

KERALA UNIVERSITY OF HEALTH SCIENCES

THRISSUR

SYLLABUS FOR Ph.D. YEAR END EXAMINATION

RESEARCH METHODOLOGY, ETHICS IN BIO-MEDICAL RESEARCH AND STATISTICS (Common Paper)

A. Research methodology

1. Introduction to Medical Research: Meaning, characteristics and objectives of medical research, Use of scientific method in research, research process, Classification of research.
2. Research topic, Research question and Hypothesis: Source of research ideas, identification of a research topic, Defining and refining a research question, essential attributes of a good Research Question, Formulation of hypothesis. Null and alternate hypothesis
3. Research designs: Observational and Experimental studies
Observational: Descriptive- Case reports, Case series, Cross-sectional and Evaluation of a diagnostic test.
Observational: Analytical- case control, cohort and ecological studies
Experimental: Clinical trials, Field trials, Community intervention trials
Randomized controlled trials, crossover study, Before-after study
4. Sample Design: Probability and non-probability sampling. Types of probability sampling techniques- simple random sampling, systematic sampling, stratified random sampling, cluster sampling, multi-stage sampling, multi-phase sampling, and consecutive sampling. Sampling and non-sampling errors. Types of non-probability sampling techniques
5. Sample size calculation: Sample size for different study designs. Type 1 error, Type2 error and Statistical power
6. Methods of data collection: Primary and secondary data. Tools for data collection, Questionnaire design, Reliability and validity in measurement.
7. Methodological problems in clinical research

8. Qualitative Research: Characteristics of qualitative research, common qualitative research methods, sampling techniques and sample size in qualitative research, qualitative data analysis.
9. Writing a research protocol and thesis/ dissertation: General format for a research protocol and also of completed Thesis/dissertations

B. Ethics in Bio-medical Research

1. Importance of Ethics in medical research
2. General ethical principles in bio-medical research
3. Ethics committee/ Institutional Review Board
4. Protocol requirement for ethical review, Elements of ethical review
5. Informed consent Process: Informed consent documents- participant/patient information sheet and consent form, consent from special groups /vulnerable subjects, audio-visual consent in clinical trial

C. Statistics (Descriptive and Inferential)

1. Types of data and scales of measurement
2. Summarizing data:
Measures of central tendency: mean, median, mode
Measures of variability: Range, Standard deviation, Coefficient of variation, Standard error.
Percentages, proportions, ratios and rates
3. Presenting data: Tabular-Frequency distribution tables, Figures and graphs-bar chart, pie chart, histogram, line graph, frequency polygon, scatter diagram
4. Distribution of data: The binomial, Poisson and Normal distribution
5. Probability, Statistical significance, confidence intervals
6. Statistical tests: Parametric Tests (Difference between means)- Student 't' Test, paired 't' Test, F test and Analysis of variance.
7. Statistical tests: Non- parametric Tests: Wilcoxon Rank Sum test/ Mann-Whitney 'U' Test, Wilcoxon Signed Rank Test, Chi-Square Test, Fisher's Exact Test
8. Correlation and Regression

9. Cross tabulations: Chi-square test, Odds ratio, Relative risk. Sensitivity, Specificity, Positive and Negative predictive values, Accuracy, Likelihood Ratios and ROC curve. Agreement-Kappa statistics.

D. Research and Publication Ethics (RPE)

1. Awareness about publication ethics and publication misconducts
2. Prevention of Academic Integrity and Prevention of Plagiarism