. (1991). Practical statistics for medical research. London: ChapmanPrinciples of Medical Statistics by A. Bradford Hill
5. Interpretation and Uses of Medical Statistics by Leslie E Daly, Geoffrey J Bourke, James MC Gilvray.
6. Research in Ayurveda-M S Baghel
7. research methodlogy in ayurveda-V.J.Thakar,Gujarat Ayurved University
8. Ayurveda anusandhan paddhati-P.V.Sharma
9. Research methodology methods and statistical techniques- Santosh Gupta. Greenhouse SW.
10. The growth and future of biostatistics: (A view from the 1980s). Statistics in Medicine 2003; 22:3323–3335.
11. Knapp GR & Miller MC. Clinical epidemiology and Biostatistics, NMS series Antonisamy B, Christopher S & Samuel PP. Biostatistics : Principles and practice
12. Sundara Rao PSS & Richard J. An introduction to Biostatistics, PHI
13. Senn S (1997). Statistical Issues in Drug Development. Chichester: John Wiley & Sons.
14. Methods in Bio-statistics for Medical Students- BK Mahajan
15. Vaidyakeeya Sankhiki Shastra- Dr.S.S.Savrikar

YENEPOYA

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

Program Name: MDS

Workshop Title: Basic Research Methodology Workshop

ATTESTED

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

YENEPOYA
UNIVERSITY

BASIC RESEARCH METHODOLOGY WORKSHOP FOR FIRST YEAR DENTAL POSTGRADUATES

PROGRAM SCHEDULE

The workshop is conducted for all the post-graduate student before initiating their dissertation research

Topic	Learning Objectives
Choosing a topic and Framing a Research Question	Role and importance of dissertation for PG Define what is a research question Be able to formulate a research hypothesis/es Writing research objectives(s)
Study designs	List the types of study designs Describe the uses of various study designs Recognise key elements of various study designs
Review of literature	Recognize the importance of performing a literature review Describe the steps in performing a literature review Outline the steps in writing a literature review Pub med search How to archive references
Study population and Sampling methods	Recognise the importance of sampling in research Outline the strengths and limitations of sampling methods
Bio statistical consideration in research including sample size calculation	1. To define and explain the different types of variables with appropriate examples. 2. To outline the information needed for sample size calculation.
Principals of data collection Data collection tools and validation of tools	1. To describe the essential steps in data collection 2. To understand the types and steps involved in design of a questionnaire 3. To explain the concepts of validity and

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Mangalore - 575 018, Karnataka

	reliability of a study tool 4. To identify the approaches to ensure quality during data collection.
Overview of data management and analysis	1. To demonstrate the salient steps in data management through a hands-on group activity. 2. To demonstrate how to write data analysis in dissertation protocol.
Ethical considerations in Designing and Conducting Research study	Principles of Research Ethics Informed consent, participant information sheet Procedure to be followed for submission of protocol to IEC
Research opportunities at YRC and funding agencies	List the various intra mural and extra mural funding agencies Appraisal of facilities at YRC
Lunch break	
Protocol Writing	Describe the various steps in writing a research protocol

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Program Name: MD/MS

Workshop Title: Basic Research Methodology Workshop

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Mangalore - 575 018, Karnataka

YENEPOYA
UNIVERSITY

BASIC RESEARCH METHODOLOGY WORKSHOP

FOR FIRST YEAR POSTGRADUATE STUDENTS

PROGRAM SCHEDULE

The workshop is conducted for all the post-graduate student before initiating their dissertation research

Topic	Learning Objectives
Choosing a topic and Framing a Research Question	Role and importance of dissertation for PG Define what is a research question Be able to formulate a research hypothesis/es Writing research objectives(s)
Study designs	List the types of study designs Describe the uses of various study designs Recognise key elements of various study designs
Review of literature	Recognize the importance of performing a literature review Describe the steps in performing a literature review Outline the steps in writing a literature review Pub med search How to archive references
Study population and Sampling methods	Recognise the importance of sampling in research Outline the strengths and limitations of sampling methods
Bio statistical consideration in research including sample size calculation	1. To define and explain the different types of variables with appropriate examples. 2. To outline the information needed for sample size calculation.
Principals of data collection Data collection tools and validation of tools	1. To describe the essential steps in data collection 2. To understand the types and steps involved in design of a questionnaire 3. To explain the concepts of validity and

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	reliability of a study tool 4. To identify the approaches to ensure quality during data collection.
Overview of data management and analysis	1. To demonstrate the salient steps in data management through a hands-on group activity. 2. To demonstrate how to write data analysis in dissertation protocol.
Ethical considerations in Designing and Conducting Research study	Principles of Research Ethics Informed consent, participant information sheet Procedure to be followed for submission of protocol to IEC
Research opportunities at YRC and funding agencies	List the various intra mural and extra mural funding agencies Appraisal of facilities at YRC
Research integrity	Importance and the need for transparency and accountability in research
Protocol Writing	Describe the various steps in writing a research protocol

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Workshop Title: Intensive Summer Workshop on Ethics and Research (I-SWEAR) - Every Year from 2016 to 2020

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Centre for Ethics, Yenepoya deemed to be University, Mangalore

Four-Day Intensive Summer Workshop in Ethics and Research (I-SWEAR)

