KLE Academy of Higher Education & Research

(Deemed-to-be-University)

[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No. F.9 -19/2000-U.3 (A)]

Accredited 'A' Grade by NAAC (2nd Cycle)

Placed in Category 'A' by MHRD (GoI)

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
Deemed-to-be-University u/s 3 of the UGC Act, 1956)


# Syllabus for Ph.D.

# Research Scholars in Health Sciences and Inter-Disciplinary areas

## (Pre-Ph.D. Examination)

## 2016 Onwards

**Edition Year : 2019-20**



**Director, Academic Affairs**
Email: diracademic@kledeemeduniversity.edu.in

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**VISION**

To be an outstanding University of excellence ever in pursuit of newer horizons to build self reliant global citizens through assured quality educational programs.

**MISSION**

- To promote sustainable development of higher education consistent with statutory and regulatory requirements.
- To plan continuously provide necessary infrastructure, learning resources required for quality education and innovations.
- To stimulate and to extend the frontiers of knowledge, through faculty development and continuing education programs.
- To make research a significant activity involving staff, students and society.
- To promote industry / organization, interaction/collaborations with regional/national / international bodies.
- To establish healthy systems for communication among all stakeholders for vision oriented growth.
- To fulfill the national obligation through rural health missions.

**OBJECTIVES**

The objectives are to realize the following at university and its constituent institutions:

- To implement effectively the programs through creativity and innovation in teaching, learning and evaluation.
- To make existing programs more career oriented through effective system of review and redesign of curriculum.
- To impart spirit of enquiry and scientific temperament among students through research oriented activities.
- To enhance reading and learning capabilities among faculty and students and inculcate sense of life long learning.
- To promulgate process for effective, continuous, objective oriented student performance evaluation.
- To ordinate periodic performance evaluation of the faculty.
- To incorporate themes to build values. Civic responsibilities & sense of national integrity.
- To ensure that the academic, career and personal counseling are in-built into the system of curriculum delivery.
- To strengthen, develop and implement staff and student welfare programs.
- To adopt and implement principles of participation, transparency and accountability in governance of academic and administrative activities.
- To constantly display sensitivity and respond to changing educational, social, and community demands.
- To promote public-private partnership.

## [I] PREAMBLE:

KLE University is determined to encourage quality research in different disciplines of Health Sciences, keeping in view the global requirements of health care, with national needs as the focal point.

The Doctor of Philosophy (Ph.D.) Program in Health Sciences and Inter-disciplinary area (wherein one of the disciplines shall be health sciences) is proposed with an objective of promoting the cause of quality research in thrust or priority areas. The UGC expects from Deemed Universities activities related to research, development, extension and consultation, all being aimed at attaining academic excellence.

The infrastructure facilities and human resources available at the KLE University health science institutions shall be effectively utilized for promoting quality research in health sciences and inter-disciplinary areas. To facilitate interdisciplinary research, a Dean and separate Board of Studies has been constituted.

## [II] AIMS & OBJECTIVES OF THE Ph.D. PROGRAMME

- To gain expertise and knowledge in a specialized field of research.
- Design, implement & report a research project.

## III. DISCIPLINES:

Admission to Ph.D. program will be made under the following faculties, covering a wide spectrum of disciplines:

## I. FACULTY OF MEDICINE:

**A) Pre-Clinical:**
- Anatomy
- Physiology
- Biochemistry



**B) Para-Clinical:**
- Pharmacology
- Pathology
- Microbiology
- Forensic Medicine
- Community Medicine

**C) Clinical:**

Medicine and Allied Subjects:
- Medicine
- Paediatrics
- Pulmonary Medicine
- Dermatology
- Psychiatry

Surgery and Allied Subjects:
- Surgery
- Orthopaedics
- ENT & Head & Neck Surgery (HNS)
- Ophthalmology

Obstetrics & Gynaecology, Anaesthesiology and Radiology:
- Obstetrics & Gynaecology
- Anaesthesiology
- Radiology

**D) Superspecialities:**
- Cardiovascular and Thoracic Surgery
- Urology
- Plastic Surgery
- Cardiology
- Neurology
- Neurosurgery
- Paediatric Surgery

**Other Disciplines of Health Sciences:**

- Hospital Administration
- Public Health

**E) Medical Education**

**II. FACULTY OF DENTISTRY:**

**A) Pre-Clinical:**

- Dental Anatomy & Oral Histology
- Dental Material

**B) Clinical:**

- Prosthodontics
- Orthodontics
- Periodontics
- Oral Surgery
- Pedodontics
- Oral Diagnosis and Radiology
- Conservative Dentistry
- Community Dentistry
- Oral Pathology and Microbiology

**III. FACULTY OF PHARMACEUTICAL SCIENCES:**
All subjects of Pharmaceutical Sciences

**IV. FACULTY OF AYURVEDA:**
All subjects of Ayurvedic Sciences

**V. FACULTY OF NURSING:**
All subjects of Nursing Sciences

**VI. FACULTY OF PHYSIOTHERAPY:**
All subjects of Physiotherapy

**VII. FACULTY OF SCIENCE (Inter-disciplinary Studies / Research) (Involving Health Sciences) which also includes:**

- Biostatistics, M.Sc., M.Lib., Masters in Physical Education

**VIII. BASIC MEDICAL SCIENCES.**



## PRE-Ph.D. EXAMINATION
**(Based on UGC Guidelines, 2016)**

i) The candidates admitted to Ph.D. Programme shall have to appear for Pre-Ph.D. examination.

ii) Pre-Ph.D. examination shall be conducted after one year from the date of registration.

iii) The Controller of Examinations shall conduct the Pre-Ph.D. examination. The registration of such candidates, who do not pass the Pre-Ph.D. examination in five consecutive attempts from the date of registration, shall be cancelled.

iv) The Pre-Ph.D. examination for all the faculties shall consist of examination in three theory papers. The first two papers of three hours duration with 100 marks each and biostatistics paper is of two hours with 50 marks. The common paper (Paper I) shall be on the topics covered in the syllabus for orientation programme as described under course work of 300 hours. The paper two shall be on the topics related to the research discipline of the candidate. The biostatistics paper (Paper III) on the topics covered in the syllabus for the orientation programme of 150 hours as described. The syllabi for the papers shall be notified by the Dean and Director Academic Affairs with the approval of Vice-Chancellor. The Examiner appointed by Vice-Chancellor shall set the common paper and special paper and biostatistics paper. The two Examiners appointed by Vice-Chancellor shall evaluate the papers and the average of the two will be taken into consideration.

v) The minimum pass marks of all the 3 papers shall be 55 %. If the candidate fails in a paper he or she has to appear only in that paper.

# Ph.D. ORIENTATION PROGRAMME

## PAPER – I (Research & Research Methodology)
## Theory: 180 hrs *(Credits: 6)*;
## Practicals: 120 hrs (*Credits: 2)*

**1. Introduction to Ph. D Programme:** **Th: 10hrs**

Introduction to the course, course objectives, Open House Discussion, timely submission of Half yearly Reports & Synopsis submission, publication and submission of articles.

National Knowledge Commission, National Assessment and Accreditation Council (NAAC) & University Grant Commission (UGC).

**2. Historical Perspectives:** **Th: 15hrs**

Historical narration about conduct of research on human subject, Biblical times, research on vulnerable population, tackling of ethical issues in the past century. Ethical code, Nuremberg code, Helsinki declaration, Belmont principles in conduct of research in human subject.

**3. Ethical Issues in Research:** **Th: 40hrs**

Background, general principles on ethical considerations involving human participants, general ethical issues, Ethical Review Committee – need, relevance and working, rules & regulations as applicable in India. Ethical Review Procedures, IRB. Principles for clinical evaluation of drugs/ devices/diagnostics/vaccines/ herbal remedies. Informed Consent Process – Preparing an informed consent for a research project.

**4. Approach to Research in Health Science: Th: 16 hrs;Pr: 25hrs**

Research protocol development.

Research Methodology – Defining research questions/



Hypothesis, Study designs - cross sectional study, case control study and randomized clinical trials.

Clinical Trials – Introduction, composition, procedures & records, Informed consent, responsibility & rules applicable to investigators and sponsors, reporting of adverse events and other related ethical issues.

**5. Grant Writing :** **Th: 5 hrs; Pr: 8 hrs**

Introduction, specific aims, review of literature, measures, methodology, study plan and statistical analysis. Protection of human participants, proposed budget and time line for the proposal. Serious Adverse Effects, Pre-Clinical Research / Translational Research.

Information regarding National /International organizations to avail research grants.

Patents and Intellectual Property Rights.

**6. Manuscript Writing:** **Th: 5 hrs**

Writing a scientific manuscript, structured writing and language editing, writing respondents & presentation, impact factor, plagiarism, bibliography, referencing & citations, Good Clinical Practices (GCP) and safety.

Hands-on workshop on writing abstracts and manuscripts.

**7. Critical Appraisal of Article Published in Scientific Journal: Th: 6 hrs; Pr: 16 hrs**

What is critical appraisal and why critical appraisal, present scenario of scientific publications, methodology of critical appraisal, format for critical appraisal.

**8. Thesis Writing:** **Th: 5 hrs**

Introduction to thesis writing, prescribed format for thesis writing, seminar presentations, preparation for Viva-Voce & communication skills.

9. **Health care delivery systems in India:** **Th: 8 hrs**

National Population Policy.

National Health Policy.

National Rural Health Mission (NRHM program).

RCH program.

Current Health Problems.

Environment & health related challenges of India.

Non Communicable Diseases.

Biomedical waste management.

Emerging and re-emerging infectious diseases in the world and in India.

Population explosion causes and its impact.

10. **Online Certificate Course on "Health Research Fundamentals" by ICMR:** **Pr: 5 hrs**

11. **Attending Ph.D. 6-monthly presentations:** **Th: 50 hrs**

12. **Visit to Regional Medical Research Centre (RMRC), Belagavi:** **Pr: 18 hrs**

13. **Visit to Basic Science Research Centre (BSRC):** **Pr: 18 hrs**

14. **Library Hours for Self Study:** **50 hrs**



## Paper II (Syllabus related to Research Discipline)

**Theory: 60 hrs (*Credits: 2*);**

**Practicals: 120 hrs (*Credits: 2*)**

1. **Topics related to research discipline: Th: 60 hrs; Pr: 30 hrs**

Topics related to the research discipline of the candidate and the research supervisors are required to submit the detailed syllabus to the Office of the Academic Affairs within three months of the registration of the candidate.

