Programme Structure

Sharda School of Allied Health Sciences

Master of Science (Clinical Research)

Programme Code: SAH0101

Batch: 2023-2025

SHARDA UNIVERSITY

Sharda School of Allied Health Sciences

Programme: Master of Science (Clinical Research)

Batch: 2023-2025

Semester: I

Subject Code	Theory subjects	Teaching Load			Credits	Core/Elective	Type of Course[1]:
		L	T	P			
RMS 002	Biostatistics and Research Methodology	4	-	--	4	Core	CC
MCR 103	Human physiology	4	-	--	4	Core	CC
MCR 104	Microbiology and pathology	4	-	--	4	Core	CC
MCR 105	Clinical biochemistry	4	-	--	4	Core	CC
MCR 120	General pharmacology	2	1	--	3	Core	CC
MCR 107	Introduction to clinical research	4	-	--	4	Core	CC
Practical/viva-voce/jury							
RBL001	RBL-1	-	-	-	0	Core	CC
MCR 108	Human physiology(lab)	--	--	4	2	Core	CC
MCR 109	Microbiology and pathology(lab)	-	-	4	2	Core	CC
MCR 110	Clinical biochemistry(lab)	-	-	2	1	Core	CC
TOTAL CREDITS					**28**		

[1] CC: Core Course, AECC: Ability Enhancement Compulsory Courses, SEC: Skill Enhancement Courses, DSE: Discipline Specific Courses

SHARDA UNIVERSITY

Sharda School of Allied Health Sciences
Programme: Master of Science (Clinical Research)
Batch: 2023-2025
Semester- II

Subject Code	Theory subjects	Teaching Load			Credits	Core/Elective	Type of Course[2]:
		L	T	P			
Theory subjects							
MCR 112	Systemic pharmacology	4	-	-	4	Core	CC
MCR 113	Clinical trial process and good clinical practices	4	-	-	4	Core	CC
MCR 114	Introduction to management (Hospital and Healthcare)	4	-	-	4	Core	CC
MCR 115	Medical terminologies and conditions	4	-	-	4	Core	CC
MCR 116	Epidemiology and Biostatistics	4	-	-	4	Core	CC
MCR 121	Research methodology in clinical settings	2	-	-	2	Core	AECC
Practical/viva-voce/jury							
RBL002	RBL-2	-	-	-	0	Core	CC
OPE	Open elective	2	-	-	2	Elective	SEC
MCR 117	Systemic pharmacology (lab)	-	-	2	1	Core	CC
MCR118	Community posting and application of biostatistics (CA)	-	-	4	2	Core	AECC
TOTAL CREDITS					**27**		

[2] CC: Core Course, AECC: Ability Enhancement Compulsory Courses, SEC: Skill Enhancement Courses, DSE: Discipline Specific Courses

SHARDA UNIVERSITY

Sharda School of Allied Health Sciences

Programme: Master of Science (Clinical Research)

Batch: 2023-2025

Semester- III

Subject Code	Subjects	Teaching Load			Credits	Core/Elective	Type of Course[3]:
		L	T	P			
Theory subjects							
MCR 203	Clinical trial management	4	-	-	4	Core	SEC
MCR 204	Regulations in clinical research	4	-	-	4	Core	DSE
MCR 205	Documentation and data management in clinical research	4	-	-	4	Core	SEC
MCR 206	Pharmacovigilance and Pharmacoeconomics	4	-	-	4	Core	CC
MCR 207	Psychology and patient counselling	4	-	-	4	Core	CC
MCR 218	Recent developments in clinical research	2	-	-	2	Core	SEC
Practical/viva-voce/jury							
MCR 201	Faculty-Student-Industry-Connect (CA)	-	-	-	0	Core	CC
MCR 202	MS office (Advance excel) (CA)	-	-	2	1	Core	AECC
RBL 003	Research Based Learning-3	-	-	4	2	-	SEC
VAM303	Campus to corporate for allied health	-	-	-	0	-	-
MCR 216	Training (ETE Exam-Viva)	-	-	6	3	Core	AECC
MCR 209	Documentation in clinical research (CA)			4	2	Core	SEC
TOTAL CREDITS					**30**		

[3] CC: Core Course, AECC: Ability Enhancement Compulsory Courses, SEC: Skill Enhancement Courses, DSE: Discipline Specific Courses

SHARDA UNIVERSITY

Sharda School of Allied Health Sciences

Programme: Master of Science (Clinical Research)

Batch: 2023-2025

Semester- IV

Subject Code	Subjects/ Practical/viva-voce/jury	Teaching Load			Credits	Core/Elective	Type of Course[4]:
		L	T	P			
OPE	Open elective	2	-	-	2	Elective	CC
RBL004	RBL-4	-	-	-	2	Core	SEC
MCR 217	Dissertation (ETE)	-	-	34	18	Core	DSE
TOTAL CREDITS					**22**		

[4] CC: Core Course, AECC: Ability Enhancement Compulsory Courses, SEC: Skill Enhancement Courses, DSE: Discipline Specific Courses

Course Modules
of
Master of Science (Clinical Research)

SYLLABUS FOR THEORY AND PRACTICAL SUBJECTS
Semester-1

School:	SSAHS
Batch:	2023-2025
Programme:	Master of Science (Clinical Research)
Academic Year:	2023-2024
Semester:	I
Subject:	Biostatistics and Research Methodology
Credit:	4
Lecture:	4-0-0
Code:	RMS 002
Course Objective	1. To develop analytical skills in the students 2. To impart examples of research in decision making 3. To train the students in evaluating research articles
Course Outcomes	CO1: Define the basic concepts and methods of research. CO2: Explain the descriptive statistics. CO3: Apply the application of descriptive statistics on data. CO4: Classify the inferential statistics and its application. CO5: Evaluate the parametric test and its application on data. CO6: Discuss the non-parametric test and its application on data
Course Description	To help the students to understand the basic principles of biostatistics and research methodology and applied to draw the inferences from the data.

Outline syllabus		CO Mapping
Unit 1	**Descriptive statistics**	
A	Type of variables, Data entry and presentation	CO1
B	Summarization of data, Frequency distribution	CO1
C	Measures of central tendency, Variability measures	CO1
Unit 2	**Probability theory**	
A	Definition of Probability; Mutually exclusive and independent events. Joint, marginal and conditional probabilities,	CO2
B	Probability distributions: Binomial, Poisson and Normal	CO2
C	Bayes theorem	CO2
Unit 3	**Measures of association**	

A	Cross-tabulation; Chi-square test, Odds ratio, Relative risk, Regression analysis	CO3
B	Correlation coefficient. Interpretation of the Pearson correlation coefficient	CO3
C	Lab session with software.	CO3
Unit 4	**Sampling and sample size determination**	
A	Concepts of population and sample Parameter and estimator, Sampling distribution and Methods of Sampling	CO4, C05
B	Sample size calculation	CO4, C05
C	Lab session with software	CO4, C06
Unit 5	**Estimation**	
A	CLT, Point and interval, Confidence intervals and their use.	CO4, CO5, C06
B	Hypothesis testing: Null and Alternative hypothesis Type I and Type II errors. Level of Significance, Critical Region, Power of a test, Decision making using critical value approach and p-value approach	CO4, CO5, C06
C	Lab session with software.	CO4, CO5, C06
Mode of examination	Theory/Jury/Practical/Viva	
Weightage Distribution	CA	MTE	ETE
	25%	25%	50%
Text book/s*	Mahajan's Methods in Biostatistics for Medical Students and Research Workers. Bratati Banerjee, Jaypee Brothers.	
Other References	Biostatistics by Dr. Qazi Shoeb Ahmad, Dr. Mohd. Vaseem Ismail, Shadab Ahmad Khan, Laxmi Publications	

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Biostatistics and Research Methodology RMS 002	CO1	3	2	3	2	3	2	3	3	2
	CO2	2	1	2	1	2	1	3	2	3
	CO3	1	3	2	3	1	2	3	3	3
	CO4	2	1	3	1	2	1	3	3	2
	CO5	3	2	1	2	3	1	3	1	3
	CO6	3	3	2	2	3	3	3	2	3

School: SSAHS		Batch: 2023-2025
Academic Year:	2023-2024	
Semester:	1	
Programme:	Master of Science (Clinical Research)	
Course Code	MCR 105	
Course Title	Clinical Biochemistry	
Credits	4	
Contact Hours (L-T-P)	4-0-0	
Course Status	Compulsory	
Course Objective	1. To train the students in the management of medical laboratory along with handling a variety of laboratory chemicals and instruments including electronic and advanced equipment used in modern medical laboratories. 2. To make the students able to do routine laboratory testing under stipulated conditions. 3. To prepare specimens and operate machines that automatically analyse samples. 4. To provide the conceptual basis for understanding biochemical and particularly address the fundamental mechanisms of the biomolecules to facilitate the life. 5. To develop diagnostic skills in clinical biochemistry and to provide an advanced understanding of the core principles and topics of Biochemistry and their experimental basis.	
Course Outcomes	CO1: Define the importance of acid, base, buffers and biochemical reaction CO2: Explain the importance of chemistry of carbohydrates and proteins CO3: Apply the chemistry to understand the lipids and fatty acid for biological process CO4: Classify the clinical importance of enzymes and energy metabolism CO5: Evaluate the clinical importance of nucleic acid and organ function test CO6: Discuss the importance of biomolecules	
Course Description	• Acid, Base and Indicators, biochemical reactions • Carbohydrate and Protein Chemistry • Lipid Chemistry and Fatty acids • Enzyme and Energy metabolism • Nucleic acid and Clinical Chemistry	
Outline syllabus (Theory)		
Unit 1	**Basic concept of biochemical reactions**	
A	Acid- base reactions, buffer, water Organic reaction mechanisms, Calorific values	CO1