Dates: I-SWEAR is conducted every year in the last week of May

Participants: Faculty, researchers, Medical/ Dental/ Nursing/ Physiotherapy/ AYUSH students, PG Diploma students and Ethics Committee members

Resource persons: In-house faculty of the Centre for Ethics and visiting faculty with expertise in research ethics

Workshop content

S.No	Topic	Topics to be covered/Learning objectives
1.	Round of introduction	a. Introduction of participants and resource persons b. Overall program structure and objectives
2.	What is research? (Case study discussion)	a. Define research b. Distinguish research from innovations in practice c. How different are ethics standards for research and practice
3.	Ethics of clinical practice and clinical research (Presentation and discussion)	a. Doctor patient-relationship in practice vis-à-vis doctor-participant relationship in research b. Uncertainty in practice and research c. Concepts of clinical equipoise and therapeutic misconception d. Brief history of research ethics
4.	Methodology for ethical analysis: principles and theories (Presentation and discussion)	a. Principles and theories of ethics and basic tools for moral reasoning b. Identifying ethical issues in research
5.	Movie/ documentary	Identifying ethical issues in research through movie/

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		documentary
6.	Discussion on the movie/documentary	a. Identify various ethical issues in the film b. Application of theories, principles and guidelines c. Making scientific design to confirm ethical standards
7.	Vulnerability of participants	a. Clarifying concept of vulnerability, and method of identifying different kinds of vulnerabilities of participants b. Individual and group vulnerabilities c. Appropriate ethical standards for protection of the vulnerable and ensuring benefits of research to them
8.	Voluntary informed consent (IC) (Case studies/film, presentation, discussion)	a. Operationalizing the principle of participant's autonomy b. Elaboration of each component of IC: voluntariness, disclosure, comprehension and documentation c. Importance of consent process - who, where, how
9.	Privacy and confidentiality in clinical research (Case study, presentation and discussion)	a. Clarifying concepts: autonomy in relation to privacy/confidentiality b. Methods to operationalize protection of privacy and confidentiality c. Levels of confidentiality protection d. Limits of confidentiality protection
10.	Guidelines	a. ICMR guidelines b. Stem cell research guidelines c. Good clinical practices guidelines d. Other guidelines
11.	Assessment of risks and benefits in clinical research (Case study, presentation, discussion)	a. Clarifying concepts – various types of risks, potential harms and benefits b. Methods to assess risks and benefits: components analysis, net-risk test, decision studies methods c. Who should do the risk assessment?
12.	Laws and regulations	a. Good Clinical Practice Guidelines: Major

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	related to clinical trials (Presentation and discussion)	provisions on competence & responsibilities of investigators, institutions, CROs and Sponsors b. Provisions for highest scientific standards of clinical trials c. Accreditation of EC
13.	Ethics committees: Institutional and Independent (Presentation and discussion)	a. Structure and composition of ethics committees b. Functioning and responsibilities: Review, continuous review, monitoring, site visits c. Essential provisions in the Standard Operating Procedure (SOP)
14.	Formation of ethics committees of participants and protocols for mock ethics review	a. Getting to know each other in groups b. Identifying the various roles for the members of the group c. Brief overview of mock protocol
15.	Regulations for SAE and compensation (Presentation and discussion)	a. Serious Adverse Events (SAE) reporting; injuries and deaths b. Provision of full and free medical management of SAEs c. Criteria for provision of compensation and the quantum d. Role and responsibilities of ethics committees and national expert committee/panel on compensation e. Registration & responsibilities of ECs f. Trial inspections by CDSCO
16.	Clinical trials	a. Clinical trial agreements: Sponsor-CRO, CRO-Institution-Investigator b. Application for clinical trial to CDSCO: who, how c. Various types of CROs, their functions and responsibilities, strengths, weakness d. Clinical Trial insurance: What it covers, procedure for claims
17.	Community engagement	a. Need for engagement – issues in relevance of research to community, community benefits and its protection b. Community permission and consent understanding power relations Culture sensitivity

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		and developing cultural competence of researchers
18.	Conflict of interest	a. Clarifying concept, its importance for credibility, quality and ethics of research b. How it is managed c. Disclosure of conflict of interest to participants, ethics committee, in publication etc d. Measures to be taken when significant or irreconcilable conflict of interests
19.	Standards of care	a. Standards of care in clinical practice and research b. History and international debate on standards of care Ancillary care and its importance for uninsured patients in India c. Post-trial obligations of research - need for institutional and national mechanism
20.	EC functioning- group activity	a. Members will discuss ethical issues in their groups based on previous day's activities
21.	Transparency and social accountability in clinical research (Presentation and discussion)	a. Clinical trials as social function for development of new treatment, prevention methods and products b. Recent debates on making clinical trial data available to doctors and researchers c. Limits of trade/business secrets, and primacy of welfare of people d. Chain of responsibilities – who is accountable to whom
22.	Scientific misconduct (Discussion on cases on the topic and presentation)	a. Data falsification and fabrication b. Plagiarism, self-plagiarism, salami publication c. Ghost writing, Authorship credit d. Vancouver protocol
23.	Ethical use of animals in Research	a. History of debate on the way animals were used in research; for the better treatment of animals b. Alternatives to animal use available c. Ethical guidelines for animal use, ethics committee for review and monitoring of the animal use.