2. **Attending Discipline-related Workshops/CMEs/Seminars/ Conferences:** **Pr: 35 hrs**

3. **Attending Ph.D. Open House Seminars:** **Pr: 25 hrs**

4. **Attending Ph.D. Open Defence Viva:** **Pr: 30 hrs**

## Paper III (Biostatistics)

**Theory: 90 hrs *(Credits: 3)*;**

**Practicals: 60 hrs *(Credits: 1)***

**Basic Statistics:**

1. Introduction to Bio-statistics, translating research problem into hypothesis, hypothesis testing, Type I & Type II errors in statistics, checking errors in data and correcting them.
2. Study designs & sample size estimation, sampling techniques, methods in statistical inference, sampling distribution.
3. Types of variables and types of data measurements scales, Data Collection methods & Scrutiny, presentation & organization of data – Tabular / Graphical Form, Analysis of quantitative, qualitative & categorical data.
4. Sampling Designs, Descriptive Statistics - Measures of central tendency & measures of dispersion, Correlation Analysis, Regression Analysis, Probability Theory - Binominal distribution, Poisson distribution, normal distribution, concept of testing of hypothesis.
5. Test of Significance- Parametric tests-Z test, T test, ANOVA and Non Parametric tests- Chi- Square test, Wilcoxson Rank test, Kruskal Wallis test.
6. Devising conclusion from data analysis.
7. Use of computers, statistical software's, data cleaning.



### SCHEME OF PRE-Ph.D. Examination

**Paper – I:** All topics covered in the syllabus for orientation programme as described under course work of 300 hours.

**Paper – II:** The topics related to the research of the candidate.

**Paper – III:** Biostatistics: The topics covered in the syllabus for orientation programme as described under course work of 150 hours.



### PATTERN OF QUESTION PAPERS

**Paper I & II** shall be of 3 hours duration with 100 marks each. Both papers shall contain 2 long questions of 20 marks each and 6 questions of 10 marks each. The candidate has to attempt all the questions. **Paper III** shall be of 2 hours duration of 50 marks. The paper shall contain 2 long questions of 10 marks each and 5 short questions of 6 marks each.

The candidate has to score minimum of 55 % marks in each paper for being declared as pass.

Two Examiners appointed by Vice-Chancellor shall evaluate the papers and the average of the two will be taken into consideration.

A Ph.D. scholar has to obtain a minimum of 55% or its equivalent grade in the UGC 7-points scale (or an equivalent grade/ CGPA in a point scale wherever grading system is followed) in the course work in order to be eligible to continue the programme and submit the thesis, as depicted in the table below:

**Letter Grade and Grade Point equivalent to marks in percentage and performance**

| Marks Obtained (%) | Grade Point | Grade | Performance |
|---|---|---|---|
| 91.00-100.00 | 10 | O | Outstanding |
| 81.00-90.99 | 9 | A+ | Excellent |
| 71.00-80.99 | 8 | A | Good |
| 61.00-70.99 | 7 | B | Average |
| 55.00-60.99 | 6 | P | Pass |
| Less than 55 | 00 | F | Fail |
| Absent | 00 | F | Fail |

If the candidate fails in a paper, he/she has to re-appear only in that paper.

# Ordinance Governing

# 4th Professional BAMS
# Bachelor of Ayurvedic Medicine and Surgery

## Syllabus/Curriculum

# 2017-18

EMPOWERING PROFESSIONALS

KLE
ACADEMY OF HIGHER EDUCATION AND RESEARCH
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www.kleuniversity.edu.in info@kleuniversity.edu.in

Ref.No.KLEU/MF-2/18-19/D-2161 13th November 2018

# NOTIFICATION

**Sub: Ordinance governing the syllabus/curriculum of 4th Year/Profession BAMS (Revised Scheme).**

Ref: Minutes of the meeting of the Academic Council of the University held on 24th September 2018.

In exercise of the powers conferred under Rule A-04 (i) of the Memorandum of Association of the University, the Academic Council of the University in its meeting held on **24th SEPTEMBER 2018** has approved the Ordinance governing the syllabus / curriculum for **4Th Professional BAMS** program of revised scheme.

The Ordinance shall be effective for the students admitted to **4Th Professional BAMS** program (revised scheme) under the Faculty of Ayurveda in the constituent college of the University viz. **KAHER Shri B. M. Kankanawadi Ayurveda Mahavidyalaya, Belagavi** applicable to 2015, 2016 and 2027 batches from the academic session 2017-18.

By Order

REGISTRAR

To

The Dean
Faculty of Ayurveda,
BELAGAVI.

CCto:

1. The Secretary, University Grants Commission, New Delhi
2. The PA to Hon. Chancellor, KAHER, Belagavi
3. The Special Officer to Hon. Vice-Chancellor, KAHER, Belagavi
4. All Officers of the KAHER, Academic Affairs / Examination Branch.
5. The Principal. KLEU. Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya Belagavi.

# CONTENTS

# RESEARCH METHODOLOGY AND MEDICAL STATISTICS

**AIMS**

Providing basic knowledge about research methodology, biostatistics and its need and importance in present trend of Ayurveda. To ignite the young minds with the research vision at primary level so that the hidden potential of Ayurveda science can be explored and put forth of present evidence based medicine era. Initiative effort to accomplish the vision of Tradition, Technology and Innovation in the field of Ayurveda.

**OBJECTIVES**

By the end of 4th profession the students should have basic knowledge about the methods of research and biostatistics.

**Knowledge:**

- The literal meaning of word research and its implication in Ayurveda
- Brief historical background of research in Ayurved and contemporary medical science Evidences of researches in ayurvedic classics
- Types of Research
- Research process
- Research tools
- The concept and importance of ethics in research
- Concept of Evidence Based Medicine and Scientific Writing
- Importance of IT in data mining and important research data portals concerned with Ayurved and contemporary medical science
- Definition, scope and importance of the Medical statistics
- Collection and Presentation of data
- Measures of location, central tendency.
- Variability and its measurement
- Introduction to probability and test of significance Parametric tests and non-parametric tests
- Introduction to commonly used statistical soft-wares.

**Skills:**

- To make capable of applying different research designs for different studies
- Skill of using particular statistical test for particular data
- Journal browing skills and keep them updated about the happenings in the field of Ayurveda
- Making eligible to read, understand and write the different articles in different journals

**Attitude:**

- Research oriented attitude towards the concepts of Ayurveda
- Evidence based practice
- Proper documentation and its importance
- Exploring the hidden potentials of Ayurveda through modern technology

# RESEARCH METHODOLOGY

| THEORY: 1 Paper (50 Mark) | Teaching Hours (Each 1 Hour): 50 Hours |
|---|---|

**Part- A**

**30 Marks** — **30 Hours**

| Sl.No | Topic | Hours |
|---|---|---|
| 1 | Brief historical background of research in Ayurved and contemporary medical science Evidences of researches in ayurvedic classics | 2 Hours |
| 2 | Etymology, definitions and synonyms (Anveshana, Gaveshana, Prayeshana, Anusandhan and Shodha) of the word Research | 2 Hours |
| 3 | Research in Ayurved - Scope, need, importance, utility | 2 Hours |
| 4 | Types of Research (familiarization of the terms)<br>a) Pure and Applied<br>b) Qualitative, Quantitative and Mixed Observational and interventional. | 5 Hours |
| 5 | Research process (Importance of each steps in brief)<br>a. Selection of the topic<br>b. Review of the literature<br>c. Formulation of Hypothesis<br>d Aims and Objectives<br>e. Materials and methods<br>f. Observations and results<br>g. Methods of communication of Research | 10 Hours |
| 6 | Research tools – Role of the pramanas as research tools | 2 Hours |
| 7 | The concept and importance of ethics in research | 2 Hours |
| 8 | Concept of Evidence Based Medicine and Scientific Writing | 2 Hours |
| 9 | Importance of IT in data mining and important research data portals concerned with Ayurved and contemporary medical science (DHARA, PubMed, Ayush Research Portal, Bioinformatics Center, Research Management Informatic System etc.) | 3 Hours |

## MEDICAL STATISTICS

**Part- B**

**20 Marks** — **20 Hours**

| | | |
|---|---|---|
| 1 | Definition, scope and importance of the Medical statistics | 1 Hour |
| | Common statistical terms and notations<br>a. Population<br>b. Sample<br>c. Data<br>d. Variable<br>e. Normal distribution | 1 Hour |
| 2 | Collection, Types and Presentation of data<br>a. Tabular<br>b. Graphical<br>c. Diagrammatical | 2 Hours |
| 3 | Measures of location<br>a. Average | 1 Hour |

| | | |
|---|---|---|
| | b. Percentile | |
| 4 | Measures of Central Tendency<br>a. Arithmetic mean<br>b. Median<br>c. Mode | 2 Hours |
| 5 | Variability and its measurement<br>a. Range<br>b. Standard deviation<br>c. Standard error | 2 Hours |
| 6 | Introduction to probability and test of significance<br>Parametric tests<br>and non parametric tests | 10 Hours |
| 7 | Introduction to commonly used statistical soft-wares. | 1 Hour |