B	Respiratory quotient, Basal metabolic rate		CO1
C	Biological Oxidation and Bioenergetics		CO1
Unit 2	**Carbohydrate and Protein Chemistry**		
A	Definition, general classification with examples of Carbohydrate		CO2
B	Glycosidic bond, Structures, composition, sources, properties and functions of Monosaccharides, Disaccharides, Oligosaccharides and Polysaccharides		CO2
C	Peptide bond, biologically important peptides, isoelectric pH, properties of amino acid and structural organisation of protein		CO2
Unit 3	**Lipid Chemistry and Fatty acids**		
A	Definition, classification, properties and functions of lipids.		CO3
B	Triacylglycerol and Phospholipids.		CO3
C	Cholesterol and essential fatty acids and their importance, Lipoproteins		CO3
Unit 4	**Enzymes and Energy metabolism**		
A	Enzyme kinetics		CO4, C05
B	Electron transport chain		CO4, C05
C	Oxidative phosphorylation and uncouples.		CO4, C06
Unit 5	**Nucleic acid and Clinical Biochemistry**		
A	Structure, properties of purines and pyrimidine bases, Conformation of Nucleic acids (A, B, Z-DNA, tRNA, micro-RNA), Stability of Nucleic acid structure		CO4, CO5, C06
B	Kidney function tests, Liver function tests, Cardiac markers		CO4, CO5, C06
C	ELISA, PCR, DNA based diagnostics		CO4, CO5, C06
Theory			
CA	MTE	ETE	
25%	25%	50%	
Text book/s*	Lehninger Principles of Biochemistry by Lehninger. WH Freeman; 2017 edition		
Other References	Textbook of Biochemistry for Medical Students by Vasudevan, Sreekumari and Kannan Vaidyanathan Jaypee Brothers Medical Publishers		

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Clinical Biochemistry MCR105	**CO1**	3	2	2	1	1	3	3	2	2
	CO2	3	2	2	1	1	2	3	2	2
	CO3	3	3	1	2	2	3	2	3	1
	CO4	2	3	1	1	2	2	3	2	2
	CO5	3	3	1	1	2	2	2	2	2
	CO6	3	2	2	1	3	3	3	3	3

School:		SSAHS
Batch:		2023-2025
Programme:		Master of Science (Clinical Research)
Academic Year:		2023-2024
Semester:		I
Course Code		MCR 120
Course Title		General Pharmacology
Credits		3
Contact Hours (L-T-P)		2-1-0
Course Type		Compulsory
Course Objective		To equip with the basic knowledge about drugs, their types, mode of action, effect etc. which would lay the foundation for their courses in the next semester.
Course Outcomes		By the end of the course, student will be able to: CO1: Define nature, source, route, forms and recognising the drugs. CO2: Explain the mechanisms of drugs, dose response relationship, pharmacokinetics and biotransformation of drugs CO3: Applying, performing and demonstrating concept of basic pharmacology which help in appropriate diagnosis and treatment of systematic diseases. CO4: Classify the different types of drugs. CO5: Evaluate basic understanding of drug development process in clinical trial CO6: Discuss drug development and phases of clinical trial. _____.
Course Description		This course is designed to develop an understanding of the theoretical concepts surrounding pharmacology, such as the pharmacokinetics and pharmaco-dynamics of drugs, and the concepts surrounding pharmacotherapy.
Outline syllabus			CO Mapping
	Unit 1	**General Pharmacology**	
	A	Drugs- nature, Sources.	CO1
	B	Doses Forms	CO1
	C	Routes of drug Administration.	CO1
	Unit 2	**Action of Specific Agents**	
	A	Mechanisms or drug action.	CO2
	B	Dose–response relationship	CO2
	C	Pharmacokinetics of drug absorption, distribution, biotransformation, excretion and toxicity, Factors influencing drug metabolism of drug action	CO2
	Unit 3	**Pharmacology**	
	A	Drug action and effectiveness	CO3

	B	Drug safety; Factors influencing the objectively demonstrated response.			CO3
	C	Pharmacodynamic.			CO3
	Unit 4	**Drug Discovery Process**			
	A	Bioavailability and Bioequivalence			CO4, C05
	B	Drug Development			CO4, C05
	C	Discovery of New Drugs			CO4, C06
	Unit 5	**Pre-clinical Evolution and toxicity studies**			
	A	Introduction to clinical trial			CO4, CO5, C06
	B	Phase 1 clinical trials			CO4, CO5, C06
	C	Phase 2 clinical trials			CO4, CO5, C06
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	K D Tripathi: Essentials of Medical Pharmacology. 5th edition, Jaypee, New Delhi, 2004			
	Other Reference/s	Ashok Garg: Manual of Ocular Therapeutics, Jaypee, New Delhi.			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
General Pharmacology MCR 120	CO1	3	2	1	1	1	3	3	2	1
	CO2	3	2	2	2	3	2	3	2	3
	CO3	2	2	2	1	1	2	3	3	2
	CO4	3	3	2	2	2	2	3	3	3
	CO5	3	3	3	3	2	2	2	2	2
	CO6	3	3	3	3	3	3	3	3	3

School:	SSAHS	
Batch:	2023-2025	
Programme:	Master of Science (Clinical Research)	
Academic Year:	2023-2024	
Semester:	I	
Course Code	MCR 103	
Course Title	Human Physiology	
Credits	4	
Contact Hours (L-T-P)	4-0-0	
Course Type	Compulsory	
Course Objective	1.To understand the normal physiological functioning of various organ systems of the body and their interactions 2.To be able to comprehend the pathophysiology of commonly occurring diseases	
Course Outcomes	By the end of the course, student will be able to: CO1: Define the cardiovascular system of the human body. CO2: Explain the human digestive and excretory system. CO3: Apply the clinical approaches to understand human CNS and skeletal system. CO4: Classify the respiratory system CO5: Evaluate the endocrine and reproductive system CO6: Discuss the physiology of human body.	
Course Description	The course is designed to give the students aim-depth knowledge of fundamental functions of different systems of human body. The major topics to be covered include the following: the cell, muscle and nervous tissue; blood; lymphoid tissues; respiratory system; blood vessels; circulation; heart; gastro intestinal tract; endocrine and reproductive system, excretory system, central nervous system and special senses	
Outline syllabus		CO Mapping
Unit 1	**Blood and Cardiovascular System**	
A	Composition and functions of blood Blood elements	CO1
B	Physiology and functions of heart, Blood vessels and circulation (Pulmonary, coronary and systemic circulation).	CO1
C	Electrocardiogram (ECG), Cardiac cycle and heart sounds, Blood pressure – its maintenance and regulation	CO1
Unit 2	**Digestive System and Excretory System**	
A	Physiology of GIT and its functions, Composition and functions of different digestive juices. Digestion and Absorption in GIT.	CO2
B	Physiological functioning of kidney and excretory system	CO2

C	Physiology of micturition and regulation of body temperature in humans.			CO2
Unit 3	**Central Nervous System and Skeletal System**			
A	Physiology of various parts of central nervous system. Brain and its parts, functions and reflex action			CO3
B	Autonomic nervous system - functions of sympathetic and parasympathetic nervous system			CO3
C	Physiology of neuromuscular junction and muscle contraction.			CO3
Unit 4	**Respiratory system**			
A	Mechanism / physiology of respiration and regulation of respiration			CO4, C05
B	Physiological functioning of respiratory organs			CO4, C05
C	Transport of respiratory gases			CO4, C06
Unit 5	**Endocrine and reproductive System**			
A	General principles of endocrinology, Different endocrine glands and their functions			CO4, CO5, C06
B	Puberty, Spermatogenesis; semen.			CO4, CO5, C06
C	Menstruation, ovulation and contraception.			CO4, CO5, C06
Mode of examination	Theory			
Weightage Distribution	CA	MTE	ETE	
	25%	25%	50%	
Text book/s*	Text book of physiology by A.K. Jain Essentials of medical physiology by K. Sembulingam			
Other Reference/s	Tortora's Principles of Anatomy and Physiology,15th Edition by Gerard J. Tortora and Bryan H. Derrickson, Wiley.			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Human Physiology MCR103	**CO1**	3	2	2	3	3	3	3	3	2
	CO2	3	2	2	1	3	2	3	2	3
	CO3	3	3	1	2	2	3	1	3	3
	CO4	3	2	2	1	3	3	3	2	1
	CO5	3	2	2	3	1	2	3	2	3
	CO6	3	3	1	1	2	3	3	1	2

School:		SSAHS	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		I	
1	Course Code	MCR 104	
2	Course Title	Microbiology and Pathology	
3	Credits	4	
4	Contact Hours (L-T-P)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	1.To equip with the basic knowledge and concepts about microbiology that would develop a better understanding and management of the microbe's causing infections and various other ailments. 2. To equip with the basic knowledge and concepts about microbiology that would develop a better understanding of the pathology of various diseased conditions.	
6	Course Outcomes	By the end of the course, student will be able to: CO1: Define the list and recognise the extremely small forms of life. CO2: Explain the concept of microbiology in better understanding of the human infections CO3: Apply the diagnostic approaches to recognise the essential nature of disease. CO4: Classify the concept of pathological changes in human body in various diseased conditions CO5: Evaluate the importance of systemic bacteriology CO6: Discuss the microbiology and its relation to the various diseases.	
7	Course Description	The course is designed to give the students basic knowledge and concepts of microbes, pathogens, their relation and impact on various body functions and management by developing the basic understanding of the pathophysiology of various ailments.	
8	Outline syllabus		CO Mapping
	Unit 1	**Introduction**	
	A	Introduction, classification of microorganisms	CO1
	B	basic concepts- normal flora, probiotics, colonization	CO1
	C	Infection and sterilization	CO1
	Unit 2	**Bacteriology and Virology**	

