VINAYAKA MISSION'S RESEARCH FOUNDATION
(Deemed to be University under section 3 of the UGC Act 1956)

Research Methodology - Syllabus

Health Sciences

(Medicine, Dentistry, Pharmacy and Homoeopathy)

Total Lecture Hours: 60
Credits: 4

UNIT I – FOUNDATIONS OF HEALTH RESEARCH AND DEVELOPMENT OF A RESEARCH QUESTION

12 Hours

1. Introduction to Research

Meaning and characteristics of scientific research

- Scientific method and scientific reasoning
- Basic, applied, translational and clinical research
- Quantitative, qualitative and mixed-method research
- Observational and experimental research
- Interdisciplinary and multidisciplinary research
- Implementation and health-systems research
- Evidence-based medicine and evidence-informed healthcare

2. Identification of a Research Problem

- Identification of knowledge gaps
- Sources of research questions
- Feasibility and relevance of research problems
- FINER criteria
- Novelty and significance of research
- PICO/PICOT/PECO/SPIDER frameworks
- Developing a conceptual framework

3. Research Question, Objectives and Hypothesis

- Formulation of research questions

- General and specific objectives
- Characteristics of good research objectives
- Research hypothesis
- Null and alternative hypotheses
- One-tailed and two-tailed hypotheses
- Variables and operational definitions
- Independent, dependent, confounding and effect-modifying variables

4. Literature Search and Review

- Purpose and types of literature review
- Developing a search strategy
- Keywords, MeSH terms and Boolean operators
- Searching PubMed/MEDLINE, Scopus, Web of Science, Cochrane Library and Google Scholar
- Citation tracking
- Reference-management software
- Identification of research gaps
- Critical reading of biomedical literature

UNIT II – RESEARCH DESIGNS, EPIDEMIOLOGY AND CLINICAL RESEARCH

12 Hours

1. Descriptive Research Designs

- Case report
- Case series
- Ecological studies
- Cross-sectional studies
- Descriptive epidemiological studies

2. Analytical Observational Studies

- Case-control studies
- Cohort studies
- Prospective and retrospective designs
- Nested case-control studies
- Diagnostic accuracy studies
- Prognostic studies

3. Experimental Studies

- Clinical trials
- Randomised controlled trials
- Parallel, crossover, factorial and cluster designs
- Randomisation techniques
- Allocation concealment
- Blinding/masking
- Placebo and active controls
- Superiority, equivalence and non-inferiority trials
- Pragmatic versus explanatory trials

4. Epidemiological Concepts

- Measures of disease frequency
- Incidence and prevalence
- Measures of association
- Relative risk
- Odds ratio
- Attributable risk
- Confounding
- Bias and methods of controlling bias
- Effect modification

- Internal and external validity
- Causal inference and criteria for causation

5. Clinical Research

- Phases of clinical trials
- Clinical trial protocol
- Trial registration
- Good Clinical Practice
- Adverse events and serious adverse events
- Data Safety Monitoring
- Clinical Trials Registry–India
- Overview of regulatory requirements relevant to clinical research in India

6. Other Relevant Designs

- Diagnostic research
- Screening studies
- Prognostic research
- Genetic and molecular epidemiological studies
- Database/registry-based research
- Secondary data analysis
- Implementation research

UNIT III – SAMPLING, MEASUREMENT, DATA MANAGEMENT AND BIOSTATISTICS

12 Hours

1. Population and Sampling

- Target and study populations
- Sampling frame
- Probability sampling:

    - Simple random
    - Systematic
    - Stratified
    - Cluster and multistage sampling
- Non-probability sampling
- Sampling error and bias
- Sample-size estimation
- Power of a study
- Effect size
- Type I and Type II errors
- Sample-size considerations for major study designs

2. Measurement in Medical Research

- Types of variables
- Scales of measurement
- Measurement error
- Accuracy and precision
- Reliability and validity
- Sensitivity and specificity
- Predictive values
- Likelihood ratios
- ROC curves
- Development and validation of questionnaires/scales
- Pilot study and pretesting

3. Data Management

- Designing case-record forms
- Data coding

- Data dictionaries
- Database development
- Data entry and validation
- Data cleaning
- Missing data
- Data quality assurance
- Data security and confidentiality
- Data storage, backup and archiving

4. Descriptive Statistics

- Data presentation
- Frequency distributions
- Tables and graphs
- Mean, median and mode
- Range, variance and standard deviation
- Percentiles and interquartile range
- Normal distribution
- Standard error
- Confidence intervals

5. Inferential Statistics

- Principles of hypothesis testing
- Parametric and non-parametric tests
- Student's t-test
- Paired t-test
- Analysis of variance
- Chi-square test
- Fisher's exact test

- Mann–Whitney U test
- Wilcoxon signed-rank test
- Kruskal–Wallis test
- Correlation
- Linear regression
- Logistic regression
- Introduction to multivariable modelling
- Survival analysis: Kaplan–Meier curves and Cox regression
- Adjustment for confounding
- Interpretation of statistical results
- Statistical versus clinical significance
- Multiple comparisons

6. Statistical Software

Introduction and hands-on application using one or more of:

- SPSS
- R/RStudio
- Jamovi/JASP
- Excel for data management
- Other University-approved statistical software

UNIT IV – QUALITATIVE RESEARCH, EVIDENCE SYNTHESIS, COMPUTER APPLICATIONS AND EMERGING RESEARCH TOOLS

12 Hours

1. Qualitative Research

- Rationale and applications in medical research
- Qualitative versus quantitative paradigms
- Phenomenology