**REFERENCE BOOKS:**

| Research Methodology | | | |
|---|---|---|---|
| **Sl.No** | **Text Book** | **Author** | **Publisher** |
| 1. | Practical Research Methods | Dawson, Catherine, | New Delhi, UBS Publishers' Distributors 2002 |
| 2. | Research Methodology-Methods and Techniques | Kothari, C .R. | New Delhi, Wiley Eastern Limited 1985. |
| 3. | Research Methodology-A Step-by-Step Guide for Beginners | Kumar, Ranjit | (2nd.ed), Singapore, Pearson Education 2005 |
| 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 |
| **Medical Statistics** | | | |
| 6. | Health research methodology. A guide for training in research methods. | | 2nd edition.Manila, World Health Organization Regional Office for the Western Pacific, 2001. |
| 7. | Statistical methods in medical research. | P.Armitage | (Ed) Oxoford Blackwell |
| 8. | Statistical methods | Snedecor GW and Cochran, WG | |
| 9. | .. Practical statistics for medical research | Altman, D. G.(1991) | London: Chapman Principles of Medical Statistics by A. Bradford Hill |
| 10. | Interpretation and Uses of Medical | by Leslie E Daly, | |

| | | | |
|---|---|---|---|
| | Statistics | Geoffrey J Bourke, James MC Gilvray | |
| 11. | Research in Ayurveda | M S Baghel | |
| 12. | Research methodlogy in Ayurveda | V.J.Thakar | Gujarat Ayurved University |
| 13. | Ayurveda anusandhan paddhati | P.V.Sharma | |
| 14. | Research methodology methods and statistical techniques | Santosh Gupta. Greenhouse SW. | |
| 15. | The growth and future of biostatistics: (A view from the 1980s). Statistics in Medicine2003; 22:3323–3335 | | |
| 16. | Clinical epidemiology and Biostatistics | Knapp GR Miller MC | NMS series |
| 17. | Biostatistics : Principles and practice | Antonisamy B, C hristopher S Samuel PP. | |
| 18. | An introduction to Biostatistics | Sundara Rao PSS & Richard J. | PHI |
| 19. | Senn S (1997)Statistical Issues in Drug Development | Chichester: John Wiley Sons | |
| 20. | Methods in Bio-statistics for Medical Students | BK Mahajan | |
| 21. | Vaidyakeeya Sankhiki Shastra | - Dr.S.S.Savrikar | |
| 22. | Research Methodology & Medical Biostatistics | Dr. Dhulappa Mehatre | Chaukhambha Prakashan |

| Sl. No | Particulars | Details | Internal distribution (Sub distribution) | Marks distribution |
|---|---|---|---|---|
| 01 | **Records** *** | 20 & 05 Practicals conducted in CRF & Animal house. + 10 Medical Statistics related numericals. | | |
| 02 | **Procedure of any two practicals in CRF** | Writing two procedures among given set of preparations in detail **with values obtained.** | 10 Marks for each preparation. 10X2=20 | 20 |
| 03 | **Instruments** | Identification of instruments with its uses. | 10X01 regimen=10 | 10 |
| 04 | **Spotting** | Specimens present in CRF | Each specimen/Model carries 02 Marks. 2X10specimen=20 Marks | 20 |

| | | | | |
|---|---|---|---|---|
| 05 | **Stat related problem** | Selection of data and its interpretation | Any parametric/non-parametric data creation = 05 Marks, Analyasing the data with proper statistical tests = 15 | 20 |
| 06 | **Viva Voce** | Grand Viva | Part A -15 Marks<br>Part B- 15 Marks | 30 |
| **Total** | | | | **100** |

# Ordinance Governing

# Regulations & Syllabus of Post Graduate Course in Ayurveda M.D/M.S-Ayurveda Part-I

## Syllabus/Curriculum

## 2018-19

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# Ordinance Governing

# Regulations & Syllabus of Post Graduate Course in Ayurveda M.D/M.S-Ayurveda Part-I

## Syllabus/Curriculum

## 2018 - 19

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# KLE UNIVERSITY

**(Formerly known as KLE Academy of Higher Education & Research)**

[Established under Section 3 of the UGC Act, 1956 vide Government of India Notification No. F. 9-19/2000-U.3(A)]

Office of the Registrar, KLE University,

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**Web: http:// www.kleuniversity.edu.in E-mail: info@kleuniversity.edu.in**

**Ph: 0831-2444444/2493779 Fax : 0831-2493777**


Ref.No.KLEU/MF-2/18-19/D-564 2nd June 2018

## NOTIFICATION

**Sub: Ordinance governing the syllabus/curriculum for Post Graduate Degree in Ayurveda & M.D/M.S (Ayurveda ) Part-1 (Revised Scheme).**

Ref: Minutes of the meeting of the Academic Council of the University held on 16th March 2018

In exercise of the powers conferred under Rule A-04 (i) of the Memorandum of Association of the University, the Academic Council of the University is pleased to approve the Ordinance governing the syllabus /Curriculum for **Post Graduate Degree in Ayurveda & M.D/M.S (Ayurveda) Part-1** in its meeting held on 16th March 2018

The Ordinance shall be effective for the students admitted to **Post Graduate Degree in Ayurveda & M.D/M.S (Ayurveda ) Part-1** program (revised scheme) under the Faculty of Ayurveda in the constituent college of the University viz. **KLEU Shri B. M. Kankanawadi Ayurveda Mahavidyalaya, Belagavi** applicable to 2018, 2019 and 2020 batches from the academic session 2018-19.

By Order,

REGISTRAR

To
The Dean
Faculty of Ayurveda,
BELAGAVI.

CC to:

1. The Secretary, University Grants Commission, New Delhi
2. The PA to Hon. Chancellor, KLE University, Belagavi
3. The Special Officer to Hon. Vice-Chancellor, KLE University, Belagavi
4. All Officers of the University, Academic Affairs / Examination Branch.
5. ThePrincipal.KLEU.Shri.B.M.KankanawadiAyurvedaMahavidyalaya.Belag

## CONTENTS

## SYLLABUS

| Name Of The Subject : RESEARCH METHODOLOGY and MEDICAL STATISTICS | |
|---|---|
| Theory-200 Hours | Practical-200 Hours |
| Theory- 100 Marks | Practical-100 Marks |

**Part- A**

**Marks-60 RESEARCH METHODOLOGY 120 Hours**

| Unit | Topic | Hours |
|---|---|---|
| 1 | **Introduction to Research**<br>A. Definition of the term research<br>B. Definition of the term anusandhan<br>C. Need of research in the field of Ayurveda | 3 hr |
| 2 | **General guidelines and steps in the research process**<br>A. Selection of the research problem<br>B. Literature review: different methods (including computer database) with their advantages and limitations<br>C. Defining research problem and formulation of hypothesis<br>D. Defining general and specific objectives<br>E. Research design: observational and interventional, descriptive and analytical, preclinical and clinical, qualitative and quantitative<br>F. Sample design<br>G. Collection of the data<br>H. Analysis of data.<br>I. Generalization and interpretation, evaluation and assessment of Hypothesis.<br>J. Ethical aspects related to human and animal experimentation.<br>K. Information about Institutional Ethics Committee (IEC) and Animal Ethics Committee (AEC) and their functions. Procedure to obtain clearance from respective committees, including filling up of the consent forms and information sheets and publication ethics. | 18 hrs |
| 3 | Preparation of research proposals in different disciplines for submission to funding agencies taking EMR-AYUSH scheme as a model. Preparation of dummy EMR proposal (Detailed Project Report, Protocol, Budget & Timelines) | 5 hrs |
| 4. | **Scientific writing and publication skills.**<br>a. Familiarization with publication guidelines- Journal specific and CONSORT guidelines.<br>b. Different types of referencing and bibliography.<br>c. Thesis/Dissertation: contents and structure<br>d. Research articles structuring: Introduction, Methods, Results and Discussions (IMRAD)<br>e. Journal Author guidelines, Indexed Journal, Citation, Impact Factor | 5 hrs |

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| 5 | **Classical Methods of Research.**<br>Concept of Pratyakshadi Pramana Pariksha, their types and application for Research in Ayurveda.<br>Dravya, Guna, Karma Parikshana Paddhati<br>Aushadhi-yog Parikshana Paddhati<br>Swastha, Atura Pariksha Paddhati<br>Dashvidha Parikshya Bhava<br>Tadvidya sambhasha, vadmarga and tantrayukti | 10 hrs |
| 6 | Comparison between methods of research in Ayurveda (Pratigya, Hetu, Udaharana, Upanaya, Nigaman) and contemporary methods in health sciences. | 3 hr |
| 7. | **Different fields of Research in Ayurveda**<br>**Fundamental research on concepts of Ayurveda**<br>a. Panchamahabhuta and tridosha.<br>b. Concepts of rasa, guna, virya, vipak, prabhav and karma<br>c. Concept of prakriti-saradi bhava, ojas, srotas, agni, aam and koshtha. | 6 hrs |
| 8. | **Literary Research**<br>Introduction to manuscriptology: Definition and scope. Collection, conservation, cataloguing.<br>Data mining techniques, searching methods for new literature; search of new concepts in the available literature. Methods for searching internal and external evidences about authors, concepts and development of particular body of knowledge | 8 hrs |
| 9. | **Drug Research (Laboratory-based)**<br>Basic knowledge of the following:<br>Drug sources: plant, animal and mineral. Methods of drug identification.<br>Quality control and standardization aspects:<br>Basic knowledge of Pharmacopoeial standards and parameters as set by Ayurvedic Pharmacopoeia of India.<br>Information on WHO guidelines for standardization of herbal preparations.<br>Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP). | 20 hrs |
| 10. | **Safety aspects**<br>Protocols for assessing acute, sub-acute and chronic toxicity studies.<br>Familiarization with AYUSH guidelines (Rule 170), CDCSO and OECD guidelines. | 5 hrs |
| 11. | **Introduction to latest Trends in Drug Discovery and Drug Development**<br>-Brief information on the traditional drug discovery process<br>-Brief information on the latest trends in the Drug Discovery process through employment of rational approach techniques; anti-sense approach, use of micro and macro-arrays, cell culture based | 10 hrs |

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| | assays, use of concepts of systems biology and network physiology<br>-Brief introduction to the process of Drug development | |
| 12. | **Clinical research**<br>Introduction to Clinical Research Methodology identifying the priority areas of Ayurveda<br>Basic knowledge of the following:-<br>Observational and Interventional studies<br>Descriptive & Analytical studies<br>Longitudinal & Cross sectional studies<br>Prospective & Retrospectives studies<br>Cohort studies<br>Randomized Controlled Trials (RCT) & their types<br>Single-case design, case control studies, ethnographic studies, black box design, cross-over design, factorial design.<br>Errors and bias in research.<br>New concepts in clinical trial- Adaptive clinical trials/ Good clinical practices (GCP)<br>Phases of Clinical studies: 0,1,2,3, and 4.<br>Survey studies -<br>Methodology, types, utility and analysis of Qualitative Research methods. Concepts of in-depth interview and Focus Group Discussion. | 18 hrs |
| 13. | Pharmacovigilance for ASU drugs. Need, scope and aims & objectives. National Pharmacovigilance Programme for ASU drugs. | 3 hrs |
| 14. | Introduction to bioinformatics, scope of bioinformatics, role of computers in biology. Introduction to Data base- Pub med, Medlar and Scopus. Accession of databases. | 3 hrs |
| 15. | Intellectual property rights – different aspects and steps in patenting. Information on traditional knowledge digital library. | 3 hrs |