	A	Introduction, classification, general features			CO2
	B	Pathogenicity, diagnosis			CO2
	C	treatment and prevention of common infections			CO2
	Unit 3	**Mycology and parasitology**			
	A	Introduction, classification, general features			CO3
	B	pathogenicity, diagnosis			CO3
	C	treatment and prevention of common infections			CO3
	Unit 4	**Immunity**			
	A	Innate and adaptive immunity			CO4, C05
	B	Cell and Tissue response to injury, hypertrophy, hyperplasia, necrosis, apoptosis			CO4, C05
	C	Inflammation and Healing			CO4, C06
	Unit 5	**Clinical pathology**			
	A	Hypersensitivity reactions			CO4, CO5, C06
	B	Introduction to histopathology and Clinical pathology			CO4, CO5, C06
	C	Examination of body fluids and secretions			CO4, CO5, C06
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	Burton G.R.W: Microbiology for the Health Sciences Corton Kumar and Robins: Pathological Basis of the Disease			
	Other References	Prescott's Microbiology (ISE HED MICROBIOLOGY) Joanne Willey, Kathleen Sandman and Dorothy Wood, McGraw Hill.			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Microbiology and Pathology MCR104	**CO1**	3	2	2	3	3	3	3	3	3
	CO2	3	3	2	2	1	2	3	2	1
	CO3	3	3	2	2	1	2	3	3	3
	CO4	2	2	3	2	2	3	3	2	1
	CO5	3	2	3	2	2	2	3	3	3
	CO6	3	3	1	1	2	3	3	2	1

School:		SSAHS	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		I	
1	Course Code	MCR 107	
2	Course Title	Introduction to clinical research	
3	Credits	4	
4	Contact Hours (L-T-P)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	1.To have an overview of the various processes involved in the clinical development of a new drug 2.To understand some frequently used terms in clinical research 3. To understand and appreciate the roles and responsibilities of various stakeholders in clinical research 4. To understand the key concepts in evolution and responsible conduct of clinical research	
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define basic structure, prospects and evolution of the clinical research. CO2: Explain basic terminologies, standard definitions, terms and vocabulary used in clinical research. CO3: Apply the role of CROs and SMOs in understanding the basic infrastructure, working, effectiveness, requirements and importance of clinical trials. CO4: Classify the concepts and knowledge about clinical evolution of drug through various phases and role of various stakeholders. CO5: Evaluate the fraud and misconduct in clinical research and adopt ethical practices. CO6: Discuss the process of clinical research.	
7	Course Description	The course provides an introductory overview about clinical research, its evolution, history, phases, key role players and focuses on the main areas of why and how ethical and responsible clinical research is carried out.	
8	Outline syllabus		CO Mapping
	Unit 1	**Introduction**	
	A	Introduction of Clinical research	CO1
	B	History of Clinical research	CO1

	C	Definitions and terminologies of Clinical research			CO1
	Unit 2	Site Management Organization (SMO) and contract research organization (CRO)			
	A	Introduction of SMO's and CRO's			CO2
	B	Role of SMO's and CRO's			CO2
	C	Responsibilities and limitations of SMO's and CRO's			CO2
	Unit 3	**Phases of Clinical trials**			
	A	Phase 0 and 1			CO3
	B	Phase 2			CO3
	C	Phase 3 and 4			CO3
	Unit 4	**Stakeholders in Clinical research**			
	A	Sponsor and Investigator			CO4, C05
	B	Ethics review bodies			CO4, C05
	C	Clinical Research Coordinator (CRC) and clinical research associate (CRA)			CO4, C06
	Unit 5	**Fraud and Misconduct**			
	A	Introduction and definitions, identification			CO4, CO5, C06
	B	Importance of ethical and responsible trials			CO4, CO5, C06
	C	Legal implications and management			CO4, CO5, C06
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	Principles and Practice of Clinical Trial Medicine: Richard Chin, Bruce Y. Lee			
	Other References	A Concise Guide to Clinical Trial by Allan Hackshaw, BMJ publisher.			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Introduction to clinical research MCR107	**CO1**	3	2	3	1	3	2	2	3	3
	CO2	3	2	3	2	2	1	2	2	1
	CO3	3	1	3	2	3	3	1	3	3
	CO4	3	2	2	2	3	3	2	1	1
	CO5	3	2	2	3	2	2	3	3	3
	CO6	3	3	3	3	3	3	3	3	3

School:		SSAHS	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		I	
1	Course Code	MCR 108	
2	Course Title	Human Physiology	
3	Credits	2	
4	Contact Hours (L-T-P)	0-0-4	
	Course Status	Compulsory	
5	Course Objective	To understand the normal physiological functioning of various organ systems of the body and their interactions and to be able to comprehend the pathophysiology of commonly occurring diseases	
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define knowledge about the microscope and its use CO2: Explain blood group and pulse rate. CO3: To know the importance of haemoglobin estimation CO4: Classify qualitative analysis of biomolecules CO5: Evaluate device and record BP CO6: Discuss the physiological metabolism of human body	
7	Course Description	The course in physiology covers the first year is designed to give the students a depth knowledge of fundamental functions of different systems of human body. The major topics to be covered include the following: the cell, muscle and nervous tissue; blood; lymphoid tissues; respiratory system; blood vessels; circulation; heart; gastro intestinal tract; endocrine and reproductive system, excretory system, central nervous system and special senses.	
8	Outline syllabus		CO Mapping
	Unit 1	**Microscope**	
	A	Introduction	CO1
	B	Demonstration	CO1
	C	Practical	CO1
	Unit 2	**Identification of blood group and recording of pulse rate**	
	A	Briefing	CO2
	B	Demonstration	CO2
	C	Practical	CO2
	Unit 3	**Haemoglobin estimation**	
	A	Briefing	CO3
	B	Demonstration	CO3
	C	Practical	CO3

	Unit 4	**Qualitative analysis**			
	A	Qualitative analysis of Carbohydrates			CO4, C05
	B	Qualitative analysis of Proteins			CO4, C05
	C	Hydrolysis of Sucrose			CO4, C06
	Unit 5	**Blood Pressure recording**			
	A	Briefing			CO4, CO5, C06
	B	Demonstration			CO4, CO5, C06
	C	Practical			CO4, C05
	Mode of examination	Practical/Viva			
	Weightage Distribution	CA	MTE	ETE	
		25%	0%	75%	
Text book/s*		Manual Of Practical Physiology by AK Jain, Arya Publications			
Other References		Ghai's Textbook of Practical Physiology 10th Edition by Mona Bedi and VP Varshney, Jaypee Brothers Medical Publishers.			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Human Physiology MCR108	**CO1**	3	2	3	2	3	2	2	1	3
	CO2	1	2	2	3	1	3	3	2	2
	CO3	3	2	2	1	1	2	3	3	2
	CO4	3	3	1	3	2	1	3	3	3
	CO5	3	3	1	1	2	2	3	3	3
	CO6	3	3	3	3	3	3	3	3	3

School:		SSAHS	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		I	
1	Course Code	MCR 109	
2	Course Title	Microbiology and Pathology	
3	Credits	2	
4	Contact Hours (L-T-P)	0-0-4	
	Course Type	Compulsory	
5	Course Objective	1.To equip with the basic knowledge and concepts about microbiology that would develop a better understanding and management of the microbes causing infections and various other ailments. 2. To equip with the basic knowledge and concepts about microbiology that would develop a better understanding of the pathology of various diseased conditions.	
6	Course Outcomes	By the end of the course, student will be able to: CO1: Define the basic microbiological equipment and techniques CO2: Explain the formulation and preparation of different culture media CO3: Apply the microscopy based diagnostic approaches to recognise the essential nature of disease. CO4: Classify the concept of pathological changes in bleeding disorder CO5: Evaluate the importance of serological investigations in rapid diagnostics CO6: Discuss the diagnostic approaches to recognise the essential nature of disease.	
7	Course Description	The course is designed to give the students basic knowledge and concepts of microbes, pathogens, their relation and impact on various body functions and management by developing the basic understanding of the pathophysiology of various ailments.	
8	Outline syllabus		CO Mapping
	Unit 1	**Basics equipment and techniques**	
	A	Microscopy and sterilization	CO1
	B	Slide Preparation	CO1
	C	Gram staining	CO1
	Unit 2	**Culture media**	

	A	Preparation of culture media (nutrient broth and nutrient agar)	CO2
	B	Preparation of culture media (blood agar and chocolate agar)	CO2
	C	Preparation of culture media (MacConkey medium, LJ medium)	CO2
	Unit 3	**Microscopy and automation**	
	A	Microscopy (Morphology of normal blood cells and their identification)	CO3
	B	Compound microscope	CO3
	C	Centrifugation technique, principle, application uses	CO3
	Unit 4	**Blood group and bleeding disorders**	
	A	ABO Blood grouping and ESR	CO4, C05
	B	Bleeding Time. Clotting Time	CO4, C05
	C	Differential leukocyte count (DLC) Preparation of blood smear	CO4, C06
	Unit 5	**Serological**	
	A	CRP estimation	CO4, CO5,C06
	B	Widal test	CO4, CO5, C06
	C	Malaria parasite	CO4, C05
	Mode of examination	Practical/Viva	
	Weightage Distribution	CA: 25% / MTE: 25% / ETE: 50%	
	Text book/s*	Textbook of Medical Laboratory Technology by Ramnik Sood, Jaypee Brothers Medical Publishers.	
	Other References	Practical Clinical Microbiology and Infectious Diseases: A Hands-On-Guide by Firza Alexander Gronthoud, CRC Press	

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Microbiology and Pathology MCR109	**CO1**	3	2	2	3	3	3	3	3	3
	CO2	3	3	2	2	1	2	3	2	1
	CO3	3	3	2	2	1	2	3	3	3
	CO4	2	2	3	2	2	3	3	2	1
	CO5	3	2	3	2	2	2	3	3	3
	CO6	3	3	1	1	2	3	3	2	1

