

RESEARCH METHODOLOGY AND MEDICAL STATISTICS

RESEARCH METHODOLOGY

Essential Requirements:

Serial No.	Criteria	Requirement	Remarks (If any)
1	Basic eligibility of participants	Anyone who has completed AYUSH Graduation	
2	Duration of the Course	2 months	
3	Number of trainees per Batch	Max.-30	
4	Trainer Qualification	Faculty experienced in PG teaching minimum 3 years on research methodology & ones who completed PhD	
5	Number of Trainers required (Theory)	Min.- 4	
6	Number of Guest faculty required (min 4)	Min.- Medical statistics/MPH/ Graduate with CRO /PG Diploma in clinical research/ Retired scientists/ Biostatistician	
7	Number of working Technician (Skill expert) required for practical training	NA	
8	Infrastructure Technical specification requirement	Min.- As Per NCISM	
9	Assessment Method	Practical Marks (100 marks) Marks can be divided into- Spotting-10 marks Case Presentation- 15 marks Practical Biostatistics- 10 marks Lab performance (Analytical)- 15 marks Viva- 40 marks Records- 10 marks	

PART-A

SN	Topics	Time	
1	Definition of the research/ Anusandhan Need of research in the field or Ayurveda Identifying problem for Research (Literary Guess(s)) Literature review: different methods (including computer database) with their advantages and limitations : Local Databases, National Databases International Databases	4HR	
2	about FINER Criterion, CONSORT Guidelines, PICOT, PRISM etc	4HR	
3	Methods of Hypothesis formation	1HR	
4	How to design a questionnaire? Importance of a question to be asked	1HR	
5	Randomization and Masking-Concept and methods	1HR	
6	Ethical Aspects, Preparation and Filling up of the Informed consent forms	1HR	
7	Decision on research problem and process- General and specific objectives Need of study Groups	1 HR	
8	Research design: Observational and interventional : Descriptive and analytical, Preclinical and clinical : Longitudinal & Cross sectional studies : Prospective & Retrospectives studies Cohort studies	2HR	
9	Minimum Sample size Required to detect specified 'Change' in outcome	2HR	
10	Data Management, Analysis, and interpretation, Assessment of hypothesis	2HR	
11	Procedure to obtain clearance from respective committees * Institutional Review Board ORB) * Ethical aspects related to human and animal experimentation * Institutional Ethics Committee (IEC) * Animal Ethics Committee AEC	2HR	
12	Randomized Controlled Trials (RCT) & their types Phases of Clinical studies: 0, 1 23 and 4	2HR	
13	Single-case design, case control studies, ethnographic studies, black box design, cross-over design factorial design.	2HR	
14	How to prepare a good research project? Step by Step methodology Finance for stud : Exploring the interested agencies	2HR	
15	How to prepare a good research paper? Step by Step methodology	2HR	
16	Publication: publication ethics, identifying suitable journal Errors and bias in research	2HR	
17	Hands on training on above said – Problem statement Compulsory assignment on scientific writing – publication Self study – project		

Part B : Medical Statistics

SN		Hours	
1	Introduction to Medical statistics and applications in ayurvedic research	1	
2	Data, Classification, Collection and Compilation	1	
3	Presentation of data-Tabular and Graphical Methods	1	
4	Histogram, Bar Diagram, Line and frequency distribution	1	
5	Measures of central tendency-Mean, Median and Mode	1	
6	Measures of Dispersions-Variance, Standard Errors, Coefficient of Variation, Skewness etc	1	
7	Categorical Data — Rates, proportions	1	
	Normal Distribution and Checks for normality	1	
9	Statistical Significance and Confidence interval	1	
10	Probability-Concept and estimation	1	
11	Binomial and Poisson Distribution	1	
12	Correlation and Regression	2	
13	Tests of Hypothesis, Type 1 and Type 2 errors	1	
14	Levels of significance and power of test	1	
15	Test of Significance — Means for single sample, two sample and paired sample	2	
16	Test of Significance —proportions	2	
17	Contingency Table and Chi square Test of Significance	1	
18	Fisher's Exact test and Yates Correction	1	
19	Descriptive methods for categorical data -Odds Ratio, Relative risk and Risk Ratios	1	
20	Nonparametric Tests- Wilcoxon sign rank test, Wilcoxon Rank Sum Test, Mann-Whitney U-test	2	
21	One-way Analysis of Variance (ANOVA)	1	
22	Repeated measure ANOVA	1	
23	ANOVA-Kruskal Wallis test, Post-hoc tests, Friedman tests	2	
24	Demography and Vital Statistics	1	
25	Need and Method of samplings	1	
26	Random and non-random sampling -concepts and needs	1	
27	Sample size calculation based on means	2	
28	Sample size calculation based on proportion	2	
28	Sample size calculation based on correlation and other parameters	2	
30	Use of computers for calculating statistical parameters	3	
	Total	40	

1. **Research Methods Classical Approaches: 10 Hrs**
 - ✓ Definition, Need and different fields of research. Anusandhana and basic approaches (2 hr)
 - ✓ Concepts of Pratyakashadi Pramana, Dosha vidha pareeksha (4 hrs)
 - ✓ Swastha and Atura Pariksha (2 hrs) Literary research (2 hrs)

2. **Drug Research / Quality of formulations: 20 Hrs**
 - ✓ Basic information on the Drug Sources (including Plant, Animal, Mineral) (2 hrs)
 - ✓ Basic information on Dravya, Guna, Karma, Aushadhi Pariksha (2 hrs)
 - ✓ Identification methods of herbal drugs and introduction to Pharmacognosy (2 hrs)
 - ✓ Basic knowledge - Pharmacopoeias and Pharmacopoeial standards (2 hr)
 - ✓ Good Practices (GMP, GLP, GAO, G Collection P, GSP etc) (4 hrs)
 - ✓ Latest trends in drug discovery, Cell culture studies (3 hrs)
 - ✓ Hands on / Practical / Demonstrations (5 hrs)

3. **Safety / Efficacy / pre-clinical studies: 15 Hrs**
 - ✓ Introduction to pre-clinical studies. Need and importance {1 hr}
 - ✓ Basic introduction to IAEC, OECD, CPCSEA (1 hr)
 - ✓ Protocols for assessing acute, sub-acute, chronic, dermal and geno-toxicity studies (4 hrs)
 - ✓ Efficacy studies, Introduction to different models of evaluating efficacy (3 hrs)
 - ✓ Hands on / Practical / Demonstrations (5 hrs)

4. **Publication ethics: 05 Hrs**
 - ✓ Types of publications, publication ethics.
 - ✓ Types of Journals, indexing, indexing agencies, plagiarism, scientific misconduct.

3	Trainee Assessment Criteria	<p>At the end of the course; a practical examination (for 100 marks) is to be conducted. The marks can be divided into</p> <p>Spotting 10 marks</p> <p>Case presentation 15 marks</p> <p>Practical Biostatistics 10 marks</p> <p>Lab performance (Analytical) 15 marks</p> <p>Viva 40 marks Records 10 marks</p> <p>The practical will include</p> <ol style="list-style-type: none"> 1. familiarization and demonstration of common lab instruments for carrying out analysis, including pharmacognosy and safety / toxicity studies. 2. protocol development 3. case writing and presentation