**Part- B**
**MEDICAL STATISTICS**

**Marks-40** **Hours – 80**

| Unit | Topic | Hrs |
|---|---|---|
| 1. | **Definition of Statistics** - Concepts, relevance and general applications of Biostatistics in Ayurveda | 3 hr |
| 2. | **Collection, classification, presentation, analysis and interpretation of data** (Definition, utility and methods) | 5 hr |
| 3. | **Scales of Measurements** - nominal, ordinal, interval and ratio scales. | 3 hr |
| 4. | **Types of variables** – Continuous, discrete, dependent and independent variables. | 3 hr |
| 5. | **Type of series** – Simple, Continuous and Discrete | 2 hr |
| 6. | **Measures of Central tendency** – Mean, Median and Mode. | 5 hrs |
| 7. | **Variability:** Types and measures of variability – Range, Quartile deviation, Percentile, Mean deviation and Standard deviation | 5 hrs |

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|---|---|---|
| | Interquartile range, coefficient of variation | |
| 8. | **Probability**: Definitions, types and laws of probability, | 3 hrs |
| 9. | **Normal distribution**: Concept and Properties, Sampling distribution, Standard Error, Confidence Interval and its application in interpretation of results and normal probability curve. | 4 hrs |
| 10. | **Fundamentals of testing of hypotheses:** | |
| | a. Null and alternate hypotheses, type I and type 2 errors.<br>b. Tests of significance: Parametric and Non-Parametric tests, level of significance and power of the test, 'P' value and its interpretation, statistical significance and clinical significance | 2 hrs<br>6 hrs |
| 11. | **Univariate analysis of categorical data:** | |
| | Confidence interval of incidence and prevalence, Odds ratio, relative risk and Risk difference, and their confidence intervals<br>Introduction to Meta analysis | 6 hrs |
| 12. | **Parametric tests:** 'Z' test, Student's 't' test: paired and unpaired, 'F' test, Analysis of variance (ANOVA) test, repeated measures analysis of variance | 6 hrs |
| 13. | **Non parametric methods:** Chi-square test, Fisher's exact test, McNemar's test, Wilcoxon test, Mann-Whitney U test, Kruskall – Wallis with relevant post hoc tests (Dunn) | 8 hrs |
| 14. | **Correlation and regression analysis:** | |
| | a. Concept, properties, computation and applications of correlation, Simple linear correlation, Karl Pearson's correlation co-efficient, Spearman's rank correlation.<br>b. Regression- simple and multiple. | 5 hr |
| 15. | **Sampling and Sample size computation for Ayurvedic research:** | |
| | Population and sample. Advantages of sampling, Random (Probability) and non random (Non-probability) sampling. Merits of random sampling. Random sampling methods- simple random, stratified, systematic, cluster and multiphase sampling. Concept, logic and requirement of sample size computation, computation of sample size for comparing two means, two proportions, estimating mean and proportions. | 6 hrs |
| 30 | **Vital statistics and Demography**: computation and applications - Rate, Ratio, Proportion, Mortality and fertility rates, Attack rate and hospital-related statistics | 4 hr |
| 31 | **Familiarization with the use of Statistical software** like SPSS/Graph Pad | 4 hr |

| PRACTICAL:<br>RESEARCH METHODOLOGY<br>Marks - 50 Hours-120 | | |
|---|---|---|
| **Unit** | **Topic** | **Hours** |
| 1. | **Pharmaceutical Chemistry**<br>Familiarization and demonstration of common lab instruments for carrying out analysis as per API | 20 hrs |
| 2. | **Awareness of Chromatographic Techniques**<br>Demonstration or Video clips of following:<br>• Thin-layer chromatography (TLC)<br>• Column chromatography (CC)<br>• Flash chromatography (FC)<br>• High-performance thin-layer chromatography (HPTLC)<br>• High Performance (Pressure) Liquid Chromatography (HPLC)<br>• Gas Chromatography (GC, GLC) | 28 hrs |
| 3. | **Pharmacognosy**<br>Drug identification as per API including organoleptic evaluation | 6 hrs |
| 4. | 4. **Pharmacology and toxicology**<br>Familiarization and Demonstration of different techniques related to:<br>• Pharmacology and toxicology<br>• Drug administration techniques- oral and parenteral.<br>• Blood collection by orbital plexuses puncturing.<br>• Techniques of anesthesia and euthanasia.<br>• Information about different types of laboratory animals used in experimental research | 20 hrs |
| 5. | **Biochemistry (Clinical)**<br>Familiarization and demonstration of techniques related to<br>• Basic instruments used in a clinical biochemistry laboratory – semi and fully automated clinical analyzers, electrolyte analyzer, ELISA-techniques, nephelometry<br>• Demonstration of blood sugar estimation, HbA1C<br>• Lipid profiles<br>• Kidney function test<br>• Liver function test<br>• Cystatin and microalbumin estimation by nephelometry or other suitable techniques<br>• Interpretation of the results obtained in the light of the data on normal values | 20 hrs |
| 6. | **Clinical Pathology**<br>Familiarization and demonstration of techniques related to<br>• Basic and advanced instruments used in a basic clinical pathology lab<br>• Auto cell counter- urine analyzer-ESR-microscopic examination of urine | 16 hrs |

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| 7. | **Imaging Sciences**<br>Familiarization and demonstration of techniques related to the<br>• Imaging techniques<br>• Video film demonstration of CT-Scan MRI-scan- and PET-scan | 08 hrs |
| 8. | **Clinical protocol development** | 02 hrs |

| **PRACTICAL:**<br>**MEDICAL STATISTICS**<br>**Marks - 50** | | **Hours-80** |
|---|---|---|
| **Unit** | **Topic**<br>Exercises on the Problems related to following Topics | **Hrs** |
| 1. | **Collection, classification, presentation, analysis and interpretation of data** (Definition, utility and methods) | 5 hrs |
| 2. | **Types of variables** – Continuous, discrete, dependent and independent variables. | 5 hrs |
| 3. | **Type of series** – Simple, Continuous and Discrete | 5 hrs |
| 4. | **Measures of Central tendency** – Mean, Median and Mode. | 5 hrs |
| 5. | **Variability:** Types and measures of variability – Range, Quartile deviation, Percentile, Mean deviation and Standard deviation | 5 hrs |
| 6. | **Probability**: Definitions, types and laws of probability | 5 hrs |
| 7. | **Normal distribution**: Concept and Properties, Sampling distribution, Standard Error, Confidence Interval and its application in interpretation of results and normal probability curve. | 5 hrs |
| 8. | **Fundamentals of testing of hypotheses**<br>• Null and alternate hypotheses, type I and type 2 errors.<br>• Tests of significance: Parametric and Non-Parametric tests, level of significance and power of the test, 'P' value and its interpretation, statistical significance and clinical significance | 5 hrs |
| 9. | **Univariate analysis of categorical data:** Confidence interval of incidence and prevalence, Odds ratio, relative risk and Risk difference, and their confidence intervals | 9 hrs |
| 10. | **Parametric tests**<br>• 'Z' test<br>• Student's 't' test: paired and unpaired<br>• 'F' test<br>• Analysis of variance (ANOVA) test<br>• Repeated measures analysis of variance | 10 hrs |
| 11. | **Non parametric methods**<br>• Chi-square test<br>• Fisher's exact test | 8 hrs |

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|---|---|---|
| | • McNemar's test<br>• Wilcoxon test<br>• Mann-Whitney U test<br>• Kruskall – Wallis with relevant post hoc tests (Dunn) | |
| 12. | **Correlation and regression analysis**<br>Concept, properties, computation and applications of correlation, Simple linear correlation, Karl Pearson's correlation co-efficient, Spearman's rank correlation. Regression- simple and multiple. | 4 hrs |
| 13. | **Sampling and Sample size computation for Ayurvedic research**<br>• Population and sample<br>• Advantages of sampling<br>• Random (Probability) and non-random (Non-probability) sampling.<br>• Merits of random sampling.<br>• Random sampling methods- simple random, stratified, systematic, cluster and multiphase sampling.<br>• Concept, logic and requirement of sample size computation<br>• Computation of sample size for comparing two means, two proportions<br>• Estimating mean and proportions. | 8 hrs |
| 14. | **Vital statistics and Demography:** computation and applications - Rate, Ratio, Proportion, Mortality and fertility rates, Attack rate and hospital-related statistics | 2 hrs |
| 15. | **Familiarization with the use of Statistical software** like SPSS/Graph Pad | 4 hrs |

**RESEARCH METHODOLOGY & MEDICAL STATISTICS** **Practical Marks: 100**

| Sl no | Particulars | Details | Marks distribution |
|---|---|---|---|
| 01 | **Records** *** | 20 & 05 Practicals conducted in CRF & Animal house.<br>+ 10 Medical Statistics related numericals. | ---- |
| 02 | **Procedure of any two practicals** | **Procedure of any two practicals in CRF**<br>Writing two procedures among given set of preparations in detail **with values obtained.** | 20 |
| 03 | **Instruments** | Identification of instruments with its uses. | 10 |
| 04 | **Spotting** | Specimens present in CRF<br>(10 Specimens) | 20 |
| 05 | **Stat related problem** | Selection of data and its interpretation | 20 |
| 06 | **Viva Voce** | Part A -15 Marks<br>Part B- 15 Marks | 30 |
| | **Total** | | **100** |