APPROVED

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24.	Mock ethics committee- group activity and review
25.	Questions and answers and clarification of doubts

Director
Centre for Ethics
Yenepoya University

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Members of the:

Institutional Ethics Committee

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

Ref: No. YU/REG/ACA/CFE-1/2019 18.10.2019

NOTIFICATION

Sub: Reconstitution of Yenepoya Ethics Committee – 1

Ref: This Office Notification No. YU/REG/ACA/CFE/2019 dated 04.07.2019

*****

The Yenepoya Ethics Committee – 1 is reconstituted with the following members and is hereby notified.

Sl.No	Name	Designation	Internal/External
1.	Dr. Vikram Shetty	Chairperson	External
2.	Mr. Saduddin Salihi	Co-Chairman	External
3.	Dr. Uma Kulkarni	Member Secretary	Internal
4.	Dr. Ravi Vaswani	Joint Member Secretary	Internal
5.	Dr. Sayeegeetha	Lay Person	External
6.	Fr. Teji Thomas	Theologist	External
7.	Mr. YM Khurshid	Lay Person	External
8.	Dr. Sachidananda Adiga MN	Basic scientist	External
9.	Dr. Nagapati Bhat	Pharmacologist	Internal
10.	Dr. Laxminarayan Sonde	Dentist	Internal
11.	Dr. Mohammed Guthigar	Social Scientist	Internal
12.	Ms. Viji Prasad	Nurse	Internal

This reconstituted Ethics Committee-1 shall hold office for the residuary period till 03.07.2021

By Order

REGISTRAR 18/10

To,
The Chairperson and all other members

Copy To:
The Principals of the Constituent Colleges
Finance Officer
Controller of Examinations
Dy. Director-YRC
P.A. to V.C/P.A to Registrar
Academic Section

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Dr.Gangadhara Somayaji K.S.
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File No. EC/20/000299

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 22-Sep-2020

To

The Chairman
Yenepoya Ethics Committee-1
Yenepoya deemed to be University
University Road Deralakatte, Mangalore Mangalore
Dakshina Kannada Karnataka - 575018 India

Subject: Ethics Committee Re-Registration No. ECR/521/Inst/KA/2014/RR-20 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2020/9346 dated 14-Aug-2020 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/521/Inst/KA/2014/RR-20. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 04-Sep-2020 to 03-Sep-2025, unless suspended or cancelled by the Central Licencing Authority.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
(v) lay person.

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5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical,

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

non-medical, scientific and non-scientific areas with at least,

(i) one lay person;

(ii) one woman member;

(iii) one legal expert;

(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee,bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall

such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

ATTESTED

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सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 22-Sep-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Vikram Shetty	MBBS (D.Ortho., DNB-Orthopedics)	Chair Person
2	Dr. Uma Kulkarni	MBBS (DOMS,DNB-Ophthalmology)	Member Secretary
3	Dr. Sachidananda Adiga	MBBS (MD-Pharmacology)	Basic Medical Scientist
4	Dr. Laxminarayan Sonde	BDS (MDS-Public Health Dentistry and Bioethics)	Clinician
5	Dr. Ravi Vaswani	MBBS (MD-Medicine)	Clinician
6	Mr. Saduddin Salihi	LLB (LLM)	Legal Expert
7	Mr. Teji Thomas	B.Ph, (B.Th,GNM,BA-Sociology)	Social Scientist
8	Dr. Nagapati Prabhakar Bhat	MBBS (MD-Pharmacology)	Basic Medical Scientist
9	Dr. Mohammed Guthigar	BSc (MSW, M.Phil, PhD-Social Work)	Social Scientist
10	Ms. Viji Prasad C	BSc (MSc.-Nursing)	Scientific Member
11	Dr. Sayeegeetha Hegde	BA (MA-Kannada,Ph.D-Tulu Language)	Lay Person
12	Mr. Y M Khurshid	BBA (MBA)	Lay Person

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

ATTESTED
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FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. ECR/521/Inst/KA/2014/RR-20

The Central Licencing Authority hereby registers and permits Yenepoya Ethics Committee-1 , Yenepoya deemed to be University University Road Deralakatte, Mangalore Mangalore Dakshina Kannada Karnataka - 575018 Contact No.: 0824 2204670 Fax No.: 0824 2203943 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place : New Delhi

Date : 22-SEP-2020

Central Licencing Authority
Stamp

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Members of the:

Yenepoya Ethics Committee-2

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Fax: 0824 - 2203943

Ref: No/YU/REG/ACA/001/CEF-2/2020 . 24.07.2020

RENOTIFICATION

Sub: Reconstitution of Yenepoya Ethics Committee 2 of Yenepoya (Deemed to be) University

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The Yenepoya Ethics Committee 2 of Yenepoya (Deemed to be) University is reconstituted with the following members and is hereby notified.

