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

Sem	Title of the Paper	Instruction Hours / Week	Exam			
			Dur.Hrs	CIA	Marks	Total Marks
I	Paper I - Introduction to Clinical Research	6	3	25	75	100
	Paper II - Introduction to Pharmaceutical Medicine and Basics of Pharmacology	6	3	25	75	100
	Paper III - Principles of Clinical Research	6	3	25	75	100
	Paper IV - Clinical Data Management	6	3	25	75	100
	Practical - Clinical Data Management	6	-	-	-	-
II	Paper V - Clinical Research Methodology - I	6	3	25	75	100
	Paper VI - Clinical Research Methodology - II	6	3	25	75	100
	Paper VII - Bioethics and Drug Safety in Clinical Trials	6	3	25	75	100
	Practical - Clinical Data Management	6	3	20	30	50
	Dissertation Presentation and Evaluation(Basic observation in the sites)	6	-	20	30	50
		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:

1. New Drug Approval Process, Fourth Edition, Accelerating Global Registrations (Drugs and the Pharmaceutical Sciences): Richard Guarino Informa HealthCare
2. Guide Book for Drug Regulatory Submissions. John Wiley & sons Author(s): Sandy Weinberg & Sandy Weinberg
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**
History of GCP,FDA Regulations for Clinical Trials,ICH Guidelines for Good Clinical Practice , FDA Guidelines and Information Sheets , FDA Compliance Program Guidance Manuals,NIH Regulated Research,FDA Bioresearch Monitoring Program (BIMO),Good Clinical Practice (GCP) Contacting the FDA ,Protected Health Information (PHI) Recruitment of Study Subjects ,Obtaining Informed Consent under HIPAA ,The Declaration of Helsinki ,The Belmont Report (1979)

Unit - III: Ethical Guidelines
Ethical Guidelines for Biomedical Research in Human Subjects, Central Ethics ommittee 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
2. http://www.cdsao.nic.in {homepage on the internet}: New Delhi: Central Drugs Control Administration. Available from: http://www.cdsco.nic.in/index.html.
3. ICH Guidelines for Good Clinical Practice. http://www.ich.org
4. Principles and Practice of Clinical Trial Medicine Publisher: Academic Press; 1 edition.

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
2. Clinical Data Management by Richard.krondel Sheila a. Varley and Colin F. Webb

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:

1. Clinical Research Coordinator Handbook: GCP Tools and Techniques, Second Edition (Practical Clinical Trials Series) By Deborah Rosenbaum, Michelle Dresser
2. CRA'a guide to Monitoring clinical research by Mr. P.N.Reddy
3. The CRA's /CRC's Guide to Monitoring/Coordinating Clinical Research by Karen E. Wooding

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
- Clinical Research Coordinator Handbook: GCP Tools and Techniques, Second Edition
- 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
- New Drug Approval Process, Fourth Edition, Accelerating Global Registrations (Drugs and the Pharmaceutical Sciences): Richard Guarino Informa HealthCare
- 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 Sheila a. varley and Colin f. webb
- Nielsen J.R. "Handbook of Federal Drug Law," Philadelphia, PA: Lippincott, Williams & Wilkins, 1992.
- 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
- Mahajan BK. Methods in Biostatistics, 6th ed. Newdelhi: Jaypee Brothers, 2001.
- Meinert CL. Clincial Trials: Design, Conduct and analysis. Newyork: Oxford, 1986.
- .http://www.fda.gov/ {homepage on the internet}:U.S Fod and Drug Administration.
- http://www.emea.eu.int /{homepage on the internet}: European Medicines Agency.
- http://www.tga.gov.au/{home page on the internet}/Therapeutic Goods Administration, Australia. Available from: http://www.tga.gov.au/index.htm.
- ICH Guidelines for Good Clinical Practice, 1997. http://www.ich.org {homepage on the internet} :E6(R1): Switzerland: Good Clinical Practice: Consolidated Guidelines. Available from http://www.ich.org /LOB/media/MEDIA482.pdf
- http://www.cdsao.nic.in {homepage on the internet}: New Delhi: Central Drugs Control Administration. Available from: http://www.cdsco.nic.in/index.html.
- Interscience Computer Applications in Pharmaceutical Research and Development