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## **Research Methodology and Biostatics Syllabus**

### **Research Methodology: An Introduction**

Meaning of Research Objectives of Research, Motivation in Research, Types of Research, Research Approaches, Significance of Research, Research Methods versus Methodology, Research and Scientific Method, Importance of Knowing How Research is Done Research Process, Criteria of Good Research, Problems Encountered by Researchers in India.

### **Defining the Research Problem**

What is a Research Problem? Selecting the Problem, Necessity of Defining the Problem, Technique Involved in Defining a Problem, An Illustration, Conclusion

### **Research Design**

Meaning of Research Design, Need for Research Design, Features of a Good Design, Important Concepts Relating to Research Design, Different Research Designs, Basic Principles of Experimental Designs, Conclusion, Developing a Research Plan

### **Sampling Design**

Census and Sample Survey, Implications of a Sample Design, Steps in Sampling Design, Criteria of Selecting a Sampling Procedure, Characteristics of a Good Sample Design, Different Types of Sample Designs, How to Select a Random Sample, Random Sample from an Infinite Universe, Complex Random Sampling Designs, Conclusion

### **Measurement and Scaling Techniques**

Measurement in Research, Measurement Scales, Sources of Error in Measurement, Tests of Sound Measurement, Technique of Developing Measurement Tools, Scaling, Meaning of Scaling, Scale Classification Bases, Important Scaling Techniques, Scale Construction Techniques.

### **Methods of Data Collection**

Collection of Primary Data, Observation Method, Interview Method, Collection of Data through Questionnaires, Collection of Data through Schedules, Difference between Questionnaires and Schedules, Some Other Methods of Data Collection, Collection of Secondary Data, Selection of Appropriate Method for Data Collection, Case Study Method.

### **Processing and Analysis of Data**

Processing Operations, Some Problems in Processing, Elements/Types of Analysis, Statistics in Research, Measures of Central Tendency, Measures of Dispersion, Measures of Asymmetry (Skewness), Measures of Relationship, Simple Regression Analysis, Multiple Correlation and Regression, Partial Correlation, Association in Case of Attributes, Other Measures, Appendix: Summary Chart Concerning Analysis of Data



## Sampling Fundamentals

Need for Sampling, Some Fundamental Definitions, Important Sampling Distributions, Central Limit Theorem, Sampling Theory, Sandler's A-test, Concept of Standard Error, Estimation, Estimating the Population Mean, Estimating Population Proportion, Sample Size and its Determination, Determination of Sample Size through the Approach Based on Precision Rate and Confidence Level, Determination of Sample Size through the Approach Based on Bayesian Statistics

## Testing of Hypotheses-I (Parametric or Standard Tests of Hypotheses)

What is a Hypothesis? Basic Concepts Concerning Testing of Hypotheses, Procedure for Hypothesis Testing, Flow Diagram for Hypothesis Testing, Measuring the Power of a Hypothesis Test, Tests of Hypotheses, Important Parametric Tests, Hypothesis Testing of Means, Hypothesis Testing for Differences between Means, Hypothesis Testing for Comparing Two Related Samples, Hypothesis Testing of Proportions, Hypothesis Testing for Difference between Proportions, Hypothesis Testing for Comparing a Variance to Some Hypothesized Population Variance, Testing the Equality of Variances of Two Normal Populations, Hypothesis Testing of Correlation Coefficients, Limitations of the Tests of Hypotheses

## Chi-square Test

Chi-square as a Test for Comparing Variance, Chi-square as a Non-parametric Test, Conditions for the Application of  $X^2$  Test, Steps Involved in Applying Chi-square Test, Alternative Formula, Yates' Correction, Conversion of  $X^2$  into Phi Coefficient, Conversion of  $X^2$  into Coefficient by Contingency, Important Characteristics of  $X^2$  Test, Caution in Using  $X^2$  Test

## Analysis of Variance and Covariance

Analysis of Variance (ANOVA), What is ANOVA? The Basic Principle of ANOVA, ANOVA Technique, Setting up Analysis of Variance Table, Short-cut Method for One-way ANOVA, Coding Method, Two-way ANOVA, ANOVA in Latin-Square Design, Analysis of Co-variance (ANOCOVA), ANOCOVA Technique, Assumptions in ANOCOVA

## Testing of Hypotheses-II (Nonparametric or Distribution-free Tests)

Important Nonparametric or Distribution-free Test, Relationship between Spearman's  $r_s$  and Kendall's  $W$ , Characteristics of Distribution-free or Non-parametric Tests, Conclusion.

## Multivariate Analysis Techniques

Growth of Multivariate Techniques, Characteristics and Applications, Classification of Multivariate Techniques, Variables in Multivariate Analysis, Important Multivariate Techniques, Important Methods of Factor Analysis, Rotation in Factor Analysis, R-type and Q-type Factor Analyses, Path Analysis, Conclusion



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## Interpretation and Report Writing

Meaning of Interpretation, Why Interpretation? Technique of Interpretation, Precaution in Interpretation, Significance of Report Writing, Different Steps in Writing Report, Layout of the Research Report, Types of Reports, Oral Presentation, Mechanics of Writing a Research Report, Precautions for Writing Research Reports, Conclusions

## The computer: Its Role in Research

Introduction, The Computer and Computer Technology, The Computer System, Important Characteristics, The Binary Number System, Computer Applications, Computers and Researcher, Definitions

## Bioavailability and Bioequivalence

Objectives of Bioavailability studies Methods of Bioavailability measurement, Pharmacokinetic methods: Plasma level time studies, Urinary excretion studies, Pharmacodynamic methods: Acute pharmacological response, Therapeutic response, In vitro dissolution studies and bioavailability: IVIVC, Bioequivalence experimental study designs, Completely randomized designs, Randomized block designs, Repeated measures, cross over, carry-over designs, Latin square designs, Statistical interpretation of bioequivalence data, Analysis of variance (ANOVA), Confidence interval approach, Methods for enhancement of Bioavailability.

## Clinical trials

Introduction: Clinical research, Drug development phases, Pre-Phase 1 activities, Phases of Clinical trial, Regulatory approvals: IND & NDA, Summary of Clinical trial phases