SL No.	Members	Degree	Role in Ethics Committee	Affiliation
1.	Dr. Vijaya Hegde	MDS, PGDBEME	Chairperson , Bioethicist	External Member
2.	Dr. Jayaram Padakanayya	B.Com, LLB	Lawyer	External Member
3.	Ms. Jameela	BA	Lay person	External Member
4.	Dr. Kumuda Rao	MDS,PGDMLE	Risk assessor	External Member
5.	Ms. Jaklin Mary	MSc (Psycology)	HIV Counsellor/Psychologist	External Member
6.	Dr. Suphala Kotian	MSW,PhD	Social Scientist	External Member
7.	Dr. Prasanna Keshava B	MD (Ayurveda)	Clinician	External Member
8.	Dr. Prabhakar Adake	MBBS, MD	Pharmacologist	Internal Member
9.	Dr. H G Thippeswamy	MBBS, MD	Clinician	Internal Member
10.	Dr. Rashmi Jain	MBBS,MS,PGDBEME	Clinician	Internal Member
11.	Mrs. Smitha D	MPT, PGDBEME	Bioethicist	Internal Member
12.	Dr. Leena Pramod K	MSc(Zoology) PGDBEME, PGDFAO (Forensic), PhD	Risk assessor, Bioethicist	Internal Member
13.	Dr.Padmini Thalanjeri	MBBS,MD,PGDBEME	Bioethicist	Internal Member
14.	Dr. H Hari Kishore Bhat	MDS, PGDBEME, PGDCE	Bioethicist, Dentist, Member Secretary	Internal Member

By Order

REGISTRAR

To,
The Chairperson and all other members

Copy To:
The Principals of the Constituent Colleges
Finance Officer
Controller of Examinations

Dy. Director – YRC
P.A to V.C/P.A to Registrar
Academic Section

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

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

सत्यमेव जयते

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

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

Provisional Certificate

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

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

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

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

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

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

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

(Anu Nagar)
Joint Secretary
Department of Health Research
Designated Authority

File No. EC/19/000466

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 30-Jan-2020

To

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

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

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2019/5820 dated 26-Aug-2019 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/1337/Inst/KA/2020. The said registration is subject to the conditions as mentioned below:

Yours faithfully

V G SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-

(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;

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

(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
(v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,
(i) one lay person;
(ii) one woman member;
(iii) one legal expert;
(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or

ATTESTED

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

within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre: Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

ATTESTED

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

YENEPOYA

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

Members of the:

Institutional Animal Ethics Committee

भारत सरकार
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
पशु कल्याण प्रभाग
पशुओं पर परीक्षण के नियंत्रण एवं पर्यवेक्षण के प्रयोजनार्थ समिति (सीपीसीएसईए)
Government of India
Ministry of Environment, Forest and Climate Change
Animal Welfare Division
Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)

F. No. 25/47/2010 - AWD
.2017

To

Dr.Roopa P Nayak, Chairperson of IAEC
Yenepoya University, University road, Deralakatte,
Mangalore - 575 018, Karnataka.
Mobile No: 9481973923
Email ID: roopapnayak@yenepoya.edu.in

Subject: Approval of large Animal House Facility for housing of Pigs / Change in name of the establishment, - regarding.

Sir,

This is with reference to above mentioned subject. It is to inform you that CPCSEA has approved the **housing of Pigs for Research of Commercial purpose**. Now, your registration number has accordingly been amended as **347/PO/Re-S/Rc-L/01/CPCSEA** for **Research for Education purpose on small animals** and **Research for Commercial Purpose on large animals (Pigs).** Henceforth, the above registration number may be quoted in all your future correspondence with this office.

2. It is also to inform you that before commencing any research on large animals you are required to send the research protocols with due recommendation of IAEC to CPCSEA for their approval (Procedure for submission of Research Protocols is available on the Website of CPCSEA).

3. Further, this is to inform you that CPCSEA has considered your request to note the change in name of the establishment. The changed name of the establishment has been noted as under:

Yenepoya University, University road, Deralakatte,
Mangalore - 575 018, Karnataka

4. Kindly acknowledge the receipt of this letter.

Yours faithfully,

(S. Gowri Shankar)
Deputy Secretary (AW) & Member Secretary (CPCSEA)

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

5वां तल, वायु ब्लॉक, इंदिरा पर्यावरण भवन, जोर बाग रोड, नई दिल्ली–110003
दूरभाष : 011-24695231,टेलीफेक्स : 011-24695424 ईमेल : cpcsea-mef@gov.in, वेबसाईट : http://cpcsea.nic.in

5th Floor, Vayu Block, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi-110003
Phone: 011-24695231, Telefax : 011-24695424, Email : cpcsea-mef@gov.in, Website: http://cpcsea.nic.in

***

No. 25/47/2010-AWD
Government of India
Ministry of Fisheries, Animal Husbandry and Dairying
Department of Animal Husbandry and Dairying
O/o Committee for the purpose of Control and Supervision of Experiments on Animals
*****

Krishi Bhawan, New Dlhi-110001
Date:17/02/2020

To

Dr.Roopa P Nayak, Chairperson IAEC,
Yenopoya Medical and Dental College,
Nithyananda Nagar P.O., Deralakatte Mangalore - 575 018, Karnataka.
Mobile: 9481973923
E-mail: roopapnayak@yenepoya.edu.in

Subject: Revision of Institutional Animals Ethics Committee (IAEC)/ Change nominee – regarding

Madam,

Kindly refer to your application on the above subject. CPCSEA hereby accords approval to your request for revision of IAEC. Further, Dr. Shyamjith M. is been nominated as Link Nominee in place of Dr. Himanshu Joshi.