**REFERENCE BOOKS:**

**Pharmacognosy:**

| No | Name of Authors/commentrators | Title of the book | Edition | Name of the publisher |
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| 1 | Aushotosh Kar | "Pharmacognosy & Pharmacobiotechnology" | | New Age International Publisher. Latest Edition. New Delhi |
| 2 | Mayaram Uniyal | Drug Survey | 3 | Pergamon Press, Oxford |
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| 4 | Kokate, CK., Khandelwal and Gokhale, SB | Practical Pharmacognosy | 19 | Nirali Prakashan. Pune |
| 5 | Trease G E and Evans W C | Pharinacognosy | 15 | Saunders Publishers |
| 6 | Tyler V C., Brady, L R., and Robers J E., | Pharmacognosy, | | Lea and Febiger, Philadelphia |
| 7 | Tyler VE Jr and Schwarting AE., | Experimental Pharmacognosy | | Burgess Pub. Co, Minneaplis, Minnesota |
| 8 | Wallis- TE (2011)- | Practical Pharmacgonosy | 4 | Pharma Med Press, Hyderabad |
| 9 | Wallis T E, | Analytical Microscopy, | | J & A Churchill limited, London |
| 10 | Wallis T E | Text Book of Pharmacognosy | 5 | CBS Publications and Distributors |
| 11 | Geneva. | WHO guidelines on good agricultural and collection practices- (GACP) for medicinal plants (2003).World Health Organization | | |
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**Pharmaceutical chemistry, quality control and drug standardization**

| No | Name of Authors/commentrators | Title of the book | Latest edition | Name of the publisher |
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| 2 | Brain, KR and Turner, TD. (1975). | The Practical Evaluation Phytopharmaceuticals. | | Wright Scienctechnica, Bristol |
| 3 | Galen Wood Ewing | Instrumental Methods of Chemical Analysis | 5 | McGraw-Hill College ; |
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| 6 | Indian Journal of Traditional Knwoledge. 9(3): 562-575 | Kapoor, RC (2010). Some observations on the metal based preparations in Indian System of Medicine | | |
| 7 | Khopkar, S. M. | Analytical Chemistry, | | New Age International Publishers , 3 rd edition |
| 8 | Lavekar G S | Laboratory Guide for- The Analysis of Ayurved and Siddha Formulations | 1 | CCRAS, New Delhi |
| 9 | Mahadik KR, Bothara K G. | Principles of Chromatography by, | 1 | Nirali Prakashan |
| 10 | Qadry JS and Qadry S Z | Text book of Inorganic Pharmaceutical and Medicinal Chemistry | | , B. S. Shah Prakashan, Ahmedabad. |
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| 12 | Rangari V.D., | Pharmacognosy & Phytochemistry, Vol I, II, | | Career Publication |
| 13 | Sharma B.K. | Instrumental Methods of | | Goel Publishing |

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**Biochemistry and Laboratory techniques:**

| No | Name of Authors/commentrators | Title of the book | Latest edition | Name of the publisher |
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| 4 | David Sultan. | Text book of Radiology and Imaging, Vol-1 | 7 | Churchill Living Stone |
| 5 | Deb, A.C | Fundamentals of Biochemistry Books and Allied | (P) Ltd, 2002 | |
| 6 | Harold Varley. | Practical Clinical Biochemistry | | |
| 7 | Kanai L.Mukherjee. | Clinical Pathology: Medical Laboratory Technology Vol. I | 20 | TATA McGraw Hill Publishing Company Limited |
| 8 | GradWohl, | Clinical Laboratory-methods and diagnosis, Vol-I | | |
| 9 | Sabitri Sanyal, Clinical Pathology, B.I.Churchill Livingstone (P) Ltd, New Delhi.2000. | Clinical Biochemistry | | |
| 10 | Satyanarayanan,U. | Essentials of Biochemistry, Books and allied(P) Ltd.2002 | 2 | Books and Allied (P)Ltd |
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| | | Ayurvedic Samhitas and other texts | | |
| **Drug research and development:** | | | | |
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| 9 | http://www.oecd.org/document/63/0,2340,en_2649_34381_2346175_1_1_1_1,00.html OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring, 1998. | | | |
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# 2016

## THE MASTER OF PHARMACY (M. PHARM.)

# COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11, 2014)

# SCHEME AND SYLLABUS

**PHARMACY COUNCIL OF INDIA**
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

## Table of Contents

2 Ethics in Clinical Research: 12 Hrs

- Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
    - Ethical principles governing informed consent process
    - Patient Information Sheet and Informed Consent Form
    - The informed consent process and documentation

3 Regulations governing Clinical Trials 12 Hrs

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

## Semester III

## MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

## Semester III

## MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

## 4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

**Theory : 2 Hrs. /Week**

**1. Detailed syllabus and lecture wise schedule**

**1 Research Methodology**

a) Types of clinical study designs:
Case studies, observational studies, interventional studies,

b) Designing the methodology

c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d) Report writing and presentation of data

**2 Biostatistics**

2.1 a) Introduction

b) Types of data distribution

c) Measures describing the central tendency distributions- average, median, mode

d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

**2.2 Data graphics**

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

**2.3 Basics of testing hypothesis**

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)

c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.

e) Introduction to statistical software: SPSS, Epi Info, SAS.

**2.4 Statistical methods in epidemiology**

Incidence and prevalence, relative risk, attributable risk

**3. Computer applications in pharmacy**

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

**Reference books:**

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.

b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

## 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 type, 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

**Introduction to Research:** Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

**Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

**Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

**Unit-IV** **8 Hours**

Blocking and confounding system for Two-level factorials

**Regression modeling:** Hypothesis testing in Simple and Multiple regressionmodels

**Introduction to Practical components of Industrial and Clinical Trials Problems:** Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

**Unit-V** **7Hours**

**Design and Analysis of experiments:**

**Factorial Design:** Definition, $2^2$, $2^3$design. Advantage of factorial design

**Response Surface methodology**: Central composite design, Historical design, Optimization Techniques

**Recommended Books (Latest edition):**


1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

# *Ph.D. ORIENTATION PROGRAMME*

**PAPER – I (Research)**

## 1. Introduction to Ph. D Programme:

Introduction to the course, course objectives, Open House Discussion, timely submission of Half yearly Reports & Synopsis submission, publication and submission of articles.

National Knowledge Commission, National Assessment and Accreditation Council (NAAC) & University Grant Commission (UGC)

## 2. Historical Perspectives:

Historical narration about conduct of research on human subject, Biblical times, research on vulnerable population, tackling of ethical issues in the past century. Ethical code, Nuremberg code, Helsinki declaration, Belmont principles in conduct of research in human subject.

## 3. Ethical Issues in Research:

Background, general principles on ethical considerations involving human participants, general ethical issues, Ethical Review Committee – need, relevance and working rules & regulations as applicable in India. Ethical Review Procedures, IRB. Principles for clinical evaluation of drugs/ devices/diagnostics/vaccines/ herbal remedies. Informed Consent Process – Preparing an informed consent for a research project.

## 4. Approach to Research in Health Science:

Research protocol development

Research Methodology – Defining research questions/Hypothesis, Study designs - cross sectional study, case control study and randomized clinical trials.

Clinical Trials – Introduction, composition, procedures & records, Informed consent, responsibility & rules applicable to investigators and sponsors, reporting of adverse events and other related ethical issues.

Good Clinical Practices (GCP) and safety, Good Laboratory Practices (GLP).

## 5. Grant Writing :

Introduction, specific aims, review of literature, measures, methodology, study plan and statistical analysis. Protection of human participants, proposed budget and time line for the proposal. Pre-Clinical Research / Translational Research

Information regarding National /International organization to avail research grants

Patents and Intellectual Property/Rights

**6. Manuscript Writing**:

Writing a scientific manuscript, structured writing and language editing, writing respondents & presentation, impact factor, plagiarism, bibliography, referencing & citations, **7. Critical Appraisal of Article Published in Scientific Journal**:

What is critical appraisal and why critical appraisal, present scenario of scientific publications, methodology of critical appraisal, format for critical appraisal

**8. Thesis Writing:**

Introduction to thesis writing, prescribed format for thesis writing, seminar presentations, preparation for Viva-Voce & communication skills.

**9. Health care delivery systems in India:**

National Population Policy.

National Health Policy.

National Rural Health Mission (NRHM program).

RCH program.

Current Health Problems.

Environment & health related challenges of India.

Non Communicable Diseases

Biomedical waste management

Emerging and re-emerging infectious diseases in the world and in India.

Population explosion causes and its impact.

**10. Scientific Conduct**

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

Legal aspects of research

**11. Publication Ethics**

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 contributor shipIdentification of publication misconduct, complaints and appeals, Predatory publishers and journals

**12 Open Access Publishing**

Open access publications and initiatives, SHERPA/ROMEO online resource to check policies publisher copyright & self-archiving

Software tool to identify predatory publications developed by SPPU Journal finder /journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.

Critical appraisal of published literature

**13.Publication Misconduct**

Subject specific ethical issues, FFP, authorship, Conflicts of interest, Complaints and appeals: examples and fraud from India and abroad

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

**14. Databases And Research Metrics**

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

Impact Factor of journal as per Journal Citation Report. SNIP, SJR, IPP, CiteScore

Metrics: h-index, g index, il0 index, altrmetrics

**15. Online Certificate Course on "Health Research Fundamental" by ICMR:**

**16. Attending Ph.D. 6-monthly presentations**: (Atleast 25 presentations)

**17. Visit to Regional Medical Research Centre (RMRC), Belagavi:**

**18. Visit to Basic Science Research Centre (BSRC):**

**19. Library Hours for Self Study:**

**Paper II (Syllabus related to Research Discipline)**

**Theory: 60 hrs (*Credits: 2*); Practicals: 120 hrs (*Credits: 2*)**

**1. Topics related to research discipline:**

The paper II shall be on the topics related to the research discipline of the candidate and the research supervisors are required to submit the detailed syllabus to the Office of the Academic Affairs within three months of the registration of the candidate.

**2. Attending Discipline-related Workshops/CMEs/Seminars/Conferences:**

**3. Attending Ph.D. Open House Seminars: ( Atleast 15 )**

**4. Attending Ph.D. Open Defence Viva: ( Atleast 15 )**

**Paper III (Biostatistics )**

1. Introduction to Bio-statistics, translating research problem into hypothesis, hypothesis testing, Type I & Type II errors in statistics, checking errors in data and correcting them.

