BHARATHIAR UNIVERSITY, COIMBATORE 641 046.

PG DIPLOMA IN CLINICAL RESEARCH AND DATA MANAGEMENT

SCHEME OF EXAMINATION

For the candidates Admitted during the Academic year 2010-2011

<table>
<thead>
<tr>
<th>Sem</th>
<th>Title of the Paper</th>
<th>Instruction Hours / Week</th>
<th>Exam Dur.Hrs</th>
<th>CIA</th>
<th>Marks</th>
<th>Total Marks</th>
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<tr>
<td>I</td>
<td>Paper I - Introduction to Clinical Research</td>
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<td>3</td>
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<td>Paper II - Introduction to Pharmaceutical Medicine and Basics of Pharmacology</td>
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<td>Paper III - Principles of Clinical Research</td>
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<td>Paper IV - Clinical Data Management</td>
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<td>Practical - Clinical Data Management</td>
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<td>II</td>
<td>Paper V - Clinical Research Methodology - I</td>
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<td>Paper VI - Clinical Research Methodology - II</td>
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<td>Paper VII - Bioethics and Drug Safety in Clinical Trials</td>
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<td>Practical - Clinical Data Management</td>
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<td>Dissertation Presentation and Evaluation( Basic observation in the sites )</td>
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Total Marks 800

*Practical Examination to be conducted at the end of the academic year
SEMESTER I  PAPER I
INTRODUCTION TO CLINICAL RESEARCH

Unit -I: Drug discovery and Development
Introduction to Pharmaceutical Industry, New drug discovery-Target Identification-Target Prioritization/ validation, Lead identification, Lead optimization ; Preclinical studies - Preclinical technology, Chemistry manufacturing and controls / Pharmaceutics Pharmacology/Toxicology

Unit-II: Investigational New Drug Application
Investigational New Drug (IND), Clinical Trial Exception (CTX), Clinical Trial Authorization (CTA)

Unit-III: Patents
Formulation and Development, Introduction to Pharmacogenomics /Pharmacogenetics driven Clinical Trials

Unit –IV: Basics of Clinical Research
Definition of clinical research and development, History of randomized trial
Literature - Finding and Evaluation databases of Scientific Literature ; Critiquing of Research Projects, Time management and resource implications

Unit-V: Epidemiology
Experimental Procedures - Controlled Experiments, Sampling Techniques, Questioner Design, Validity and reliability of observations, Primary variables, Acquisition and using secondary data, Randomization and Blinding: Theory and practice

Reference:
3. Clinical Trials- A practical Guide to design, analysis & Reporting by Dr Duolao Wang
4. Clinical Epidemiology: How to Do Clinical Practice Research Publisher: Lippincott Williams & Wilkins; 3 edition
SEMESTER I PAPER II
INTRODUCTION TO PHARMACEUTICAL MEDICINE AND BASICS OF PHARMACOLOGY

Unit - I: Pharmaceutical Medicine
Pharmaceutical formulations, Routes of Drug Administration

Unit-II: Clinical Development of Drug
Basics of Pharmacology, Traditional system of medicines

Unit-III: General Pharmacology  I
Autonomic Nervous System, Central Nervous System, Respiratory System

Unit IV: General Pharmacology  II
Autacoids, Renal System, Cardiovascular System, Gastrointestinal System

Unit V: General Pharmacology  III
Endocrine Systematic-infective Agents, Anti-neoplastic Therapy

Reference:
1. A concise text Book of Pharmacology – Murugesh N

SEMESTER I PAPER III
PRINCIPLES OF CLINICAL RESEARCH

Unit - I: Clinical Trials Process Phases
Phase I, Phase II A & B, Phase III A & B, Phase IV & Types of Post marketing,surveillances

Unit - II: ICH and GCP Guidelines

Unit - III: Ethical Guidelines
Ethical Guidelines for Biomedical Research in Human Subjects, Central Ethics ommitee on Human Research (CECHR), ICMR, 2000,Clinical research regulation DCGI.

Unit-IV: GCP Guidelines
GCP Guidelines, Central Drugs Standardization and Control Organization, Government of India, Schedule Y
**Unit - V: Clinical Trials Planning**
Sponsor’s responsibilities, Essential documentation and Investigator’s Brochure, Protocol design, CRF design, Informed Consent Documents - Subject Information Sheet and Informed Consent Form, Ethics Committee Approvals.

