

**Theory: 180 hrs (Credits: 6); Practicals: 120 hrs (Credits: 2)**

**Th:10 hrs**

National Knowledge Commission, National Assessment and Accreditation Council (NAAC) & University Grant Commission (UGC)

**Th:15 hrs**

Historical narration about conduct of research on human subject, Biblical times, research on vulnerable population, tackling of ethical issues in the past century. Ethical code, Nuremberg code, Helsinki declaration, Belmont principles in conduct of research in human subject.

**Th:40 hrs Pr: 6hrs**

Background, general principles on ethical considerations involving human participants, general ethical issues, Ethical Review Committee – need, relevance and working rules & regulations as applicable in India. Ethical Review Procedures, IRB. Principles for clinical evaluation of drugs/ devices/diagnostics/vaccines/ herbal remedies. Informed Consent Process – Preparing an informed consent for a research project.

**Th: 16 hrs; Pr: 25hrs**

## Research protocol development

**Research Methodology – Defining research questions/Hypothesis, Study designs - cross sectional study, case control study and randomized clinical trials.**

Clinical Trials – Introduction, composition, procedures & records, Informed consent, responsibility & rules applicable to investigators and sponsors, reporting of adverse events and other related ethical issues.

Good Clinical Practices (GCP) and safety, Good Laboratory Practices (GLP).

**Th: 5 hrs; Pr: 8 hrs**

Introduction, specific aims, review of literature, measures, methodology, study plan and statistical analysis. Protection of human participants, proposed budget and time line for the proposal. Pre-Clinical Research / Translational Research

Information regarding National /International organization to avail research grants

## Patents and Intellectual Property/Rights

**6. Manuscript Writing:****Th:5 hrs**

Writing a scientific manuscript, structured writing and language editing, writing respondents & presentation, impact factor, plagiarism, bibliography, referencing & citations,

**7. Critical Appraisal of Article Published in Scientific Journal:****Th.-6 hrs; Pr.16 hrs**

What is critical appraisal and why critical appraisal, present scenario of scientific publications, methodology of critical appraisal, format for critical appraisal

**8. Thesis Writing:****Th:5 hrs**

Introduction to thesis writing, prescribed format for thesis writing, seminar presentations, preparation for Viva-Voce & communication skills.

**9. Health care delivery systems in India:****Th:8 hrs**

National Population Policy.

National Health Policy.

National Rural Health Mission (NRHM program).

RCH program.

Current Health Problems.

Environment & health related challenges of India.

Non Communicable Diseases

Biomedical waste management

Emerging and re-emerging infectious diseases in the world and in India.

Population explosion causes and its impact.

**10. Scientific Conduct****Th: 9Hr Pr: 3hrs**

Ethics with respect to science and research Intellectual honesty and research integrity

Scientific misconducts: Falsification. Fabrication, and Plagiarism (FFP), Redundant publications: duplicate and overlapping publications, salami slicing, Selective reporting and misrepresentation of data.

Legal aspects of research

**11. Publication Ethics****Th: 10 Hr Pr: 3hrs**

Publication ethics definition, introduction and importance

Best practices/ standards setting initiatives and guidelines: COPE, WAME, etc.

Conflicts of interest, Publication misconduct: definition, concept. problems that lead to unethical behaviour and vice versa, types, Violation of publication ethics, authorship and contributorship, Identification of publication misconduct, complaints and appeals, Predatory publishers and journals

**12 Open Access Publishing****Th. 9Hr Pr. 6 Hrs**

Open access publications and initiatives, SHERPA/ROMEO online resource to check policies publisher copyright & self-archiving

Software tool to identify predatory publications developed by SPPU Journal finder /journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.

Critical appraisal of published literature

**13. Publication Misconduct****Th. 6Hr Pr. 6 Hrs**

Subject specific ethical issues, FFP, authorship, Conflicts of interest, Complaints and appeals: examples and fraud from India and abroad

Use of plagiarism software like Turnitin, Urkund and other open source software tools

**14. Databases And Research Metrics****Th. 6Hr Pr. 6 Hrs**

Databases : Indexing databases, Citation databases: Web of Science. Scopus, etc.

Impact Factor of journal as per Journal Citation Report. SNIP, SJR, IPP, CiteScore

Metrics: h-index, g index, i10 index, altmetrics

**15. Online Certificate Course on “Health Research Fundamental” by ICMR: Pr: 5 hrs****16. Attending Ph.D. 6-monthly presentations:****Th: 30 hrs****17. Visit to Regional Medical Research Centre (RMRC), Belagavi:****Pr: 18 hrs****18. Visit to Basic Science Research Centre (BSRC):****Pr: 18 hrs****19. Library Hours for Self Study:****50 hrs**

## **Paper II (Syllabus related to Research Discipline)**

**Theory: 60 hrs (Credits: 2); Practicals: 120 hrs (Credits: 2)**

### **1. Topics related to research discipline:**

**Th: 60 hrs; Pr: 30 hrs**

The paper II shall be on the topics related to the research discipline of the candidate and the research supervisors are required to submit the detailed syllabus to the Office of the Academic Affairs within three months of the registration of the candidate.

### **2. Attending Discipline-related Workshops/CMEs/Seminars/Conferences: Pr: 35 hrs**

### **3. Attending Ph.D. Open House Seminars: ( Atleast 15 ) Pr: 25 hrs**

### **4. Attending Ph.D. Open Defence Viva: ( Atleast 15 ) Pr: 30 hrs**

## **Paper III (Biostatistics )**

**Theory: 90 hrs (Credits: 3); Practicals: 60 hrs (Credits: 1)**

1. Introduction to Bio-statistics, translating research problem into hypothesis, hypothesis testing, Type I & Type II errors in statistics, checking errors in data and correcting them.

2. Sample size calculation for different study designs.

3. Types of variables and types of data measurements scales, Data Collection methods, presentation & organization of data – Tabular / Graphical Form.

4. Sampling Designs, Descriptive Statistics - Measures of central tendency & measures of dispersion, Correlation Analysis, Regression Analysis, Probability Theory - Binominal distribution, Poisson distribution, normal distribution, concept of testing of hypothesis.

5. Test of Significance- Parametric tests-Z test, T test, ANOVA and Non Parametric tests- Chi-Square test, Wilcoxon Rank test, Kruskal Wallis test.

6. Devising conclusion from data analysis.

7. Use of computers, statistical software's, data cleaning.