2. Sample size calculation for different study designs.

3. Types of variables and types of data measurements scales, Data Collection methods, presentation & organization of data – Tabular / Graphical Form.

4. Sampling Designs, Descriptive Statistics - Measures of central tendency & measures of dispersion, Correlation Analysis, Regression Analysis, Probability Theory - Binominal distribution, Poisson distribution, normal distribution, concept of testing of hypothesis.

5. Test of Significance- Parametric tests-Z test, T test, ANOVA and Non Parametric tests- Chi-Square test, Wilcoxson Rank test, Kruskal Wallis test.

6. Devising conclusion from data analysis.

7. Use of computers, statistical software's, data cleaning.

KLE ACADEMY OF HIGHER EDUCATION & RESEARCH, BELAGAVI

# KLE College of Pharmacy

*(Re-Accredited by NAAC, NBA – AICTE,PCI New Delhi)*

[Declared as Deemed-to-be-University under section 3 of the UGC Act, 1956 vide Government of India Notification No. F.9-19/2000-U.3(A)]

P.B.No. 1062, 2nd Block, Rajajinagar, Bengaluru - 560 010, Karnataka, India.

☎ 080-23325611 FAX No.: 080-23425373 Web :http://www.kleblrpharm.orgE-mail:princpharmblr@kledeemeduniversity.edu.in

## RESEARCH METHODOLOGY WITH COURSE ON RESEARCH ETHICS

KLE College of Pharmacy, Bengaluru is committed to academic and research excellence, offering undergraduate, postgraduate and Ph.D. programmes. The faculty members are actively involved in various research activities. The Institution with a view to promote and encourage research, provides good infrastructure for conduct of research with total space area of 1,821.43sq.ft. which includes Basic Science Research Centre (BSRC), Animal house, Herbal garden and Pilot plant.

The Institutional follows Research ethics, by providing guideline for the responsible conduct of research. In addition, it educates and monitors faculties and research scholars to ensure high ethical standards in research.

The following are the ethical principles in research methodology:-

1. To ensure that no fabrication/misrepresentation of report data, results, methods and procedures and publication status of research work.
2. Strive to avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing and other aspects of research.
3. Critical examination of research activities to avoid errors.
4. To respect Intellectual properties and never plagiarize.
5. Protect confidential communications, such as papers or grants submitted for publication.
6. To obey relevant Institutional rules and Government policies.
7. To conduct animal experimentations as per guidelines framed by institutional ethical committee.
8. To make research a significant activity involving staff, students and society.

Principal
KLE College of Pharmacy
Bengaluru-560 010

# INSTITUTE OF PHYSIOTHERAPY

A Constituent Unit of

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(Formerly known as KLE University)

(Deemed –to-be-University established u/s 3 of the UGC Act, 1956)

Accredited 'A+' Grade by NAAC (3rd Cycle) Placed in Category 'A' by MHRD (GoI)

JNMC CAMPUS, NEHRU NAGAR, BELAGAVI – 590010, KARNATAKA STATE, INDIA

☎ Office -0831-2473906, Fax – 0831 -2474727 email: principalkipt@gmail.com, Web: klekipt.edu.in


Ref. No/KAHER/ KIPT/ Date: 09/10/2023

**CIRCULAR**

This is to inform to all the Interns of 2023 – 24 regular batch that, the Institution Research Committee is organizing a workshop on **"Research Methodology"** on **17th October 2023 from 9am to 5pm** in Presentation Room – 7a at KLE Institute of Physiotherapy, Belagavi. Attendance is mandatory for the same.

Incharge Research Committee
KLE Institute of Physiotherapy,
Belagavi

Principal
KLE Institute of Physiotherapy,
Belagavi

KLE ACADEMY OF HIGHER EDUCATION & RESEARCH INSTITUTE OF PHYSIOTHERAPY ★ BELAGAVI

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NEHRU NAGAR, BELAGAVI – 590010, KARNATAKA, INDIA

☎ Office -0831-2473906, Fax – 0831 -2474727 email: principalkipt@gmail.com Web: klekipt.edu.in


Ref. No/KAHER/ KIPT/23-24/

Date: 17/10/2023

**RESEARCH METHODOLOGY WORKSHOP FOR INTERNS REGULAR BATCH 2023 – 24**

**Resource person for the workshop:**

| Sl. No | Topic | Staff Alloted | Time |
|---|---|---|---|
| 1. | Framing the title of research proposal/ protocol Overview of IJPTR | Dr. Santosh Metgud<br>Dr. Pamela D'silva | 9:15am – 9:45am |
| 2. | Framing a research question and hypothesis | Dr. Apeksha Hungund | 9:45am – 10:00am |
| 3. | Sampling Design | Dr. Varsha Huddar | 10:00am – 10:30am |
| 4. | Review of Literature | Dr. Anand Hegganavar | 10:30am – 11:00am |
| 5. | Outcome measures in physiotherapy | Dr. Mehreen Bandmaster | 11:00am – 11:30am |
| 6. | Informed consent | Dr. Renu Pattanshetty | 11:30am – 12:00pm |
| 7. | Research design | Dr. Aarti Welling | 12:00pm – 12:30 pm |
| 8. | Contents of synopsis writing | Dr. Vinuta Deshpande | 12:30 pm – 1:00pm |
| **LUNCH BREAK** | | | |
| 9. | Data collection | Dr. Deepti Bagewadi | 2:30pm – 3:00pm |
| 10. | Data analysis and overview of SPSS software | Dr. Sushil Kumar | 3:00pm – 3:30pm |
| 11. | Contents of Manuscript writing | Dr. Arati Mahishale | 3:30pm – 4:00pm |
| 12. | Reference writing | Dr. Dhaval Chivate | 4:00pm – 4:30pm |

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Ref. No/KAHER/ KIPT/23-24/ Date: 17/10/2023

The schedule for "**Research Methodology**" Workshop **17.10.2023**

| Sl. No. | Topic | Staff Allotted | Signature |
|---|---|---|---|
| 1. | Framing the title of research proposal/ protocol<br>Overview of IJPTR | Dr. Santosh Metgud | |
| | | Dr. Pamela D'silva | |
| 2. | Framing a research question and hypothesis | Dr. Apeksha Hungund | |
| 3. | Sampling Design | Dr. Varsha Huddar | |
| 4. | Contents of Manuscript writing | Dr. Arati Mahishale | |
| 5. | Review of Literature | Dr. Anand Hegganavar | |
| 6. | Outcome measures in physiotherapy | Dr. Mehreen Bandmaster | |
| 7. | Research design | Dr. Aarti Welling | |
| 8. | Informed consent | Dr. Renu Pattanshetty | |
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| 10. | Data collection | Dr. Deepti Bagewadi | |
| 11. | Data analysis and overview of SPSS software | Dr. Sushil Kumar | |
| 12. | Reference writing | Dr. Dhaval Chivate | |

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Ref. No/KAHER/ KIPT/23-24/ Date: 17/10/2023

**Research Methodology Workshop for Interns Regular Batch 2023 – 24**

| Sl. No | Register No | Name of Candidates | Morning | Afternoon |
|---|---|---|---|---|
| 1 | LA0119003 | Ms. Akanksha Suresh Desai | | |
| 2 | LA0119007 | Mr. Anurag Mukul Pai Raiturkar | | |
| 3 | LA0119008 | Mr. Anvekar Saiesh Shyam | | |
| 4 | LA0119009 | Ms. Apurva Atul Paidarkar | | |
| 5 | LA0119011 | Ms. Ashwini V Nippani | | |
| 6 | LA0119012 | Ms. Avantika A Patil | | |
| 7 | LA0119013 | Ms. Bagwan Saniya Mansoor Ali | | |
| 8 | LA0119014 | Ms. Bali Deepshikha Girish | | |
| 9 | LA0119015 | Ms. Bhalekar Radhika Vinayak | | |
| 10 | LA0119016 | Ms. Bhavsar Renuka Rajesh | | |
| 11 | LA0119017 | Ms. Bibibatul M Patvegar | | |
| 12 | LA0119018 | Mr. Delano Nicholas Fernandes | | |
| 13 | LA0119019 | Ms. Deshpanade Mrunmayi Milind | | |
| 14 | LA0119021 | Ms. Emberly Fernandes | | |
| 15 | LA0119022 | Mr. Govind Mukesh Sharma | | |
| 16 | LA0119023 | Ms. Grace Poojari | | |
| 17 | LA0119024 | Ms. Harshita Patil | | |
| 18 | LA0119025 | Ms. Hazel Felix Dsouza | | |
| 19 | LA0119026 | Ms. Heeda A Sanadi | | |
| 20 | LA0119028 | Ms. Isha Shah | | |
| 21 | LA0119029 | Ms. Isheta Kimberly Cardoso | | |
| 22 | LA0119030 | Mr. Jadhav Kaustubh Maheshkumar | | |
| 23 | LA0119032 | Ms. Jenisha Rajendra Dalal | | |
| 24 | LA0119033 | Ms. Joshi Vedashri Vivek | | |
| 25 | LA0119034 | Ms. Kalsekar Pranali Dhananjay | | |
| 26 | LA0119036 | Ms. Kavya S Bharbhari | | |
| 27 | LA0119037 | Ms. Khanolkar Radhika Jitendra | | |
| 28 | LA0119038 | Ms. Kothari Bhavana | | |
| 29 | LA0119039 | Mr. Kottur Srinivas Vijaykumar | | |
| 30 | LA0119040 | Ms. Krupa Jagadeesh Metgud | | |
| 31 | LA0119042 | Mr. Kugatoli Adarsh Shivanand | | |
| 32 | LA0119043 | Ms. Kulkarni Anushka Amit | | |
| 33 | LA0119047 | Ms. Mansi A Herekar | | |
| 34 | LA0119048 | Ms. Mascarenhas Rasilia Marlien | | |
| 35 | LA0119050 | Ms. Mugdha Vijaykumar Pendse | | |
| 36 | LA0119051 | Mr. Nabil Khan | | |
| 37 | LA0119052 | Ms. Naik Reena Devidas | | |