2. Accordingly, the revised IAEC is as under:

S.No.	Name of IAEC Members	Designation in IAEC
1	Dr.Roopa P Nayak	Scientist Incharge of Animal House Facility, Chairperson
2	Dr. Megha Rani N	Biological Scientist, Member Secretary
3	Dr. Bindhu S	Scientist from different discipline
4	Dr. Vidya Pai	Scientist from different discipline
5	Dr. Suprith Surya	Veterinarian
6	Dr. Hemanth Gowda K.	Main Nominee
7	Dr. Shyamjith M.	Link Nominee*
8	Dr. K.L. Krishna	Scientist from outside the Institute
9	Dr. Murali B.	Socially Aware Nominee

3. It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC mettings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and Main Nominee, Scientist from outside of the Institute and Socially aware must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailablity in writing to the chairman IAEC. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

Yours sincerely,

(Dr.S.K.Dutta)
Member Secretary (CPCSEA)

Copy for information to Nominees of CPCSEA:
1 Dr. Hemanth Gowda K., Main Nominee
2 Dr. Shyamjith M., Link Nominee
3 Dr. K.L. Krishna, Scientist from outside the Institute
4 Dr. Murali B., Socially Aware Nominee

ATTESTED

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

YENEPOYA

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

Members of the:

Institutional Biosafety Committee

ATTESTED

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

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

University Road, Deralakatte, Mangalore – 575 018

No. YU/REG/PA/BSC/NOT/May/2019 Date: 02.05.2019

NOTIFICATION

Sub: Re-constitution of Institutional Biosafety Committee – reg.

Ref: 1.This Office Notification No. YU/REG/PA/BSC/NOT/Nov/2015 dated 14.11.2015.

2. O.M. No. BT/BS/17/645/2015-PID DT. 30.4.2019 from the Department of Biotechnology, Ministry of Science & Technology, Govt. of India.

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As per Section 4 of Guidelines and Hand Book for Institutional Biosafety Committees, the Institutional Biosafety Committee is reconstituted with following members and is hereby notified;

1. **Vice Chancellor** — **Chairman**
   Yenepoya (Deemed to be University)

2. **Dr. R.C.Koumar** — **Member**
   Associate Professor
   Yenepoya Research Centre

3. **Dr. Prashanth Kumar Modi** — **Member**
   Sr. Scientific Officer
   Yenepoya Research Centre

4. **Dr. Suparna Laha** — **Member**
   Assistant Professor
   Yenepoya Research Centre

5. **Dr. Raghu bhushan** — **Member**
   Assistant Professor
   Yenepoya Research Centre

6. **Dr. Rouchelle Tellis** — **Member**
   Associate Professor
   Department of Microbiology
   Yenepoya Medical College
   Mangalore.

..2

ATTESTED

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

7. **Dr. Irfan. K.** — **Biosafety Officer**
   Associate Professor
   Department of Respiratory Medicine
   Yenepoya Medical College

8. **Dr. Chandrakala Shenoy** — **DBT Nominee**
   Professor
   Department of Biosciences
   Mangalore University
   Mangalore.

9. **Dr. Shrikala Baliga** — **External Expert**
   Professor,
   Dept. of Microbiology
   K.M.C. Mangalore.

10. **Dr. Sudheer Shenoy P** — **Member Secretary**
    Associate Professor
    Yenepoya Research Centre
    Yenepoya University

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

To:

The members concerned.

Cc to:
All the Statutory Officers
Principals of all the constituent colleges
IQAC, Academics, YRC

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

IBGM File

भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
बायोटेक्नोलॉजी विभाग
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

सत्यमेव जयते

स्वच्छ भारत
एक कदम स्वच्छता की ओर

ब्लाक-2, 7वां तल, सी0 जी0 ओ0 कम्प्लेक्स
लोधी रोड, नई दिल्ली-110003
Block-2, 7th Floor, C.G.O. Complex
Lodhi Road, New Delhi-110003

23/05/2019

Office of Vice - Chancellor
Desp. No.: 1087
Date: 23/5/19

BT/BS/17/635/2015-PID Dated: 30.04.2019

OFFICE MEMORANDUM

Subject: Nomination of DBT representative in the IBSC of **YENEPOYA (Deemed to be University), Mangalore.**

In accordance with the Notification of the Ministry of Environment and Forests vide Gazette Notification No. GSR 1037 (E) dated 05.12.1989, notified under the E.P. Act 1986, the Department of Biotechnology (DBT) had evolved the "Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017" for achieving for personnel and environmental safety in the use of genetically manipulated organisms in research, manufacture and applications. The constitution of the Institutional Biosafety Committee (IBSC) is mandatory in R&D Centres at the institutions/ universities/ industries/ any other organization which intend to carry out or are engaged in research activities involving genetic manipulation of genetic materials, microorganisms, plants or animals.