School:		SSAHS	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		I	
1	Course Code	MCR 110	
2	Course Title	Clinical Biochemistry	
3	Credits	1	
4	Contact Hours (L-T-P)	0-0-2	
	Course Status	Compulsory	
5	Course Objective	1. To train the students in the management of medical laboratory along with handling a variety of laboratory chemicals and instruments including electronic and advanced equipment used in modern medical laboratories. 2. To make the students able to do routine laboratory testing under stipulated conditions. 3. To prepare specimens and operate machines that automatically analyse samples. 4. To provide the conceptual basis for understanding biochemical and particularly address the fundamental mechanisms of the biomolecules to facilitate the life. 5. To develop diagnostic skills in clinical biochemistry and to provide an advanced understanding of the core principles and topics of Biochemistry and their experimental basis.	
6	Course Outcomes	CO1: Define the importance of acid, base, buffers and biochemical reaction CO2: Explain the importance of chemistry of carbohydrates and proteins CO3: Apply the chemistry to understand the lipids and fatty acid for biological process CO4: Classify the clinical importance of enzymes and energy metabolism CO5: Evaluate the clinical importance of nucleic acid and organ function test CO6: Discuss the importance of biomolecules	
7	Course Description	• Introduction of Glassware and safety measures • Preparation of Solutions • Determination of strength of acids and bases • TLC, DLC, RBC counts and HB estimation • BT, CT and BG	
8	Outline syllabus		CO Mapping
	Unit 1	**Introduction of glassware and safety measures**	
	A	Introduction to Laboratory apparatus	CO1

	B	Safety measurements in biochemistry lab			CO1
	C	Maintenance of Laboratory apparatus and glassware			CO1
	Unit 2	**Acid, Base, pH and Preparation of Solutions**			
	A	Preparation of acids of different concentration			CO2
	B	Preparation of bases of different concentration			CO2
	C	Demonstration of pH meter			CO2
	Unit 3	**Determination of strength of acids and bases, Calorimetry**			
	A	Determination of the strength of NaOH solution			CO3
	B	Demonstration of Colorimeter			CO3
	C	Lambert Beer law			CO3
	Unit 4	**TLC, DLC, RBC counts and HB estimation**			
	A	Briefing			CO4, C05
	B	Demonstration			CO4, C05
	C	Practical			CO4, C06
	Unit 5	**BT, CT and BG**			
	A	Briefing			CO4, CO5,C06
	B	Demonstration			CO4, CO5, C06
	C	Practical			CO4, C05
	Mode of examination	Jury/Practical/Viva			
	Weightage Distribution	CA	MTE	ETE	
		25%	0%	75%	
	Text book/s*	Techniques Of Biochemistry and Molecular Biology, 8th edition by Wilson and Walker, Cambridge University Press.			
	Other References	Practical Manual of Biochemistry by Dr. G. Sattanathan; Dr. S.S. Padmapriya; Dr. B. Balamuralikrishnan, Skyfox Publishing Group.			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Clinical Biochemistry MCR110	**CO1**	3	2	2	1	1	3	3	2	2
	CO2	3	2	2	1	1	2	3	2	2
	CO3	3	3	1	2	2	3	2	3	1
	CO4	2	3	1	1	2	2	3	2	2
	CO5	3	3	1	1	2	2	2	2	2
	CO6	3	2	2	1	3	3	3	3	3

Semester-II

School:		SSAHS	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		II	
1	Course Code	MCR 112	
2	Course Title	Systemic Pharmacology	
3	Credits	4	
4	Contact Hours (L)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	At the end of the course the students will be equipped with the basics knowledge about, Medicine which would lay the foundation for their courses in the next semester.	
6	Course Outcomes	**CO1: Knowledge:** defining, listing and recognising the drugs. **CO:2 Comprehension:** understanding, characterising, explaining, identifying and locating the various drugs that are useful in treatment and management of diseases. **CO3: Application:** performing, demonstrating, implementing and applying the concept of basic pharmacology which help in appropriate diagnosis and treatment of systematic diseases. **CO4: Analysis:** analysing, categorising, comparing and differentiating type of drugs. **CO5:** Evaluate drug development in clinical Research **CO6:** Discuss various drugs in therapeutics.	
7	Course Description	At the end of the course the students will be equipped with the basics knowledge about certain concepts, which would lay the foundation for their courses in the next semester.	
8	Outline syllabus		CO Mapping
	Unit 1	**Drugs affecting blood and cardiovascular system**	
	A	Drugs used in Hypertension	CO1
	B	Drugs affecting Coagulation	CO1
	C	Drugs used in Heart Failure	CO1
	Unit 2	**Drugs Affecting nervous system**	
	A	Introduction to Autonomic Nervous system	CO2
	B	Cholinergic system and Agent or Adrenergic System and Agents	CO2

	C	Anti-Depressant Drugs			CO2
	Unit 3	**Drugs affecting Respiratory system and GIT**			
	A	Drugs used in Asthma and COPD			CO3
	B	Drugs for Peptic Ulcer			CO3
	C	Drugs for Diarrhoea and Constipations			CO3
	Unit 4	**Hormones and hormone Antagonist**			
	A	Anti-diabetic Agents			CO4, C05
	B	Thyroid and Anti Thyroid Drugs			CO4, C05
	C	**Corticosteroids**			CO4, C06
	Unit 5	**Antimicrobial and Anti- inflammatory Drugs**			
	A	Introductions to Anti-microbial drugs			CO4, CO5, C06
	B	Anti-Fungal Drugs			CO4, CO5, C06
	C	NSAID			CO4, C05
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	K D Tripathi: Essentials of Medical Pharmacology. 5th edition, Jaypee, New Delhi, 2004 Essentials of Pharmacotherapeutics by F. S. K. Barar Essentials of Medical Pharmacology by Tripathi Pharmacology and Pharmacotherapeutics by R. S. Satoskar.			
	Other References	LIR Pharmacology by Sangeetha Sharma, Wolters India Pvt ltd.			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Systemic Pharmacology MCR112	**CO1**	3	2	1	1	1	3	3	2	1
	CO2	3	2	2	2	3	2	3	2	3
	CO3	2	2	2	1	1	2	3	3	2
	CO4	3	3	2	2	2	2	3	3	3
	CO5	3	3	3	3	2	2	2	2	2
	CO6	3	3	3	3	3	3	3	3	3

School:		SSAHS	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		II	
1	Course Code	MCR 113	
2	Course Title	Clinical trial process and good clinical practices	
3	Credits	4	
4	Contact Hours (L-T-P)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	1.To provide a comprehensive introduction to the clinical research process, conduct and management of clinical trials. 2.To make student more familiar with roles/jobs as part of the study team. 3.To provide extensive Knowledge and application in different aspects of Clinical research process. 4.To understand the historical development, the principles and content of international guidelines for clinical research (Declaration of Helsinki, ICH-GCP) and their influence	
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define latest technological advancement in clinical practices with professional and ethical uprightness and socio-economic concerns. CO2: Explain GCP and regulatory guidelines during clinical research process. CO3: Apply timelines/guidelines and standard operating procedures for day-to-day clinical trial activities. CO4: Classify the different phases and working process of clinical drug development CO5: Evaluate the investigator's role and responsibilities in a clinical study, particularly regarding informed consent and safety reporting CO6: Discuss recent advance good clinical practices.	
7	Course Description	This course gives insight of the clinical trial process, its conduct and management as per GCP guidelines. Good clinical practice provides a framework of principles which aim to ensure the safety of research participants and the integrity and validity of data. This course aims to provide with the basic principles of GCP and how these principles can be applied practically in the research setting.	
8	Outline syllabus		CO Mapping
	Unit 1	**Regulatory filing applications**	
	A	Investigational New drugs (IND)	CO1
	B	New drug application (NDA)	CO1
	C	Abbreviated new drug application (ANDA), Bioavailability and Bioequivalence	CO1
	Unit 2	**Trial process**	

	A	Site selection and initiation			CO2
	B	Patient recruitment and retention, informed consent			CO2
	C	Study closes out			CO2
	Unit 3	**Site monitoring**			
	A	Introduction and importance- audit, inspection and monitoring, analysis of reports, improvements and corrections etc.			CO3
	B	Audit and inspection-process, responsibilities, concerned bodies and people, reports, submissions etc.			CO3
	C	Monitoring- process, responsibilities, concerned bodies and people, reports, submissions, analysis etc.			CO3
	Unit 4	**Historical evolution of GCP**			
	A	Nuremberg code			CO4, C05
	B	Declaration of Helsinki			CO4, C05
	C	Belmont report, ICH			CO4, C06
	Unit 5	**Ethics in clinical research**			
	A	Principles of ethics, ICH-GCP			CO4, CO5,C06
	B	GCP guidelines			CO4, CO5, C06
	C	Challenges in implementation of GCP guidelines			CO4, C05
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	Principles and Practice of Clinical Trial Medicine: Richard Chin, Bruce Y. Lee			
	Other References	A Concise Guide to Clinical Trials by Allan Hackshaw, BMJ Books.			
		Quick Guide to Good Clinical Practice: How to Meet International Quality Standard in Clinical Research by Cemal Cingi and Nuray Bayar Muluk, Springer International Publishing AG			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Clinical trial process and good clinical practices MCR113	**CO1**	1	2	3	1	1	3	3	2	3
	CO2	3	2	2	2	3	2	2	2	3
	CO3	2	2	2	1	1	2	3	3	2
	CO4	3	3	1	2	2	2	3	2	1
	CO5	3	3	3	2	3	3	2	3	3
	CO6	3	3	3	3	3	3	3	3	2