| | | | | |
|---|---|---|---|---|
| 38 | LA0119054 | Ms. Needa Munaf Shaikh | | |
| 39 | LA0119055 | Ms. Niharika Ramesh Sunagad | | |
| 40 | LA0119056 | Mr. Nikhil Hadgal | | |
| 41 | LA0119057 | Mr. Niranjan Ghatage | | |
| 42 | LA0119058 | Mr. Nouman Rahmatullah Chajju | | |
| 43 | LA0119059 | Ms. Palmate Shraddha Raju | | |
| 44 | LA0119060 | Ms. Parab Ankita Ashok | | |
| 45 | LA0119061 | Ms. Pathak Arya Jitendra | | |
| 46 | LA0119062 | Ms. Patil Pranjal Satish | | |
| 47 | LA0119063 | Mr. MD Rehan Zakir Hussain Tankasali | MD. Rehan | MD. Rehan |
| 48 | LA0119064 | Ms. Patil Gauri Prakash | | |
| 49 | LA0119065 | Ms. Prachi Bajaj | | |
| 50 | LA0119066 | Mr. Prasad Premanand Rane | | |
| 51 | LA0119067 | Ms. Rakshita Vijay Shiroorkar | | |
| 52 | LA0119068 | Ms. Raveena M Mathapati | | |
| 53 | LA0119069 | Ms. Reeya Nakuldas Sawant | | |
| 54 | LA0119070 | Ms. Richa Aklekar | | |
| 55 | LA0119072 | Ms. Riya Girish Sabarad | | |
| 56 | LA0119073 | Ms. Rochelle Felosha Diniz | | |
| 57 | LA0119074 | Ms. Rutuja A Birje | | |
| 58 | LA0119075 | Ms. Sachi Chikodi | | |
| 59 | LA0119076 | Ms. Sahana Rachayya Mathapati | | |
| 60 | LA0119077 | Mr. Saiprasad Dulu Kerkar | | |
| 61 | LA0119078 | Ms. Saisha Moreshwar Kamat | | |
| 62 | LA0119079 | Mr. Salil Anil Korde | | |
| 63 | LA0119080 | Ms. Samant Sanyukta Vishwajeet | | |
| 64 | LA0119081 | Ms. Sanjana B Hubballi | | |
| 65 | LA0119082 | Mr. Sanskar Ramchandra Dabolkar | | |
| 66 | LA0119083 | Ms. Jiya Sanjay Kharbe | | |
| 67 | LA0119084 | Ms. Sejal S Ashtekar | | |
| 68 | LA0119085 | Ms. Sejal Santosh Shet Dessai | | |
| 69 | LA0119087 | Ms. Shamimakhtar Peerzade | | |
| 70 | LA0119088 | Ms. Sharief Rabia Mohammed Rafi | | |
| 71 | LA0119089 | Mr. Shetye Rajas Alais Raghavenra Sachindra | | |
| 72 | LA0119090 | Ms. Shreya Vikas Patil | | |
| 73 | LA0119091 | Ms. Shrisha Sachin Purohit | | |
| 74 | LA0119092 | Ms. Shriya Deepak Raibagi | | |
| 75 | LA0119093 | Ms. Sneha Nandkumar Sonar | | |
| 76 | LA0119094 | Mr. Steven D'Silva | | |
| 77 | LA0119095 | Mr. Sudarshan Digambar Shewale | | |
| 78 | LA0119096 | Mr. Umran Usman Mulla | | |
| 79 | LA0119097 | Ms. Vaidya Mrunmai Pritam | | |
| 80 | LA0119098 | Ms. Vanessa Lisa Gomes | | |
| 81 | LA0118052 | Ms. Miraje Sakshi Ram | | |
| 82 | LA0118061 | Ms. Niralagi Pradnya Vinod | | |
| 83 | LA0117059 | Mr. Navelkar Pawan Rajanikant | | |
| 84 | LA0117083 | Ms. Sanjana Naik | | |

# INSTITUTE OF PHYSIOTHERAPY

A Constituent Unit of

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(Declared as Deemed –to-be-University u/s 3 of the UGC Act, 1956)

Accredited 'A+' Grade by NAAC (3rd Cycle) Placed in Category 'A' by MHRD (GoI)

NEHRU NAGAR, BELAGAVI – 590010, KARNATAKA, INDIA

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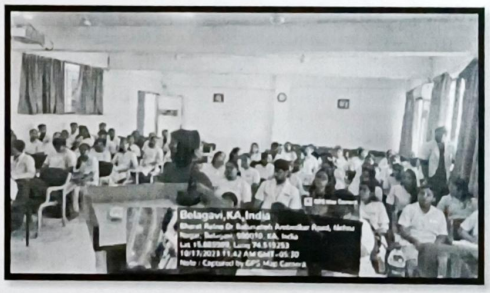
Date: 17/10/2023

## RESEARCH METHODOLOGY WORKSHOP REPORT

KAHER Institute of Physiotherapy's Research and Development Committee organized Research methodology workshop for Interns regular batch 2023 – 24 on 17th October 2023 from 9:00am – 5:00pm. Topics like, Framing the title of research proposal, framing a research question, hypothesis, research design, sampling design, review of literature, outcome measures in physiotherapy, informed consent, data collection, data analysis, overview of SPSS software, contents of synopsis writing, contents of manuscript writing and reference writing were covered in the one day workshop. The workshop was well appreciated by all the 84 delegates and expressed that the topics covered would help them in their course work for intern research project. The workshop was organized under the guidance of Dr. Sanjiv Kumar, Principal, Dr. Deepa Metgud, Dean and Incharge, Dr. Santosh Metgud, Professor and member, and Dr. Apeksha Hungund, Assistant Professor and member, Institutional Research and Development Committee.


Incharge
Research Committee
KIPT, Belagavi

KLE ACADEMY OF HIGHER EDUCATION & RESEARCH INSTITUTE OF PHYSIOTHERAPY ★ BELAGAVI

Principal

## RESEARCH METHODOLOGY AND ETHICS, EVIDENCE BASED PHYSIOTHERAPY (SUBJECT CODE: 1124)

**Teaching Hours:** 70 hours (Theory: 70 hours)

**Maximum Marks:** 100 (Theory: 100)

**Assessment:** Written, Internal and University examination.

**Internal Examination:** 20 marks Theory University Examination: 80 marks Theory

**Objectives:** On successful completion of this unit, it is expected that students will be able to understand basic research methodology and ethics in physiotherapy. The objectives are to develop an understanding about evidence based physiotherapy and its applications.

**Course Outcome:**

At the completion of the course students will be able to:

| | |
|---|---|
| 3.5.1 | Develop an understanding of the basic concepts of research methodology & basic biostatistics |
| 3.5.2 | Develop an understanding of the application of research methodology principles to Physiotherapy research |
| 3.5.3 | Develop an understanding of the historical aspects & basic concepts of research & Human ethics |
| 3.5.4 | Develop an understanding of the importance & application of ethical principles in Physiotherapy research & clinical practice |
| 3.5.5 | Develop an understanding of the basic concepts of evidence based practice & its role/importance in Physiotherapy research & clinical practice |

**Note: Long question and MCQs should be asked only from "Must Know" and Short Essay and Short Answers from "Must Know" and "Good to Know".**

**80% of Questions in the university exam will be included from must know content 15% from desirable to know and 5% from nice to know**

## 1. RESEARCH METHODOLOGY

**Basic concepts (MUST KNOW)**

- Meaning and definition
- Research process (GOOD TO KNOW)
- Research types and approaches
- Objectives of research in physiotherapy
- Barriers for research in physiotherapy (NICE TO KNOW)
- Research problem or research question (GOOD TO KNOW)

**Research ethics (MUST KNOW)**

- Introduction
- Helsinki's declaration (GOOD TO KNOW)
- Plagiarism (GOOD TO KNOW)

**Literature search (MUST KNOW)**

- Steps in literature search
- Purpose
- Methods and techniques (GOOD TO KNOW)

**Research designs (MUST KNOW)**

- Meaning and definition
- Types of research designs
- Steps in preparation of research designs
- Factors affecting research designs

**Sampling (GOOD TO KNOW)**

- Principles
- Methods
- Designs
- Process

6. **Research variables (GOOD TO KNOW)**
   - Introduction
   - Types
   - Reliability and validity
   - Specificity and sensitivity
7. **Pilot study and pre-testing (NICE TO KNOW)**
   - Need
   - Advantages
8. **Data collection (MUST KNOW)**
   - Introduction
   - Sources
   - Methods
   - Types
9. **Biostatistics (MUST KNOW)**
   - Introduction of biostatistics (tabulation, graphical presentation)
   - Measures of central tendency, variation, location, association and correlation for qualitative and quantitative data, bivariate distribution.
   - Probability theory, normal, binomial and Poisson distributions
   - Sampling methods and sample size estimation
   - Simple regression analysis, Multivariate analysis; concepts and interpretation, Logistic regression analysis; concepts and interpretation
   - Concepts in generalization of statistics computed from a sample and the utilities in research, including tests for significance.
10. **Research report (NICE TO KNOW)**
    - Introduction
    - Types
    - Publication

## II. ETHICS

- Introduction, History & General Principles of ethics involving human participants **(NICE TO KNOW)**
- Ethical consideration in physiotherapy practice- State, National & international rules & regulations governing physiotherapy practice **(GOOD TO KNOW)**
- Informed consent process **(MUST KNOW)**
- Good clinical practices (GCP) **(MUST KNOW)**
- Ethical codes and conduct for physiotherapy profession**(GOOD TO KNOW)**
- Influence of values & valuing on patient care **(NICE TO KNOW)**
- Documentation skills- History, examination, treatment planning, organization & execution **(NICE TO KNOW)**

## III. EVIDENCE BASED PHYSIOTHERAPY

**Introduction to Evidence Based Practice: (GOOD TO KNOW)**

- Definition
- Development of Evidence based knowledge **(NICE TO KNOW)**
- Evidence Based Physiotherapy Practice **(MUST KNOW)**
- Evidence Based Practitioner: The Reflective Practitioner, The E Model, Using the E Model **(GOOD TO KNOW)**
- Concepts of Evidence based Physiotherapy: Awareness, Consultation, Judgment, Creativity **(GOOD TO KNOW)**

**Finding the Evidence (MUST KNOW)**

- Measuring outcomes in Evidence Based Practice
- Measuring Health Outcomes
- Measuring clinical outcomes **(GOOD TO KNOW)**
- Inferential statistics and Causation **(NICE TO KNOW)**

**Searching for the Evidence (MUST KNOW)**

- Different sources of evidence ,Electronic **(GOOD TO KNOW)**
- Bibliographic databases **(NICE TO KNOW)**

- World Wide Web (NICE TO KNOW)
- Literature search(MUST KNOW)

3. **Assessing the Evidence (MUST KNOW)**
   - Evaluating the evidence
   - Levels of evidence in research using quantitative methods
   - Levels of evidence classification system
   - critical review of research using qualitative methods
4. **Reviewing the evidence (GOOD TO KNOW)**
   - Stages of systematic reviews (GOOD TO KNOW)
   - Meta-analysis (NICE TO KNOW)
   - The Cochrane collaboration (NICE TO KNOW)
5. **Economic evaluation of the evidence (GOOD TO KNOW)**

   Types of economic evaluation

   Conducting economic evaluation
   - Critically reviewing economic evaluation
   - Locating economic evaluation in the literature

6. ***Practice guidelines*: (NICE TO KNOW)**
   - Recent trends in health care
   - Clinical Practice Guidelines (CPG)
   - Communicating evidence to clients, managers and funders

**Research dissemination and transfer of knowledge (NICE TO KNOW)**

## Suggested Readings


Bowling, S., Price CJ, & Straker L. (1998). The researching therapist. A practical guide to planning, performing and communicating research. Edinburgh: Churchill Livingstone.