2. In conformity with the above, institutions engaged in genetic engineering research have constituted their IBSCs and the department has nominated its representatives in all such committees. Accordingly, **Prof. Chandrakala Shenoy K., Deptt. of Biosciences, Mangalore University, Mangalagangothri – 574 199 (Karnataka),** has been nominated to act as a DBT representative in the IBSC constituted at **Yenepoya (Deemed to be University), University Road, Deralakatte, Mangalore.**

The complete composition of the IBSC is as under:

Chairman	:	Prof. M. Vijayakumar, Vice Chancellor, YENEPOYA, Mangalore
DBT Nominee	:	Prof. Chandrakala Shenoy K., Deptt. of Biosciences, Mangalore University, Mangalagangothri
Member Secretary	:	Dr. Sudheer Shenoy P., Associate Professor, YENEPOYA, Mangalore
Outside Expert(s)	:	Dr. Shrikala Baliga, Professor, Div. of Microbiology, Kasturba Medical College, Manipal
Biosafety Officer	:	Dr. Irfan K., Associate Professor, Respiratory Medicine, Yenepoya Medical College, Mangalore
Internal Member (s)	:	Dr. R. C. Koumar, Associate Professor, YENEPOYA, Mangalore
	:	Dr. Prashanth Kumar Modi, Sr. Scientific Officer, YENEPOYA, Mangalore
	:	Dr. Suparna Laha, Assistant Professor, YENEPOYA, Mangalore
	:	Dr. Raghu Bhushan, Assistant Professor, YENEPOYA, Mangalore

3. The DBT nominee serves as the link between the department and the respective IBSC. The nominee should ensure that:

- the committee has been constituted as per the norms of the guidelines.
- the Recombinant DNA Safety Guidelines are strictly followed in the company.
- the IBSC meets regularly (at least twice in a year) to review the ongoing activities and provide yearly reports to RCGM/ DBT in the prescribed *proforma*.
- all the activities within the purview of the guidelines are in the knowledge of RCGM/DBT and to guide the IBSC on biosafety issues.
- the IBSC will follow the 'Simplified Procedures/ Guidelines on Exchange (inter-state and inter-institutional supply/ receipt within India), Import and Export of Genetically Engineered Organism and Product(s) thereof for Research Purpose', as per the Department's OM Nos. BT/BS/17/635/2015/PID dated 22.09.2015 and dated 01.04.2018.

-Contd.

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

Noted

Vice Chancellor
(Deemed to be University)

4. **He/she will work for 3 years on the respective committee. On the expiry of term of nominee, institution/ organizations are required to reconstitute its IBSC in prescribed *proforma*.**

5. The DBT, on the expiry of the term of its nominee shall re-nominate or appoint a new nominee, and such nomination shall be communicated to the institutes/ organizations.

6. Any special invitee/s to IBSC should be communicated to RCGM/ or taken prior approval.

7. **The IBSC of the institution will meet at least twice in a year. The institutes having the IBSC are required to submit yearly report of progress (1st January to 31st December) within one month, following the expiry of the period of Progress Report to the DBT for enabling the proper monitoring and consolidation of this information by the RCGM and the Government. The DBT nominee may visit the R & D facility of the institute periodically, and interact with investigators involved in rDNA research/activities with hazardous microorganisms. Such visits undertaken are duly recorded in Annual Report of IBSC.**

8. The university will meet the TA/DA & honorarium to the DBT nominee as per the GOI norms.

(S. R. Rao)
Sr. Advisor/Scientist-'H', DBT &
Member Secretary, RCGM

To,

Prof. M. Vijayakumar,
Chairman – IBSC, Vice Chancellor
Yenepoya (Deemed to be University),
University Road, Deralakatte,
Mangalore – 575 018 (Karnataka)

Copy to:

1. Prof. Chandrakala Shenoy K., Depeartment of Biosciences, Mangalore University, Mangalagangothri – 574199 (Karnataka). (Kindly access website i.e. http://www.dbtindia.nic.in/guidelines/guidelines-for-biosafety/ for IBSC Guidelines & role of DBT nominee).
2. Dr. Sudheer Shenoy P., Member Secretary-IBSC & Associate Professor, Yenepoya (Deemed to be University), University Road, Deralakatte, Mangalore.
3. Office Copy
4. Guard file

(S. R. Rao)
Sr. Advisor/Scientist-'H', DBT &
Member Secretary, RCGM

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

No BT/IBKP/227/2020 Dated: 01-May-2020

OFFICE MEMORANDUM

Subject : Nomination of DBT representative in the IBSC of **Yenepoya (Deemed to be) University (YENEPOYA-773), Mangalore.**

1. In accordance with the Notification of the Ministry of Environment and Forests vide Gazette Notification No. GSR 1037 (E) dated 05.12.1989, notified under the E.P. Act 1986, the Department of Biotechnology (DBT) had evolved the "Regulations and Guidelines on Biosafety of recombinant DNA Research and Bio containment, 2017 " for achieving personnel and environmental safety in the use of genetically manipulated organisms in research, manufacture and applications. The constitution of the Institutional Biosafety Committee (IBSC) is mandatory in R&D Centers at the institutions/ universities/ industries/ any other organization which intends to carry out or are engaged in research activities involving genetic manipulation of genetic materials, microorganisms, plants or animals.