**Reference:**
1. A Concise Guide to Clinical Trials by Allan Hackshaw

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**SEMESTER I PAPER IV**

**CLINICAL DATA MANAGEMENT**

**Unit-I**
Data Capture, Data Collection Tool Design, Forms Management, Receipt and Review of Data.

**Unit-II**
SOPs, Data Entry, Data Validation & Data Cleaning, Query/Discrepancy Management, Coding.

**Unit-III**
Data Transfer – ECG and Bioimaging, Lab Data, Safety Data Management, Database Closure, QC/QA.

**Unit-IV**
Medical Writing/Documentation, Introduction to Clinical Data Interchange Standards Consortium (CDISC).

**Unit-V:**
Introduction to statistical Inference (Basics)- Interval Estimation, Confidence Intervals, T-Distribution & Hypothesis testing, ANOVA, Chi-Square Test, Regression and Correlation, SPSS.

**Reference:**
1. Management of Data in Clinical Trials, 2nd Edition by Eleanor McFadden
SEMESTER I & II          PRACTICALS

CLINICAL DATA MANAGEMENT

- System Overview, Basic Study Set Up
- Global Library Management
- Simple CRF Modelling
- CRF Modelling for PDF
- Data Entry
- Discrepancies, Data Clarification
- Validation and Derivations
- Batch Data Loading and Laboratory Overview
- Data Extract and Access from SAS/SPSS
- Data Loading and Security, Copy Groups

SEMESTER II          PAPER V

CLINICAL RESEARCH METHODOLOGY - I

Unit-I: Designing of Clinical Trial
The elements of trial design sources and bias, Designing a multicenter trial, Clinical trial Protocol, Elements of Protocol, Protocol review and sign off, Amendments.

Unit-II: Project Outsourcing
Strategic concepts of outsourcing, Contract out, Geographical attraction for outsourcing, Choosing the optional CRO, Evaluating time and cost involved.

Unit-III: Investigator Selection
Identification, Site management, Selection Criteria, Site Visit, Meeting with Investigator, Review of site.

Unit-IV: Research Initiation
Clinical Trial Agreement, Ethics submission and approval, Site initiation, Drug storage

Unit-V: Pharmacovigilance
Adverse events, Laboratory safety data, Vital signs and Physical findings, Investigator’s brochure, Breaking the treatment Lind, Data safety, Monitoring boards, Spontaneous reporting, Prescription event monitoring, Industry sponsored PMS.

Reference:
1. Designing clinical research: An epidemiologic approach by Stephen B Hulley, Steven R Cummings
2. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers Josef Kolman (Editor), Paul Meng (Editor), Graeme Scott (Editor)
SEMESTER II  
PAPER VI  
CLINICAL RESEARCH METHODOLOGY - II  

Unit-I: Project Management in Drug Development  
History of project management, Project management tools, Use of management tools in clinical research.  

Unit-II: Protocol study procedure  
Documentation, data handling and reporting, CRF, ICF, and CTRB, Laboratory management, lab related reports, Monitoring visit – significance and preparation  

Unit-III: Audits and Inspections I  
Elements of GCP quality systems, Clinical quality assurance audits.  

Unit-IV: Audits and Inspections II  
Types of inspections and audit, Inspection by regulatory authorities, Preparation for audit and inspection.  

Unit-V: Project Close out  
Key stakeholders, Business strategy influence on projects success, Problem solving and decision making, Managing and controlling change during clinical project  

Reference:  
1. Essentials of Clinical Research by Stephen P Glasser  
2. Clinical Epidemiology: How to Do Clinical Practice Research Publisher: Lippincott Williams & Wilkins  
3. Cognitive Methods And Their Applications To Clinical Research By Amy Wenzel, David C. Rubin Publisher: American Psychological Association
SEMESTER II   PAPER VII

BIOETHICS AND DRUG SAFETY IN CLINICAL TRIALS

Unit-I: Bioethics I
Revised Declaration of Helsinki, Role & Responsibilities of Sponsor, Role & Responsibilities of Investigator, Role & Responsibilities of IRB/IEC.