Domholdt, E. (2000) Physical therapy research: Principles and applications, 2nd ed. WB Saunders, Philadelphia, USA.

American physical therapy association: Guide to physical therapy practice, 2nd edition 2001.

Professionalism in physical therapy: History, practice and development by Laura Lee Swisher and Catherine G.Page,(Elsevier publication 2005)

Handbook of Research Method – Sproull, Screcrow Press, 1998.

Elements of Research in Physical Therapy, Currier D. P, Williams & Wilkins, Baltimore, 1990, Ed 3.

Effective documentation for physical therapy professionals by Eric shamus & Debra(McGraw Hill company 2004).

Carolyn Hicks: Research for physiotherapists: project design and analysis, 2 Ed, Churchill Livingstone, New York, 1995.

Thomas JR, Nelson JK: Research Methods in Physical Activity. 4th Ed, Human Kinetics, New Zealand, 2001.

Evidence-Based Practice in Nursing and Health Care: A Guide to Best Practice, by Bernadette

Melnyk (Editor), Ellen Fineout-Overholt (Editor)

Evidence-Based Rehabilitation: A Guide to Practice,by Mary Law

Achieving Evidence-Based Practice, by Susan Hamer, BA, MA, RGN, FETC(DIST),

The Evidence-Based, Randy A Haye

# Section III

## 1st Year Common Subjects to all specialties

### Content:

| | |
|---|---|
| TITLE OF THE PAPER I: PAPER-I PHYSIOTHERAPY EDUCATION, RESEARCH, BIOSTATISTICS & ETHICS | |
| Duration : 0-12 Months | Max Marks = 100 |
| Teaching Scheme | |
| Theory : 150 hrs. | |
| Practical 250 hrs. | |
| Distribution of marks – Research 50 marks, Ethics 30 marks , Physiotherapy Education 20 marks | |
| Course Descriptions | |

**RESEARCH & BIOSTATISTICS**

| Content | Hours |
|---|---|
| 1. Principles of Research | 02 |
| 2. Review of scientific methods. | 02 |
| 3. Research question, Research Design, Quantitative and Qualitative Research Paradigms. | 05 |
| 4. Sampling design, Data sampling and methods of data collection, Probability | 04 |
| 5. Measurement &Scaling Techniques. | 03 |
| 6. Introduction to Biostatistics | 02 |
| 7. Source and presentation of Data | 05 |
| 8. Measures of Location, Average and Percentile | 03 |
| 9. Measures of Central Tendency | 03 |
| 10. Variability and its measures | 05 |
| 11. Normal Distribution and Normal Curve | 04 |
| 12. Demography Study | 03 |
| 13. Measures of Population and Statistics | 03 |
| 14. Data analysis: Descriptive and Inferential Statistics, Correlations and Hypothesis Testing. | 08 |
| 15. Quantitative Data Analysis: Revision of Descriptive and Inferential Statistics, Correlations and Hypothesis Testing, General Linear Model, Power and Effect. | 08 |

| | |
|---|---|
| 16. Analysis of Variance and Covariance Multivariate Designs, Nonparametric Data Analysis and Selection of Nonparametric Tests. | 10 |
| 17. Qualitative Data Analysis: Major Qualitative Methodologies, Techniques in Data Collection and Analysis. | 10 |
| 18. Role of Technology in Research. | 03 |
| 19. Protocol writing, Manuscript writing and Grant writing | 06 |
| **ETHICS** | |
| 1. Introduction, History & General Principles of ethics involving human participants. | 02 |
| 2. Ethical consideration in physiotherapy practice- State, National & international rules & regulations governing physiotherapy practice. | 06 |
| 3. Ethical review procedures- Protocol Writing, Ethical Committee. | 06 |
| 4. Informed Consent Process | 03 |
| 5. Plagiarism | 03 |
| 6. Good Clinical Practices (GCP) | 04 |
| 7. Ethical codes and conduct for physiotherapy profession. | 04 |
| 8. Documentation skills- History, examination, treatment planning, organization & execution. | 05 |
| **PHYSIOTHERAPY EDUCATION** | |
| 1.Education – Formal and Non-Formal – Philosophy of Health Education, Aims, Philosophy and Trend and Issues In Education Including – Aims, Agencies, Philosophies of Education (Modern and Contemporary) Philosophies of Education In India – Past, Present and Future Current Issues and Trends in Education | 05 |
| 2.Concepts of teaching and learning – theories of teaching, relation between teaching and learning, dynamics of behavior, learning perception, individual differences, intelligence and personality . | 05 |

| | |
|---|---|
| 3. Principles and methods of teaching – strategies and planning, organization and teaching methods - micro teaching, socialized teaching method. | 05 |
| 4.Teaching technology - Traditional and newer trends in teaching learning methods, interactive learning, clinical teaching, methods of assessment of student competencies | 03 |
| 5. Curriculum formation – committee framing, development & types of curriculum, formation of philosophy & course objectives, Placing, master plans of courses, Clinical assignments ·Current trends and curriculum plan | 05 |
| 8.Measurement& evaluation- standardized & non standardized tests, steps of constructing a test measurement, measurement of cognitive domain, assessment techniques of effective psychomotor domains, administrating, scanning and reporting standard tools, important test of intelligence, aptitude, Instrument, personality, achievement, and status scale, program evaluation | 05 |

**Recommended reading:**


1. Domholdt, E. (2000) Physical therapy research: Principles and applications, 2nd ed. WB Saunders, Philadelphia, USA.
2. Kuzma, J. W., &Bohnenblust, S. E. (2004). Basic statistics for the health sciences. (5th ed.). Boston: McGraw Hill.
3. Munro, B. H. (1997). Statistical methods for health care research (3rd ed.). Philadelphia: Lippincott.
4. Coakes, S. J., & Steed, L. G. (2003). SPSS: Analysis without anguish: Version 11.0 for Windows. Milton, Australia: John Wiley & Sons Inc.
5. Jenkins, S., Price CJ, &Straker L. (1998). The researching therapist. A practical guide to planning, performing and communicating research. Edinburgh: Churchill Livingstone.

Campbell, M.J., &Machin, D. (1993). Medical statistics: A commonsense approach (2nd ed.). Chichester, UK: John Wiley.

American physical therapy association: Guide to physical therapy practice, 2nd edition 2001.

8. Professionalism in physical therapy: History, practice and development by Laura Lee Swisher and Catherine G.Page,(Elsevier publication 2005)

9. International classification of functioning, disability and health: Short version.(IT'S publication)

10. Effective Documentation for physical therapy professionals by Eric Shamus and Debra (McGraw Hill Company 2004).

11. Physical therapy Documentation: From examination to outcome by Mia Erickson, Ralph Utzman (Slack incorporated 2008)

12. Writhing SOAP notes with patient / Client management formats by GingeKettenbach PhD, PT,3rd edition 2004,F.A.Davis company ,Philadelphia.

13. Practical Evidence Based Physiotherapy, Rob Herbert, GroJamtvedt, Judy Mead, KareBirger Hagen Elsevier Butter Worth Heinemann; Oxford UK (2005)

14. Guide to Evidence Based Physical Therapy Practice by Dianne V. Jewell, PT, PhD, Virginia Commonwealth University, Virginia.

15. Introduction to Research in Health Sciences – Polgar S, Churchill Livingstone, London, 1988

16. Handbook of Research Method – Sproull, Screcrow Press, 1998.

17. Elements of Research in Physical Therapy, Currier D. P, Williams & Wilkins, Baltimore, 1990, Ed 3.

18. Public Power and Administration – Wilenski, Hale and Iremonger, 1998.

19. Public Therapy Administrations and Management – Hickik Robert J.

20. Management Principles for Physiotherapists – Nosse Lorry J.

21. Public Power and Administration – Wilenski, Hale And Iremonger, 1986

22. Physical Therapy Administration and Management – Hick Robert J

23. Management Principles for Physiotherapists – Nosse Lorry J.

24. Medical Education: Principles and Practice: Published by the Nat
teacher Training Center, JIPMER, Pondicherry: latest Edition

25. Medical Education: Trainer's Manual: Published by the National tea
Training Center, JIPMER, Pondicherry: latest Edition

26. Basics in Medical Education: Zubair Amin &HoonEngKhoo: W
Scientific: 2009

27. A Practical Guide for Medical Teachers: John A Dent& Ronald M Harc
Elsevier Health Sciences: 2009

28. International Handbook of Medical Education: Abdul W Saj
Christie H McGuire et al: Greenwood Press 1994

29. PRINCIPLES OF MEDICAL EDUCATION, Tejinder Singh, Piyush Gup
Daljit Singh, year: 2009. Edition: 3rd edition Publisher: JAYPEE brothe

30. Pedagogy Physiotherapy Education –C S Ram