School:		**SSAHS**	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		II	
1	Course Code	MCR 114	
2	Course Title	Introduction to management (Hospital and healthcare)	
3	Credits	4	
4	Contact Hours (L-T-P)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	1. To enable students to define and describe the evolution of management and various behavioural science contributions; nature and scope of management. 2.Discuss and communicate the difference between management and administration 3. To understand various levels and functions of management 4. To describe the various skills, abilities and tools that are necessary for successful managers.	
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define the influence of historical forces on the current practice of management. CO2: Explain how organizations adapt to an uncertain environment and identify techniques managers use to influence and control the internal environment. CO3: Apply the process of management's four functions: planning, organizing, leading, staffing and controlling. CO4: Classify use of vocabularies within the field of management to articulate one's own position on a specific management issue and communicate effectively with varied audiences. CO5: Evaluate leadership styles to anticipate the consequences of each leadership style. CO6: Discuss hospital and health care management in real time.	
7	Course Description	This course provides the basic concept about management and its functions of planning, organizing, staffing, directing, and controlling resources to accomplish organizational goals. The role of the manager at each level of the organization along with the abilities, skills and tools required to be an effective manager/leader are also emphasized. An insight of organizational behaviour is also covered.	
8	Outline syllabus		CO Mapping
	Unit 1	**Basics of management**	
	A	Definition, concept and principles	CO1
	B	Historical perspectives and various theories	CO1
	C	Various models of management	CO1

	Unit 2	**Functions of Management**			
	A	Planning and organizing			CO2
	B	Leading and staffing			CO2
	C	Controlling and evaluating			CO2
	Unit 3	**Management vs administration**			
	A	Administration			CO3
	B	Comparison with management			CO3
	C	Similarity with management			CO3
	Unit 4	**Leadership**			
	A	Definition, concept, managers vs leaders			CO4, C05
	B	Leadership qualities			CO4, C05
	C	Leadership styles			CO4, C06
	Unit 5	**Organizational behaviour**			
	A	Definition, concept, importance			CO4, CO5, C06
	B	Personality development, leadership, motivation			CO4, CO5, C06
	C	Groups, cooperation and conflicts			CO4, C05
	Mode of examination	Theory/Jury/Practical/Viva			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	Principles of Management by PC Tripathi, PN Reddy and Ashish Bajpai, McGraw Hill			
	Other References	L. M. Prasad, Principles and Practice of Management			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Introduction to management (Hospital and healthcare) MCR114	**CO1**	1	3	1	2	2	3	1	3	3
	CO2	2	3	2	2	2	3	3	2	3
	CO3	2	2	2	3	1	2	3	3	2
	CO4	3	3	1	2	2	2	3	2	1
	CO5	2	3	3	2	3	3	1	3	3
	CO6	3	3	3	3	3	3	3	3	2

School:		**SSAHS**	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		II	
1	Course Code	MCR 115	
2	Course Title	Medical terminologies and conditions	
3	Credits	4	
4	Contact Hours (L-T-P)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	1. To identify and define the roles of the basic word parts including prefixes, suffixes, root words and combining forms. 2. To interpret abbreviations for common signs, symptoms, medical conditions and diagnostic testing and therapeutic procedures. 3. To interpret major symptoms and signs in clinical evaluation. 4. To have an understanding of a basic differential diagnosis for problems affecting each organ system.	
6	Course Outcomes	CO1: Define prefixes, roots and suffixes associated with each body system and make use of correct medical terms CO2: Explain several pathological conditions affecting each body systems. CO3: Apply symptomatic and diagnostic terms in medical communication, documentation and dealings. CO4: Classify the meanings of abbreviations associated with different body systems CO5: Evaluate surgical, clinical and laboratory procedures. CO6: Discuss surgical, clinical and laboratory procedures related to health care.	
7	Course Description	Covers prefixes, suffixes, root words, abbreviations, conditions, symptoms and procedure terms. Course taught by body systems. This course also discusses some of the most common medical conditions and gives an insight into how a human body works and how professionals diagnose ailments.	
8	Outline syllabus		CO Mapping
	Unit 1	**Introduction**	
	A	Components of medical terms	CO1
	B	Prefixes and suffixes	CO1
	C	Terms related to body as a whole	CO1
	Unit 2	**Integumentary, musculoskeletal system**	
	A	General pathologic conditions	CO2
	B	Symptomatic terms, diagnostic terms	CO2
	C	General abbreviations oncology terms	CO2

	Unit 3	**Cardio-vascular and respiratory system**			
	A	General pathologic conditions			CO3
	B	Symptomatic terms, diagnostic terms			CO3
	C	General abbreviations oncology terms			CO3
	Unit 4	**Urinary, Nervous and Sensory system**			
	A	General pathologic conditions			CO4, C05
	B	Symptomatic terms, diagnostic terms			CO4, C05
	C	General abbreviations oncology terms			CO4, C06
	Unit 5	**Endocrine and Reproductive system**			
	A	General pathologic conditions			CO4, CO5, C06
	B	Symptomatic terms, diagnostic terms			CO4, CO5, C06
	C	General abbreviations oncology terms			CO4, C05
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	Medical Terminology Systems: Barbara A. Gylys			
	Other References	Medical Terminology: A Short Course by Davi-Ellen Chabner, Saunders.			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Medical terminologies and conditions MCR115	**CO1**	1	3	2	2	2	2	1	2	2
	CO2	2	2	3	2	2	1	3	3	2
	CO3	2	2	3	3	3	3	2	2	3
	CO4	3	2	3	3	2	3	3	3	2
	CO5	3	3	3	2	2	3	3	3	2
	CO6	3	3	3	3	3	3	3	3	3

School:		**SSAHS**	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		II	
1	Course Code	MCR 116	
2	Course Title	Epidemiology and Biostatistics	
3	Credits	4	
4	Contact Hours (L-T-P)	3-1-0	
	Course Type	Compulsory	
5	Course Objective	1.To introduce the basic principles and methods of epidemiology and demonstrate their broad applicability. 2.To provide fundamental skills needed to interpret and critically evaluate literature relevant to public health professionals. 3.To provide a structured method for organizing and analysing raw data and to interpret and communicate the results. 4. To describe preferred methodological alternatives to commonly used statistical methods when assumptions are not met.	
6	Course Outcomes	CO1: Define the contribution of epidemiology and biostatistics to the scientific study of health and disease. CO2: Explain the concepts of health, disease, determinants and indicators of health CO3: Apply knowledge, concepts and understanding of levels of prevention, patterns of epidemic, epidemic forecasting etc. for successful management of epidemic CO4: Classify the principal methods of statistical inference and design. CO5: Evaluate the statistical analyses accurately and effectively. CO6: Discuss the application of statistics in epidemiology.	
7	Course Description	The course is designed to help the students develop essential knowledge and skills in quantitative public health research by integrating the core disciplines of epidemiology and biostatistics in one course. This course will enable the students to apply an epidemiological approach to the study of disease and illness. This study will help in interpreting and assessing the evidence quality of a range of study designs and to apply appropriate statistical techniques in the analysis.	
8	Outline syllabus		CO Mapping
	Unit 1	**Health and disease**	
	A	Concept and definition	CO1
	B	Natural history of disease	CO1
	C	Determinants and indicators of health	CO1
	Unit 2	**Levels of prevention**	
	A	Primary, Secondary and Tertiary	CO2

	B	Measurements of disease			CO2
	C	Diagnostic test			CO2
	Unit 3	**Epidemiology**			
	A	Concept, principle and definition			CO3
	B	Descriptive and analytical Epidemiological			CO3
	C	Study design			CO3
	Unit 4	**Epidemic management**			
	A	Patterns of epidemic			CO4, C05
	B	Epidemic forecasting			CO4, C05
	C	Epidemic management			CO4, C06
	Unit 5	**Biostatistics**			
	A	Descriptive statistics			CO4, CO5, C06
	B	Parametric and non-parametric test			CO4, CO5, C06
	C	Application of excel and SPSS software in research			CO4, C05
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	Park's Textbook of preventive and social medicine by K Park, Banarsidas Bhanot Publishers			
	Other References	The Connected Community: Discovering the Health, Wealth, and Power of Neighborhoods by Russell, McKnight and Palmer, Berrett-Koehler Publishers			

Course Code and Course Name	**POs COs**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PSO1**	**PSO2**
Epidemiology and Biostatistics MCR116	**CO1**	1	3	3	1	2	2	2	2	3
	CO2	2	3	2	3	2	2	3	3	2
	CO3	2	2	3	3	3	3	3	2	3
	CO4	3	2	3	3	2	3	3	3	2
	CO5	3	3	3	2	2	3	3	3	3
	CO6	3	3	3	3	3	3	3	3	3

School:		**SSAHS**	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		II	
1	Course Code	MCR 117	
2	Course Title	Systemic Pharmacology LAB	
3	Credits	1	
4	Contact Hours (P)	2	
	Course Type	Compulsory	
5	Course Objective	To equip with the basics knowledge about drugs,their types, mode of action, effect etc. which would lay the foundation for their courses in the next semester.	
6	Course Outcomes	CO1: Knowledge: defining, listing and recognising the drugs. CO:2 Comprehension: understanding, characterising, explaining, identifying and locating the various drugs that are useful in treatment and management of diseases. CO3: Application: performing, demonstrating, implementing and applying the concept of basic pharmacology which help in appropriate diagnosis and treatment of systematic diseases. CO4: Analysis: analysing, categorising, comparing and differentiating type of drugs.	
7	Course Description	This course is designed to develop an understanding of the theoretical concepts surrounding pharmacology, such as the pharmacokinetics and pharmacodynamics of drugs, and the concepts surrounding pharmacotherapy	
8	Outline syllabus		CO Mapping
	Unit 1	**Practical based on General Pharmacology**	
	A	Mechanisms or drug action	CO1
	B	Dose–response relationship	CO1
	C	Pharmacokinetics of drug absorption, distribution, biotransformation, excretion and toxicity, Factors influencing drug metabolism of drug action	CO1
	Unit 2	**Study of different doses forms.**	
	A	Introduction to Drug Doses	CO2
	B	Introduction to Routes	CO2
	C	Calculation of Drug Dose	CO2
	Unit 3	**Drug Labelling and Package insert**	
	A	Demonstrate to Labelling the bottle	CO3
	B	Demonstrate Insert drug in the bottle	CO3

