

LJ UNIVERSITY

LJ INSTITUTE OF PHARMACY

M. PHARM SEMESTER: II

Subject Name: RESEARCH METHODOLOGY & BIostatISTICS

Subject Code: MRM204T

Scope: This course is designed to impart knowledge on the area of advances in research methodology.

Objectives: On completion of this course it is expected that students will be able to understand,

1. Basic steps to be followed for identifying the potential research areas.
2. Various reliable sources for literature review. Different sources for research funding.
3. Different research tools and statistical tools.
4. Preclinical and clinical practice guideline and requirement.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
4	-	-	4	75	25	-	-

Sr No	Course Content	Total Hrs
1	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.	12
2	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 (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12
3	Medical Research: History, values in medical ethics, autonomy, beneficence, nonmaleficence, 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	12

4	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	12
5	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	12
Total Hours		60

Recommended Books:

1. Research Methodology by C.R. Kothari
2. Compendium of CPCSEA 2018
3. Presentation skills - Michael Hallon- Indian Society for Institute education
4. Pharmaceutics Statistics by Sanford Bolton, Charles Bon
5. Pharmaceutical Experimental Design By Gareth Lewis and Didier Mathieu
6. www.cpcsea.nic.in
7. www.icmr.nic.in
8. Experimental Design & Patent by Hardik D. Shihora & Vipul P. Patel
9. Basic Biostatics for pharmacy by Dr. G.K. Jani
10. https://www.who.int/medicines/areas/quality_safety/safety_efficacy/gcp1.pdf