Unit-II: Bioethics II
Role & Responsibilities of Clinical research Associate (CRA)/ Monitor, Role & Responsibilities of Auditor, Role & Responsibilities of Clinical research coordinator, Role & Responsibilities of Clinical research organization.

Unit-III: Role of Laboratory Investigations in Clinical Research
Need for clinical investigation, Hematological Data, Pathology, Urine analysis, Collection and preservation of samples, Masking of samples and drugs, Interpretation of results.

Unit-IV: Pharmacokinetics
Introduction to Pharmacokinetics, Selection of volunteers.

Unit-V: Drug Interactions
Factors influencing Pharmacokinetic and Pharmacodynamic interactions.

Reference:
2. CRA's guide to Monitoring clinical research by Mr. P.N.Reddy

SEMESTER II   DISSERTATION

Basic observations, Designing a CRF, Protocol and Feasibility study in the sites to be submitted as Dissertation.
SUGGESTED READINGS

• Principles and Practice of Clinical Research by John I.Gallin,Fredrick P.Ognibene Publisher: Academic Press
• Guide Book for Drug Regulatory Submissions by Sandy Weinberg Publisher. John Wiley & sons
• The CRA’s /CRC’s Guide to Monitoring/Coordinating Clinical Research by Karen E. Wooding
• Clinical and Translational Science Authors : David Robertson and Grodon Harold Williams
• Handbook for Synthesizing Qualitative Research by Margarete Sandelowski, Julie Barroso, Publisher: Springer Publishing Company
• Wiley Encyclopedia of Clinical Trials Author(s): Ralph B. D'Agostino, Lisa Sullivan, Joseph Massaro, Publisher: Wiley-Interscience
• Dictionary for Clinical Trials, 2nd Edition -Wiley, Publisher: Wiley
• Design and Analysis of Cross-Over Trials by Byron Jones , Michael G. Kenward
• Introduction to Randomized Controlled Clinical Trials, Second Edition, Publisher: Chapman & Hall/CRC
• Clinical Trials- A practical Guide to design, analysis & Reporting by Dr Duolao Wang
• CRA'a guide to Monitoring clinical research by Mr. P.N.Reddy
• A Concise Guide to Clinical Trials by Allan Hackshaw
• Essentials of Clinical Research by Stephen P Glasser Publisher:Springer
• Principles and Practice of Clinical Trial Medicine Publisher: Academic Press
• Clinical Epidemiology: How to Do Clinical Practice Research Publisher: Lippincott Williams & Wilkins
• The Pharmaceutical Regulatory Process by Ira R. Berry International Regulatory Business Consultants, L.L.C
• Cognitive Methods And Their Applications To Clinical Research By Amy Wenzel, David C. Rubin Publisher: American Psychological Association
• Good Clinical Practice: Standard Operating Procedures for Clinical Researchers Josef Kolman (Editor), Paul Meng (Editor), Graeme Scott (Editor)
• Careers in Clinical Research: Obstacles and Opportunities Editors: William N. Kelley and Mark A. Randolph
• Clinical Research Coordinator Handbook: GCP Tools and Techniques, Second Edition (Practical Clinical Trials Series) By Deborah Rosenbaum,&nbsp Michelle Dresser
• Designing clinical research: An epidemiologic approach by Stephen B Hulley, Steven R Cummings
• Clinical trials:A practical approach by Pocock ,Stuart J. Pocock
• Randomization in clinical trials: Theory and practice by William F Rosenberger, John M Lachin
• Oxford textbook of clinical research by Ezekiel J. Emanuel, Christine Graddy, Robert A. Crouch, Reider K. Lie, Franklin G. Miller, David Wendler
• Clinical research coordinator handbook. GCT tools and techniques by Deborah Rosenhaun, Michalle Dresser
• Clinical research: what it is and how it works by Lori A. Nesbitt
• Data Monitoring in Clinical Trials by David L. DeMets
• Management of Data in Clinical Trials, 2nd Edition by Eleanor McFadden
• Clinical Data Management by Richard k. Rondel Sheil a. varley and Colin f. webb
• World Medical Association Declaration of Helsinki, Ethical principles for medical research involving human subjects, adopted by the 18 WMA General assembly Helsinki, Finland, June 1964 and its subsequent amendments
• http://www.emea.eu.int/ {homepage on the internet}: European Medicines Agency.
• Interscience Computer Applications in Pharmaceutical Research and Development