	C	Demonstrate Package of the bottle			CO3
	Unit 4	**Experimental and Clinical Pharmacology Practical**			
	A	Animal Care, and Sex Determination			CO4, C05
	B	Animal Handling			CO4, C05
	C	Dose Calculation for Experimental animal			CO4, C06
	Unit 5	**Practical based on Preparation of drugs**			
	A	Anti-glaucoma; Sulphonamides			CO4, CO5, C06
	B	Antibiotics; Corticosteroids			CO4, CO5, C06
	C	Anaesthetics; Proteolytic enzymes			CO4, C05
	Mode of examination	Practical			
	Weightage Distribution	CA	MTE	ETE	
		25%	0%	75%	
	Text book/s*	K D Tripathi: Essentials of Medical Pharmacology. 5th edition, Jaypee, New Delhi, 2004 Essentials of Pharmacotherapeutics by F. S. K. Barar Essentials of Medical Pharmacology by Tripathi Pharmacology and Pharmacotherapeutics by R. S. Satoskar.			
	Other References	LIR Pharmacology by Sangeetha Sharma, Wolters India Pvt ltd.			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Systemic Pharmacology (Lab) MCR117	**CO1**	3	2	1	1	1	3	3	2	1
	CO2	3	2	2	2	3	2	3	2	3
	CO3	2	2	2	1	1	2	3	3	2
	CO4	3	3	2	2	2	2	3	3	3
	CO5	3	3	3	3	2	2	2	2	2
	CO6	3	3	3	3	3	3	3	3	3

School:		SSAHS	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		II	
1	Course Code:	MCR118	Course Name: Community posting and application of biostatistics
2	Course Title	Community posting and application of biostatistics	
3	Credits	2	
4	Contact Hours (L-T-P)	0-0-4	
	Course Status	Compulsory	
5	Course Objective	1. The objective of assigning the project related to community work is to expose our students to different social issues faced by the people in different sections of society. 2. This type of project work will help the students to develop better understanding of problems of people living in disadvantage position in the society, may be socially, medically, economically, or otherwise. 3. This type of live project work will help our students to connect their class-room learning with practical issues/problems in the society.	
6	Course Outcomes	Students will be able to: **CO1: Students develop awareness** of the social, health, and environmental challenges faced by the community **C02: Students are more appreciative** of socio-economic realities beyond textbooks and classrooms **CO3: Students learn to apply their knowledge** through research, awareness creation, and services for community benefit **CO4: Students are able to carry** out community-based projects with sincerity, teamwork and timely delivery **CO5: Students learn to respectfully engage** with communities with purposive intent to contribute to society and sustainable development **C06: Students are able to document and present** their community project findings in an academically robust manner	
7	Course Description	In Community Connect projects, students will learn how to identify problems of rural and underprivileged communities by conducting surveys, or will help the communities by providing services or solutions for the issues faced by them.	
8	Outline syllabus		CO Mapping
	Unit 1	Team/Group formation and Project Assignment. Problem Definition and Finalizing the problem statement, Resource requirement, if any.	CO1
	Unit 2	Develop a useful questionnaire or service to the community that will aid in achieving the objectives of the project.	CO2

	Unit 3	Learn how to interact with the community members, whether in survey or service-based project – to help develop a more open mindset in the students.			CO3
	Unit 4	Analysis of survey data and/or impact on the community members.			CO4, C05
	Unit 5	Demonstrate and justify their findings in light of the data they have gathered, or show the benefits to the community of the actions they have taken.			CO4, CO5, CO6
	Mode of examination	Practical /Viva			
	Weight age Distribution	CA	MTE	ETE	
		100%	NA	NA	
Text book/s*		Comprehensive textbook of biostatistics and research methodology by Dr. S. Kartikeyan, Bhalani Publishing House			
Other References		A Community Connection by Marilyn G Stewart, Davis Publications			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Community posting and application of biostatistics MCR118	**CO1**	1	3	2	3	2	2	3	3	3
	CO2	3	2	2	2	3	3	3	2	3
	CO3	2	2	3	1	3	2	3	3	3
	CO4	3	3	2	2	2	3	3	3	3
	CO5	3	3	3	3	2	2	2	2	2
	CO6	3	3	3	3	3	3	3	3	3

School:		**SSAHS**	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2023-2024	
Semester:		II	
1	Course Code	MCR 121	
2	Course Title	Research methodology in clinical settings	
3	Credits	2	
Contact Hours (L-T-P)		2-0-0	
	Course Type	Compulsory	
5	Course Objective	1.To equip with knowledge and skills necessary in conducting research work and formulating research synopsis and report. 2.To impart knowledge for enabling students to develop data analytics skills and meaningful interpretation to the data sets so as to solve any research problem. 3.To Use theory and previous research to create research questions and hypotheses and to identify and analyse the appropriate method and variables needed for research questions	
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define various kinds of research, objectives, research designs and sampling. CO2: Explain qualitative and quantitative research techniques CO3: Apply analytical skills on measurement and scaling and quantitative data. CO4: Classify the research process. CO5: Evaluate ethical issues in research CO6: Discuss the issues in using quantitative and qualitative research	
7	Course Description	This course is designed to provide students with the practical tools of doing research and the theoretical background for critiquing and designing research on various topics. This course will also engage students in the discussion of ethics, studying how personal values, ethical models and reflective processes shape our ethical decision making in a leadership context.	
8	Outline syllabus		CO Mapping
	Unit 1	**Purpose of research**	
	A	Introduction to research, what is Research?	CO1
	B	Objectives and motivations for research	CO1
	C	Types of Research, Problem Formulation	CO1
	Unit 2	**Principles of Research in quantitative and qualitative approaches: Research design**	
	A	Steps in Research Process	CO2
	B	Introduction to Research Design	CO2
	C	Experimental and analytical research	CO2

	Unit 3	**Methods of data collection and types of data**			
	A	Introduction to Primary and Secondary data			CO3
	B	Measurement and Scaling Technique, Questionnaire Designing, Scales of Measurement			CO3
	C	Application of SPSS and other statistical Software			CO3
	Unit 4	**The Research Cycle**			
	A	Analysis and Report Writing, Data Preparation, Data aggregation, Data accuracy, Data structure, Data transformation			CO4, C05
	B	Inferential Statistics, Hypothesis Testing Process, Concept of Parametric and Non-Parametric Test			CO4, C05
	C	Application of SPSS and other statistical Software			CO4, C06
	Unit 5	**Values, Social Responsibility and Ethics in Research**			
	A	Values and Ethics			CO4, CO5, C06
	B	Uses of ethical theories, Multinational corporations, Environmental ethics, computer ethics			CO4, CO5, C06
	C	Application of SPSS and other statistical Software			CO4, C05
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
Text book/s*		Malhotra N.K. (2011) Marketing Research, Pearson Education, Inc. Zikmund W.G. (2007) Business research Methods, Thomspns, Akash Press New Delhi.			
Other References		Beri G.C. (2010) Marketing Research 3rd Edition, TMH Publishers Ltd, New Delhi			

Course Code and Course Name	POs Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Research methodology in clinical settings MCR121	**CO1**	3	3	3	2	2	3	2	2	2
	CO2	2	2	2	1	3	3	3	3	3
	CO3	3	3	3	3	2	2	1	3	3
	CO4	2	3	3	2	2	1	3	3	3
	CO5	3	3	3	2	2	2	3	3	3
	CO6	3	3	3	3	3	3	3	3	2

Semester-III

School:	**SSAHS**
Batch:	2023-2025
Programme:	Master of Science (Clinical Research)
Academic Year:	2024-2025
Semester:	III
Course Code	MCR 203
Course Title	Clinical trial management
Credits	4
Contact Hours (L-T-P)	4-0-0
Course Type	Compulsory
Course Objective	1. To provide Understanding of how to effectively manage clinical trials through applying a range skills and knowledge 2. To develop effective strategies and problem solving for managing clinical trials
Course Outcomes	On successful completion of this course, student will be able to: CO1: Define investigator and site selection, site management and conflict resolution in clinical trial. CO2: Explain level feasibility plan and structure of a study budget. CO3: Apply the concept of clinical research process to conduct and management the clinical trials. CO4: Classify the serious adverse events on site, development of recruitment strategies. CO5: Evaluate the staff requirements and construct timelines to target the appropriate study CO6: Discuss the population to store, shift and dispense a study drug or device and how to review case report forms, protocols and study budget.
Course Description	This course will equip the students with the imperative skills of clinical trial management. This course gives a methodical understanding of the core areas of clinical trial management thus enhancing skills and knowledge to the level expected of a Clinical Trial Project Manager

Outline syllabus		CO Mapping
Unit 1	**Introduction, Training and meeting**	
A	Introduction to CT Management and Importance	CO1
B	Roles and Responsibilities in CTM	CO1
C	Organizing Meetings – Investigator and vendors, CRC	CO1

Unit 2	**SOPs**	
A	Introduction, concept, definition	CO2
B	SOP writing, review and editing	CO2
C	Implementation, challenges in implementation	CO2
Unit 3	**Monitoring and record retention**	
A	Audit, inspection and monitoring- types and process, responsibilities of stakeholders	CO3
B	Regulatory binder and record retention	CO3
C	Master files	CO3
Unit 4	**IP management**	
A	Storage and handling	CO4, C05
B	IP accountability	CO4, C05
C	Confidentiality and other challenges	CO4, C06
Unit 5	**Outsourcing**	
A	Overview, process and types	CO4, CO5, C06
B	Finance and budgeting	CO4, CO5, C06
C	Basis for selection for outsourcing to CROs/SMOs, Agreements	CO4, C05