2. In conformity with the above, institutions engaged in genetic engineering research constitute their IBSCs and the department nominate its representatives in all such committees. Accordingly, **Dr CHANDRAKALA SHENOY, Professor, Mangalore University, Mangalore, KARNATAKA**has been nominated to act as a DBT representative in the IBSC constituted at **Yenepoya (Deemed to be) University (YENEPOYA-773) , Yenepoya University, University Road, Derlakatte,, University Road, Derlakatte, Dakshina Kannada, KARNATAKA-575018 .**

   The complete composition of the IBSC is as under:

Chairman	:	Dr M. Vijayakumar, Chairman, Mangalore, KARNATAKA
DBT Nominee	:	Dr CHANDRAKALA SHENOY, Professor, Mangalore University, Mangalore, KARNATAKA
Member Secretary	:	Dr Sudheer Shenoy P, Member Secretary, Mangalore, KARNATAKA
Outside Experts	:	Dr Srikala Baliga, Outside Expert, Mangalore, KARNATAKA
Biosafety Officer	:	Dr Irfan Khan, Biosafety Officer, Mangalore, KARNATAKA
Internal Experts	:	Dr Prachant Modi, Internal Member, Mangalore, KARNATAKA## Dr R.C.Koumar, Internal Member, Mangalore, KARNATAKA## Dr Raghubhushan, Internal Member, Mangalore, KARNATAKA## Dr Rouchelle Tellis, Internal Member, Mangalore, KARNATAKA## Dr Suparna Laha, Internal Member, Mangalore, KARNATAKA

3. The DBT nominee serves as the link between the department and the respective IBSC. The nominee should ensure that:

   - the committee has been constituted as per the norms of the guidelines,
   - the Recombinant DNA Safety Guidelines are strictly followed in the company,
   - the IBSC meets regularly (at least twice in a year) to review the ongoing activities and provide yearly reports to RCGM/ DBT in the prescribed proforma,
   - all the activities within the purview of the guidelines are in the knowledge of RCGM/DBT and to guide the IBSC on biosafety issues.
   - the IBSC will follow the 'Simplified Procedures/ Guidelines on Exchange (inter-state and inter- institutional supply/ receipt within India), Import and Export of Genetically Engineered Organism and Product(s) thereof for research Purpose', as per the Department's OM dated 22-09-2015.

4. **He/she will work for 3 years on the respective committee. On the expiry of term of nominee, institution/ organizations are required to reconstitute its IBSC in prescribed proforma.**

5. The DBT, on the expiry of the term of its nominee shall re-nominate or appoint a new nominee, and such nomination shall be communicated to the institutes/ organizations.

6. Any special invitee/s to IBSC should be communicated to RCGM/ or taken prior approval.

7. **The IBSC of the institution will meet at least twice in a year. The institutes having the IBSC are required to submit yearly report of progress (1st January to 31st December) within one month, following the expiry of the period of Progress Report to the DBT for enabling the proper monitoring and consolidation of this information by the RCGM and the Government.**

8. The institute will meet the TA/DA & honorarium to the DBT nominee as per the GOI norms.

Member Secretary,
RCGM, DBT

To
Dr M. Vijayakumar, Chairman, Mangalore, KARNATAKA

Copy to:
1. Office Copy
2. Guard file
3. Dr CHANDRAKALA SHENOY, Professor, Mangalore University, Mangalore, KARNATAKA
4. Dr Irfan Khan, Biosafety Officer, Mangalore, KARNATAKA

Member Secretary,
RCGM, DBT
डॉ. नितिन कुमार जैन / Dr. NITIN K. JAIN
वैज्ञानिक 'एफ' / Scientist 'F'
बायोटेक्नोलॉजी विभाग / Deptt. of Biotechnology
विज्ञान और प्रोद्यो. मंत्रालय / M... of S&T
भारत सरकार, नई दिल्ली / Govt. of India, N. Delhi

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

YENEPOYA

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

Members of the:

Stem Cell Research Committee

ATTESTED

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

YENEPOYA

Ref: No. YU/REG/ACA/001/Stem Cell/2018 08.06.2018

NOTIFICATION

Sub: Reconstitution of Stem Cell Research Committee

*****

Stem Cell Research Committee of Yenepoya (Deemed to be University) is reconstituted in accordance with the Guidelines of ICMR (DHR) and DBT 2017 for the period of 3 years with the following members

Sl. No.	Name	IC-SCR Designation
1.	Prof.P. B. Sheshagiri Professor, Department of Molecular Reproduction, Development and Genetics, Indian Institute of Science (IISc.), Bangalore, India	Chairman
2.	Dr. Mohan Wani Scientist 'F', National Centre for Cell Science, Pune, India	Vice chairman/ Stem Cell Expert
3.	Dr. Smita Sudheer Assistant Professor, Department of Genomic Science Central University of Kerala, Kerala, India	Stem Cell Expert
4.	Dr. Anirban Chakraborty Professor, Nitte University Centre for Science Education and Research, Paneer campus, Mangalore, India.	Molecular Biology Expert
5.	Dr. G. Bhanuprakash Reddy Scientist 'F', National Institute of Nutrition (NIN), Hyderabad, India	Molecular Biology Expert
6.	Dr. Suresh P. S. Assistant Professor, Department of Biosciences, Mangalore University	Molecular Biology Expert
7.	Mr. Ranjan Rao Lawyer in Mangalore District; Private Practice	Legal Expert
8.	Dr. Sheetal Ullal Associate Prof. Dept of Pharmacology, KMC, Mangalore	Ethics Expert
9.	Dr. Rameela Shekhar Dean, School of Social work, Roshni Nilaya, Mangalore, India	Social Scientist
10.	Mr. Pushparaj Accounts Officer, MESCOM Corporate office, MESCOM Bhavana, Kavoor cross road, Bejai, Mangalore.	Layman
11.	Mr. Isllyas Saqafi	Religious Expert
12.	Dr. Raghu Bhushan Assistant Professor, Yenepoya Research Centre, Yenepoya (Deemed to be University), Mangalore, India.	Member Secretary