- Grounded theory
- Ethnography
- Case-study methodology
- Narrative research
- Participant selection and saturation
- In-depth interviews
- Focus-group discussions
- Observation
- Development of interview guides
- Transcription
- Coding
- Thematic analysis
- Content analysis
- Reflexivity
- Trustworthiness and rigour
- Reporting qualitative research

2. Mixed-Methods Research

- Rationale for mixed-method studies
- Convergent design
- Explanatory sequential design
- Exploratory sequential design
- Integration of quantitative and qualitative findings

3. Evidence Synthesis

- Narrative review
- Scoping review
- Systematic review

- Meta-analysis
- Developing a review question
- Search strategy
- Study selection
- Data extraction
- Assessment of risk of bias
- Forest plots
- Heterogeneity
- Publication bias
- Introduction to GRADE
- PRISMA reporting principles

4. Computer Applications in Research

- Internet and World Wide Web as research resources
- Electronic bibliographic databases
- Spreadsheet applications
- Electronic data capture
- Web applications for managing online surveys and databases
- Electronic health records and clinical databases
- Cloud-based collaborative research
- Reference managers
- Data visualisation
- Researcher identifiers – ORCID
- Digital object identifiers
- Data repositories and open science

5. Artificial Intelligence and Emerging Technologies in Medical Research

- Introduction to Artificial Intelligence and Machine Learning

- AI applications in biomedical and clinical research
- Natural language processing
- Medical image analysis
- Prediction models
- AI-assisted literature searches and evidence synthesis
- Generative AI in scientific research
- Responsible use of AI in research
- Verification of AI-generated content
- Bias, transparency and explainability
- Data privacy and confidentiality
- Ethical considerations in AI-assisted research

UNIT V – RESEARCH PROTOCOL DEVELOPMENT, ETHICS, REGULATION AND RESEARCH COMMUNICATION

12 Hours

1. Development of a Research Protocol

Components of a research protocol:

- Title
- Background and rationale
- Literature review
- Research question
- Aim and objectives
- Hypotheses
- Study design
- Study setting
- Study population

- Inclusion and exclusion criteria
- Sampling strategy
- Sample-size calculation
- Study procedures
- Variables and outcome measures
- Data-collection instruments
- Data-management plan
- Statistical analysis plan
- Ethical considerations
- Timeline/Gantt chart
- Budget
- Expected outcomes
- Limitations
- Dissemination plan
- References
- Annexures

2. Biomedical and Health Research Ethics

- Principles of autonomy, beneficence, non-maleficence and justice
- Informed consent process
- Participant information sheet
- Confidentiality and privacy
- Vulnerable populations
- Research involving children
- Research involving pregnant women
- Research involving biological samples

- Stored biological material and biobanks
- Genetics and genomic research
- Community-based research
- Compensation for research-related injury
- Conflict of interest
- Institutional Ethics Committee: composition and functions
- Ethics review process
- Continuing review and protocol deviations
- Publication ethics, research misconduct, plagiarism and predatory publishing

3. Regulatory and Quality Aspects

- Overview of ICMR ethical guidelines
- Good Clinical Practice
- Clinical trial registration
- Relevant Indian regulatory framework for biomedical research
- Standard Operating Procedures
- Quality assurance and quality control
- Documentation and record retention
- Research data governance

4. Research Funding and Project Management

- Identification of funding agencies
- Preparation of research grant proposals
- Budget preparation and justification
- Research timelines and milestones
- Research team and collaboration
- Multicentric and interdisciplinary research
- Project monitoring

- Management of research resources

5. Scientific Communication

- Structure of a scientific paper
- IMRaD format
- Abstract writing
- Scientific tables and figures
- Oral and poster presentation
- Thesis organisation and presentation
- Reporting guidelines:
    - CONSORT/ STROBE/PRISMA/ CARE
- Communicating research findings to different stakeholders
- Knowledge translation and implementation
- Research impact

SUGGESTED TEXTBOOKS AND RESOURCES

Research Methodology

1. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. **Designing Clinical Research.** Wolters Kluwer.
2. Park K. **Park's Textbook of Preventive and Social Medicine.** Banarsidas Bhanot.
3. Kothari CR, Garg G. **Research Methodology: Methods and Techniques.** New Age International.
4. Creswell JW, Creswell JD. **Research Design: Qualitative, Quantitative and Mixed Methods Approaches.** SAGE.

Biostatistics

5. Altman DG. **Practical Statistics for Medical Research.** Chapman & Hall/CRC.

Evidence-Based Medicine and Systematic Reviews

6. Greenhalgh T. **How to Read a Paper: The Basics of Evidence-Based Medicine and Healthcare.**

Ethics and Regulatory Guidance

7. Indian Council of Medical Research. **National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.**
8. Good Clinical Practice Guidelines applicable to clinical research.
9. Relevant CDSCO/New Drugs and Clinical Trials regulatory requirements.
10. University Grants Commission and VMRF (DU) regulations governing PhD programmes and Research & Publication Ethics.

Unit	Title	Hours
I	Foundations of Health Research and Development of a Research Question	12
II	Research Designs, Epidemiology and Clinical Research	12
III	Sampling, Measurement, Data Management and Biostatistics	12
IV	Qualitative Research, Evidence Synthesis, Computer Applications and Emerging Research Tools	12
V	Research Protocol Development, Ethics, Regulation and Research Communication	12
Total		**60 Hours / 4 Credits**