Theory			
CA	MTE	ETE	
25%	25%	50%	
Textbook/s*	Clinical Trial Management System A Complete Guide- 2020 Edition. ISBN-13: 978-1867407317		
Other References	Clinical Trial Management – an Overview (Clinical Trials Book 2). ISBN-13: 978-1393386179		

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Clinical trial management MCR203	**CO1**	2	3	3	1	2	3	1	3	3
	CO2	3	2	2	2	3	2	2	2	3
	CO3	1	2	3	3	1	3	3	2	3
	CO4	3	3	2	2	2	2	3	2	2
	CO5	3	3	3	2	3	3	2	3	3
	CO6	3	3	3	3	3	3	3	3	2

School:		**SSAHS**	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2024-2025	
Semester:		III	
1	Course Code	MCR 204	
2	Course Title	Regulations in Clinical research	
3	Credits	4	
4	Contact Hours (L-T-P)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	1. To gain the essential knowledge and skills required to help companies to work in regulatory environment. 2. Acquire the foundation to work within or in variety of areas including medical products development, pharmaceutical formulations, sales, strategic marketing and clinical investigations. 3. To know about regulatory process in drug development, formulations, API. 4. To sharpen the understanding of the laws that governs the development, manufacturing and commercialization along with the distribution of drugs, biologics and medical devices.	
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define the general principles of drug regulations and device regulation during the different phases of their life cycle. CO2: Explain the Regulatory guidance's and guidelines for filing and approval process CO3: Apply the role of national and international bodies in clinical research regulation. CO4: Classify the Dossiers and their submission to regulatory agencies in different countries CO5: Evaluate the concept of intellectual property rights, procedural knowledge to Legal system CO6: Discuss the problem relating to intellectual property rights.	
7	Course Description	The courses will provide integrated knowledge and broad perspectives needed to effectively manage the regulatory process from Innovation →Discovery → Approval→ Commercialization which implies regulatory affairs are essential to bring the product to the market globally.	
8	Outline syllabus		CO Mapping
	Unit 1	**EMA and US FDA**	

	A	Importance and functioning, Roles and responsibilities			CO1
	B	Powers, authorities, submissions			CO1
	C	Grants, compensations, promotion of research			CO1
	Unit 2	**Schedule Y and HIPAA**			
	A	Introduction, Importance, History			CO2
	B	Guidelines			CO2
	C	Details and implications			CO2
	Unit 3	**ICMR and CDSCO**			
	A	Importance and functioning, Roles and responsibilities			CO3
	B	Submissions			CO3
	C	Grants, compensations, promotion of research			CO3
	Unit 4	**Intellectual Property Rights**			
	A	Patent			CO4, C05
	B	Copyright			CO4, C05
	C	Trademark			CO4, C06
	Unit 5	**Insurance and Indemnity**			
	A	Introduction, concept, advantages, disadvantages			CO4, CO5, C06
	B	Legal implications			CO4, CO5, C06
	C	Compensation			CO4, C05
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		30%	20%	50%	
	Text book/s*	Ethics and Regulations of Clinical Research: Robert J. Levine			
		Regulatory Requirements for Drug Development and Clinical Research ISBN-13: 978-8191009132			
	Other References	ICH GCP Ethics and Regulations in Clinical Research. ASIN: B07HYZ7XTN			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Regulations in Clinical research MCR204	**CO1**	2	2	2	3	3	2	3	3	3
	CO2	3	2	2	2	3	1	2	2	3
	CO3	2	2	2	3	3	2	3	3	2
	CO4	3	2	3	2	3	2	3	3	2
	CO5	3	3	3	3	2	2	3	3	3
	CO6	3	3	3	3	3	3	3	3	2

School:		**SSAHS**	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2024-2025	
Semester:		III	
1	Course Code	MCR 205	
2	Course Title	Documentation and data management in clinical research	
3	Credits	4	
4	Contact Hours (L-T-P)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	1.To understand what data management is and the purpose of a data management plan 2.To realize factors to be considered in the design and type of a case report form 3.Considerations for data analysis 4.What is important when deciding on a data management system	
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define the key documents related to the ethical conduct of clinical trials CO2: Explain the Investigators Brochure sections and describe its use, approval, and distribution. CO3: Apply the procedures for clinical trial data collection and data management to ensure optimal quality data and outline the various quality management issues in clinical trials. CO4: Classify the various data management issues in clinical trials CO5: Evaluation and interpretation of clinical trials results CO6: Discuss the various methods of documentation and data management in clinical research.	
7	Course Description	Clinical Data Management is an integral part of the clinical trial process to transform raw data into consistent, accurate, reliable, meaningful trial output in full compliance with regulatory guidelines. This course provides a comprehensive training on scientific, practical, ethical and technical concepts of clinical data management.	
8	Outline syllabus		CO Mapping
	Unit 1	**Investigator Brochure and Clinical study protocol**	
	A	IB- Importance, contents- preclinical and clinical, other details	CO1
	B	Protocol- importance, objectives	CO1
	C	Protocol- Design, contents, adherence, challenges	CO1
	Unit 2	**Clinical study report and publication**	
	A	Importance and guidelines	CO2
	B	Format and components	CO2
	C	Applicable regulatory requirements	CO2

	Unit 3	**Essential documents and source documents**			
	A	Documents before the trial			CO3
	B	Documents during the trial			CO3
	C	Documents after the trial			CO3
	Unit 4	**Clinical data management**			
	A	Introduction to CDM, CRF Design			CO4, C05
	B	Clinical data entry and electronic data capture			CO4, C05
	C	Data validation and database lock			CO4, C06
	Unit 5	**Data Coding and Decoding**			
	A	Introduction			CO4, CO5, C06
	B	Learning			CO4, CO5, C06
	C	Practice			CO4, C05
	Mode of examination	Theory			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Text book/s*	Practical Guide to Clinical Data Management: Susanne Prokscha			
	Other References	Clinical Documentation Improvement: Principles and Practice. ISBN-13: 978-1584265023			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Documentation and data management in clinical research MCR205	**CO1**	3	3	3	2	3	**3**	2	3	3
	CO2	3	2	2	2	3	2	2	2	3
	CO3	2	2	3	1	3	2	1	3	2
	CO4	2	2	3	2	2	3	3	2	2
	CO5	3	3	3	2	3	3	2	3	3
	CO6	3	3	3	3	3	3	3	3	2

School:		**SSAHS**
Batch:		2023-2025
Programme:		Master of Science (Clinical Research)
Academic Year:		2024-2025
Semester:		III
1	Course Code	MCR 206
2	Course Title	Pharmacovigilance and Pharmacoeconomics
3	Credits	4
4	Contact Hours (L-T-P)	4-0-0
	Course Type	Compulsory
5	Course Objective	1. to understand the key concepts in the responsible conduct of research a 2. to understand how to conduct research that conforms to the highest standards for the protection of human research subjects. 3. To sensitize and equip with knowledge on Pharmacovigilance practices worldwide and on the Indian scenario in detail 4. List four primary perspectives that a pharmaco-economic analysis can be conducted from and describe how they differ. 5. Discern between different medical cost categories that can be identified, measured, and compared in a pharmaco-economic analysis.
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define the principles and practical relevance of ethical issues in clinical research and the legal and ethical provision for the protection of clinical trial subjects. CO2: Explain the role of Pharmaco-epidemiology, Pharmaco-economics in the lifecycle management of a medicine. CO3: Apply drug reactions and adverse events in terms of severity and then describe the safety reporting requirements pre- and post-approval. CO4: Classify the ongoing management of drug safety issues (including risk management plans, periodic safety update reports) CO5: Evaluate the ongoing benefit/risk assessment throughout the lifecycle of a medicine. CO6: Discuss the collection, evaluation, and reporting of adverse event data in clinical trials
Course Description		This course provides insight in to pharmaco-economics and its effect at healthcare industry. Also, gives comprehensive knowledge, understanding, emphasises importance of pharmacovigilance in the field of research.

8	Outline syllabus				CO Mapping
	Unit 1	**Introduction PV**			
	A	Basic understanding, concept and definition-PV, ADR, AE, SE, SUSAR			CO1
	B	Legal basis in selected countries			CO1
	C	Pharmacovigilance programme of India			CO1
	Unit 2	**Mechanism of ADR**			
	A	Renal, Hepatic			CO2
	B	Cardiac, Haematological			CO2
	C	Ocular, Dermatological, Gastro-intestinal			CO2
	Unit 3	**Drug safety and risk management in special conditions**			
	A	Pregnancy			CO3
	B	Paediatric Populations			CO3
	C	Geriatric Populations			CO3
	Unit 4	**Ethical oversight**			
	A	Introduction, importance and understanding ethical principles			CO4, C05
	B	Consent and confidentiality			CO4, C05
	C	CIOMS- Working groups and their Contribution to Pharmacovigilance			CO4, C06
	Unit 5	**Pharmaco-economics**			
	A	Health Economics: Overview, Healthcare Demands and Markets, Medical Economics, Behavioural Economics, Health consumerism, Health Insurance, Health Policy /analysis			CO4, CO5, C06
	B	Health Planning and Management -Health Policies, healthcare models, healthcare systems, Strategic Planning and its Parameters, Direction and clinical management of health services – Foundations of Clinical Management, Information /system, HRM in Healthcare			CO4, CO5, C06
	C	Financial Management – Measurement and analysis of costs and results in healthcare, Economic assessment of health activities, Minimizing costs, Cost-benefit analysis, Cost-effectiveness analysis, Cost-Utility analysis			CO4, C05
Mode of exam		Theory			
Weightage Distribution		CA	MTE	ETE	
		25%	25%	50%	
Textbook/s*		Drug Discovery and Clinical Research. ISBN-13: 978-9352705771			
Other Reference/s*		Pharmacovigilance: Primer for Beginner. ISBN-13: 978-6204742410			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Pharmacovigilance and Pharmacoeconomics MCR206	**CO1**	2	2	2	3	1	2	3	3	2
	CO2	3	2	2	2	3	2	2	2	3
	CO3	2	2	2	1	3	2	3	3	2
	CO4	3	3	1	2	2	3	3	2	3
	CO5	2	2	2	3	1	2	3	3	2
	CO6	3	3	3	3	3	3	3	3	2