ATTESTED

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

(Dr. G. Shreekumar Menon)
REGISTRAR

Copy to:

The Chairperson & all other members

University Road, Deralakatte, Mangalore-575018
T: +91 824 220 4676 / 4668 /4669 / 4671/ 2192 / 2193 F : +91 824 220 4667 E : reachus@yenepoya.org
www.yenepoya.edu.in

National Apex Committee for Stem Cell Research and Therapy
Department of Health Research
Ministry of Health and Family Welfare
Government of India

File No. 83/1(135)/2017-NAC-SCRT/BMS
1st January 2020

The Registrar,
Yenepoya (Deemed to be University),
University Road, Deralakatte,
Mangalore- 575018
Karnataka

Subject: Registration of IC-SCR of Yenepoya (Deemed to be University), Mangalore with the NAC-SCRT

Madam/Sir,

This has reference to your application for registration of the Institutional Committee for Stem Cell Research (IC-SCR). After review of the application and supporting documents submitted by you, the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) hereby registers the IC-SCR of Yenepoya (Deemed to be University), Mangalore. Your registration number is NAC-SCRT/135/20191609, which must be quoted in all future communications.

The IC-SCR is registered ***ONLY FOR BASIC RESEARCH USING STEM CELLS*** as defined in the National Guidelines for Stem Cell Research-2017. For documentary purposes, the institution has to give an undertaking/self declaration from authorized personnel that no stem cell clinical trial or therapy is being undertaken at the institution.

However, as and when clinical trials are to be initiated, the submission and subsequent review of the following documents by NAC-SCRT should be ensured, mandatorily, prior to initiation of the trial:

a. CDSCO certification for the GLP and GMP facility
b. Clinical trial approvals from IC-SCR, IEC and CDSCO
c. CTRI registration

The registration is valid for a period of three years (01.01.2020 to 31.12.2023) subject to compliance with National Guidelines for Stem Cell Research and fulfilment of the terms and conditions given overleaf.

Kindly note that the registration of IC-SCR should not be quoted as certification/recognition/accreditation from Government of India.

I take this opportunity to thank you for your interest in stem cell research.

To YRC

Yours faithfully,

(Dr. Vijay Kumar)
Member Secretary

Copy to: Member Secretary, IC-SCR, Yenepoya (Deemed to be University), Mangalore.

Registrar
YENEPOYA
Deemed to be University

Secretariat, ICMR Headquarters, V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110029
Telefax: +91- 11 - 26589791 Email: nacscrt.pg@icmr.gov.in

Office of the Registrar
Yenepoya (Deemed to be University)
Despatch No. 8122
Despatch Date: 6/1/20

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

Terms and Conditions:

1. The IC-SCR shall review and approved stem cell research proposals from the institutional on scientific and ethical merits.
2. The IC-SCR shall ensure that the research conducted under its ambit is scientific, ethical, and in compliance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) and National Guidelines for Stem Cell Research-2017 and all relevant regulations.
3. The IC-SCR shall maintain a record of human embryonic stem (hES) cell lines developed/imported/procured by the institute and should notify the same to NAC-SCRT.
4. The IC-SCR shall maintain a registry of all investigators in the institution working in the field of stem cell research and ensure that those engaged in clinical trials have adequate training in good Clinical Practices (GCP).
5. The IC-SCR shall submit annual report to the NAC-SCRT.
6. The Head of the institute shall allow representatives of the NAC-SCRT/ regulatory authorities to enter its premises to inspect any record, data or any documents related to IC-SCR and provide adequate clarifications/explanation to the queries raised, if any.
7. The IC-SCR shall inform the NAC-SCRT in writing when there is any change in the constitution of IC-SCR or the category of stem cell research being conducted at the institute.
8. The IC-SCR shall keep a record of severe adverse events/adverse events (SAEs/AEs), if any, and report the same to the NAC-SCRT.
9. The investigators working in the field of stem cell research and members of IC-SCR should be conversant with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), National Guidelines for Stem Cell Research-2017 and all applicable regulations.
10. The IC-SCR members will conduct a site visit routinely to review the infrastructure of the investigator's laboratory.
11. The members of IC-SCR should declare their Conflict of Interest (COI), if any, and the same should be recorded in the minutes of the IC-SCR meeting.

If the institution or the IC-SCR fails to comply with the National Guidelines for Stem Cell Research-2017 and any of the foregoing conditions of registration, as amended from time to time, the NAC-SCRT may suspend or cancel the registration of the IC-SCR for such a period as considered necessary.

ATTESTED

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