School:		**SSAHS**	
Batch:		2023-2025	
Programme:		Master of Science (Clinical Research)	
Academic Year:		2024-2025	
Semester:		III	
1	Course Code	MCR 207	
2	Course Title	Psychology and patient counselling	
3	Credits	4	
4	Contact Hours (L-T-P)	4-0-0	
	Course Type	Compulsory	
5	Course Objective	1.To help students understand the processes of emotion and relating them to diverse contexts. 2.To prepare students learn organizing their personal lives better by gaining insights into their own emotional strengths. 3. To develop skills how to deal better with peers and patients.	
6	Course Outcomes	On successful completion of this course, student will be able to: CO1: Define key concepts, principles, and overarching themes in psychology. CO2: Explain counselling and psychological practice as an applied behavioural science CO3: Formulates and conceptualizes cases; plans and implements interventions utilizing at least one consistent theoretical orientation CO4: Classify a range of factors within and outside individuals which influence mind and behaviour CO5: Evaluate forms and maintains productive and respectful relationships with clients. CO6: Discuss with peers/colleagues, supervisors, and professionals from within and across disciplines.	
7	Course Description	This course provides a comprehensive overview of cognitive psychology, the scientific study of mental processes: how people acquire, store, transform, use, and communicate information. Topics may include perception, attention, language, memory, reasoning, problem solving, decision-making, and creativity.	
8	Outline syllabus		CO Mapping
	Unit 1	**Psychology**	
	A	Introduction, scope, evolution and definition of psychology	CO1
	B	Branches of psychology	CO1
	C	Concept of normality and abnormality	CO1
	Unit 2	**Psychological disorders**	
	A	Identifying psychological disorders	CO2
	B	Anxiety disorders- panic, phobia; their signs, symptoms and management.	CO2

	C	Anxiety disorders-OCD, PTSD; their signs, symptoms and management.			CO2
	Unit 3	**Stress and learning**			
	A	Hans Selye Model of stress, Lazarus and Folkman model of stress, Sources of stress			CO3
	B	Stress, disease and health. Changing health- impairing behaviour.			CO3
	C	Learning- Meaning, definition, Theories of learning, Pavlov's classical conditioning, Skinner's operant conditioning			CO3
	Unit 4	**Therapeutic techniques**			
	A	Various techniques and their applications, Assessment and management, alcohol dependence			CO4, C05
	B	Psychotherapy- meaning and definition. (Brief introduction to psychoanalytical, behavioural and CBT techniques)			CO4, C05
	C	Relaxation-types. (Brief introduction to psychoanalytical, behavioural and CBT techniques)			CO4, C06
	Unit 5	**Communication**			
	A	Patient communication			CO4, CO5, C06
	B	History taking			CO4, CO5, C06
	C	Patient counselling			CO4, C05
	Mode of examination	Theory/Jury/Practical/Viva			
	Weightage Distribution	CA	MTE	ETE	
		25%	25%	50%	
	Textbook	Counselling Psychology: A Textbook for Study and Practice: David Murphy Roles and Contexts in Counselling Psychology: Professionals in Practice. ISBN-13: 978-0367747435			
	Other References	Psychoanalytic Psychotherapy: A Practitioner's Guide. ISBN-13: 978-1593850098			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Psychology and patient counselling MCR207	**CO1**	2	3	1	3	3	2	3	3	2
	CO2	3	2	3	2	3	3	2	3	3
	CO3	3	3	2	2	3	3	2	3	3
	CO4	3	3	2	2	3	3	3	2	2
	CO5	3	2	3	2	2	3	2	3	3
	CO6	2	3	3	3	3	2	3	3	2

School:	**SSAHS**	
Batch:	2023-2025	
Programme:	Master of Science (Clinical Research)	
Academic Year:	2024-2025	
Semester:	III	
Course Code	MCR 202	
Course Title	MS Office (Advanced Excel)	
Credits	1	
Lecture type	1-0-1	
Course Objective	1. To develop analytical skills in the students **2.** To train the students in data management	
Course Outcomes	CO1: Define basic concepts and methods of research. CO2: Explain the descriptive statistics. CO3: Apply the application of descriptive statistics on data. CO4: Evaluate documentation and its application on data. CO5: Classify the analytical application on data CO6: Discuss the techniques of advanced excel.	
Course Description	To help the students to understand the basic principles of MS office and draw the inferences from the data.	
Outline syllabus		CO Mapping
Unit 1	**Fundamental Skills**	
A	Overview of Microsoft Excel	CO1
B	Entering, Editing, and Managing Data	CO1
C	Formatting and Data Analysis	CO1
Unit 2	**Mathematical Computations**	
A	Formulas	CO2
B	Introductory Statistical Functions	CO2
C	Statistical analysis	CO2
Unit 3	**Formulas, Functions, Logical and Lookup Functions**	
A	More on Formulas and Functions	CO3
B	Logical and Lookup Functions	CO3
C	Conditional Formatting	CO3
Unit 4	**Presenting Data with Charts**	
A	Choosing a Chart Type	CO4, C05
B	Formatting Charts	CO4, C05

C	Using Charts with Microsoft Word and PPT		CO4, C06
Unit 5	**Tables**		
A	Table Basics		CO4, CO5, C06
B	Intermediate Table Skills		CO4, CO5, C06
C	Preparing to Print		CO4, C05
Mode of examination		Theory/Jury/Practical/Viva	
Weightage Distribution	CA		
	100%		
Text book/s*	Beginning Excel 2019		
Other References	Beginning Excel 2019 by Noreen Brown; Barbara Lave; Hallie Puncochar; Julie Romey; Mary Schatz; Art Schneider; and Diane Shingledecker is licensed under a Creative Commons Attribution 4.0		

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
MS Office (Advanced Excel) MCR202	**CO1**	2	1	3	2	3	2	3	2	3
	CO2	3	3	2	3	3	3	3	2	3
	CO3	2	2	3	2	2	2	3	3	2
	CO4	3	3	2	3	3	2	3	2	2
	CO5	3	3	3	2	2	2	3	2	3
	CO6	3	3	3	3	3	3	2	3	3

School:	**SSAHS**	
Batch:	2023-2025	
Programme:	Master of Science (Clinical Research)	
Academic Year:	2024-2025	
Semester:	III	
Course Code	MCR 218	
Course Title	Recent developments in clinical research	
Credits	2	
Contact Hours (L-T-P)	2-0-0	
Course Type	Compulsory	
Course Objective	1. To achieve a basic understanding of recombinant DNA technology, human genome structure, Genetic Tests, Prenatal Diagnosis of Genetic Diseases etc. 2. To equip with knowledge of Oncogenes and Malignancy, Detection of Oncogenic activation, Functions of oncogenes 3.To achieve basic understanding of Stem Cell Research and New Targets for Drug Designs	
Course Outcomes	On successful completion of this course, student will be able to: CO1: Define the scientific method to generate new knowledge, and to solve problems, regarding human heredity. CO2: Explain advanced techniques in genome analysis, recombinant DNA technology. CO3: Apply the advanced techniques for management of inherited human diseases CO4: Classify oncogenes and malignancy, their detection and management CO5: Evaluate the fundamentals of gene and nanotechnology in order to understand how such technology impacts humans. CO6: Discuss the advanced novel therapeutic approached in management of the diseases.	
Course Description	This course gives in-sight into human genetics, oncogenes, stem cell research and Biopharmaceuticals, Re-generative Medicine, Nano technology and Nano medicine etc which will lay foundation and motivate students to pick up and conduct recent challenging research proposals.	
Outline syllabus	CO Mapping	
Unit 1	**Human Genetics**	
A		
B	Molecular genetics and Human Genome Project	CO1
C	Genetic Tests, Prenatal Diagnosis of Genetic Diseases	CO1
D	Gene Therapy	CO1
Unit 2	**Cancer Research**	
A	Pathophysiology of tumour progression and metastasis	CO2
B	Diagnosis: tumour biomarkers	CO2
C	Therapeutic management	CO2
Unit 3	**Stem Cell Research**	

A	Introduction to stem cell technology			CO3
B	Cell, growth and regulation			CO3
C	Therapeutic applications of human pluripotent stem cells			CO3
Unit 4	**New Targets for Drug Designs**			
A	Biopharmaceuticals			CO4, C05
B	Re-generative Medicine			CO4, C05
C	Others			CO4, C06
Unit 5	**Nano technology and Nano medicine**			
A	Nano technology			CO4, CO5, C06
B	Nano medicine			CO4, CO5, C06
C	Others			CO4, C05
Mode of examination	Theory			
Weightage Distribution	CA	MTE	ETE	
	25%	25%	50%	
Text book/s*	Gene cloning and DNA analysis, T.A. Brown Biotechnology, B.D. Singh			
Other References	Advancements in Clinical Research (Advances in Experimental Medicine and Biology Book 952). ISBN-13: 978-3319480329			

Course Code and Course Name	POs COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PSO1	PSO2
Recent developments in clinical research MCR218	**CO1**	1	2	3	1	1	3	3	2	3
	CO2	3	2	2	2	3	2	2	2	3
	CO3	2	3	3	1	3	1	3	3	2
	CO4	2	3	2	3	2	2	3	2	3
	CO5	3	3	3	2	3	2	3	3	3
	CO6	3	3	3	3	3	3	3	3	2