SRI RAMACHANDRA

INSTITUTE OF HIGHER EDUCATION AND RESEARCH

(DEEMED TO BE UNIVERSITY)

Porur, Chennai – 600116

FACULTY OF CLINICAL RESEARCH

REGULATIONS AND SYLLABUS

FOR

B.Sc. CLINICAL RESEARCH

(Under Choice Based Credit System)

Amended 2019

B. Sc. CLINICAL RESEARCH DEGREE PROGRAM

(Under Choice Based Credit System)

INTRODUCTION

Clinical research is a branch of medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens for humans. India is making a remarkable development in the field of Clinical Research and there is a massive demand for the clinical research professionals in this fast growing field. A basic education in Clinical Research and good hands on is on the need.

SCOPE OF THE PROGRAM

This Professional Bachelor's degree in Clinical Research Degree Program would provide a platform for eligible candidates to acquire foundational knowledge and skills in various aspects of clinical research that may be utilized in the real work environment. This program include courses that encompass biology, human anatomy and physiology, clinical biochemistry, microbiology, medicinal chemistry, Pharmacology, instrumentation techniques, biostatistics, concepts of clinical research, and fundamental research designs.

SUMMARY OF THE PROGRAM

1. B.Sc. Clinical Research program is a three years program under the Choice Based Credit System with six semesters. Each year is of two semesters with 26 credits in semester I, 25 credits in semester II, 28 credits in Semester III, 27 credits in semesters IV and V, and 15 credits in Semester VI, totaling to 148 credits in 3 years.
2. The program comprises of a total of 52 courses including **36 theory courses, 14 practical courses and 1 Research Project and 1 Clinical training course** in a clinical trial setting. No exemption shall be given from the period of study and training.

PROGRAM OBJECTIVES:

- To equip students with the fundamentals of clinical research
- To prepare students for a career in Clinical research organizations

PROGRAM OUTCOMES:

Upon completion of the Program, the student will be able to:

- Explain the scope of clinical research and clinical trials.
- Differentiate various types of Clinical Research and the basic principles associated with each of them.
- Demonstrate an understanding of the fundamental concepts of biostatistics.

- Identify the basis, concepts, determinants and prevalence of diseases in human populations.
- Identify various study designs, settings, and databases that are useful in the evaluation of clinical interventions and effectively design and conduct human experiments.
- Understand the most important ethical issues in clinical research and prepare necessary documents for Institutional Review Board process
- Develop a hypothesis, select an appropriate study design, and collect data to test the hypothesis with appropriate statistical tests
- Demonstrate skills in writing and communicating results of research scientific presentations and publications.
- Demonstrate a commitment to ethical and compassionate practice in human subjects research.

- Understand the special considerations involved in conducting clinical research.

SYLLABUS

SEMESTER- I

1. COURSE TITLE: BASICS OF MEDICAL SCIENCES

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
1	UCL19CT101	CT1	Basics of Medical Sciences	3	2	0	4	75/100

*** This course is offered to UG Program of GUHS and AUNT**

Syllabus:

Learning Objectives:

This course enables the student:

- To familiarize students on human body systems
- To understand communicable and non communicable diseases

Learning Outcomes:

Upon completion of the course the student will be able to

- Explain the organization of the human body systems
- Discuss the concept of health and diseases
- Describe the demography and Health of India

2 & 8. COURSE TITLE: PHYSIOLOGY

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
2	UCL19CT103	CT2	Physiology	3	2	0	4	75/100
8	UCL19CL151	CL1	Physiology Practical	0	0	2	1	30/100

***The Course is offered by the Dept. of Physiology, SRIHER (DU)**

Syllabus:

Learning Objectives:

This course aims to enable the students to

- Understand the physiological functions of human systems

Learning Outcomes:

At the end of this course the students should be able to:

- Comprehend basic terminologies used in the field of Human Physiology
- Define and describe basic Physiological Processes governing the normal functioning of the human body
- Apply this knowledge in their Allied Health Science practice

3 & 9. COURSE TITLE: BASICS OF MEDICINAL CHEMISTRY

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
3	UCL19CT105	CT2	Basics of Medicinal Chemistry	3	2	0	4	75/100
9	UCL19CL153	CL2	Basics of Medicinal Chemistry Practical	0	0	2	1	30/100

Syllabus

Learning Objectives:

This course enables the students to:

- structure, chemistry and therapeutic value of drugs
- structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs

Learning outcomes:

After completing the course, the student will be able to:

- Explain the chemistry of drugs with respect to their pharmacological activity
- Describe the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Explain the Structural Activity Relationship (SAR) of different class of drugs

4 & 10. COURSE TITLE: BIOCHEMISTRY

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
4	UCL19CT107	CT4	Biochemistry	3	2	0	4	75/100
10	UCL19CL155	CL3	Biochemistry Practical	0	0	2	1	30/100

***The Course is offered by the Dept. of Biochemistry, SRIHER (DU)**

Learning Objectives:
This course enables the student:

- To have a knowledge about the chemistry and metabolism of various macromolecules- carbohydrate, protein and lipids
- To learn about enzymes, vitamins, minerals and nutrition
- To know the structure and function of Hemoglobins, Nucleic acids.
- To learn about the organ function tests like Liver Function Tests and Renal Function Tests.

Learning Outcomes:
At the end of the course, the students will be able to

- Explain the chemistry and metabolism of macro and micro molecules
- Describe the structure and functions of hemoglobin and Nucleic acids
- Explain the interpretation o organ function tests

5. COURSE TITLE: SOCIOLOGY FOR HEALTH SCIENCES

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
5	UCL19DE109	DE1	Sociology for Health Sciences	2	2	0	3	60/100

Syllabus

Learning Objectives:

This course aims;

i) To make the students to understand the basic concept of health in sociology,
ii) To make the students to understand the sociological perspective on health, social causes and various aspects of community health.
iii) To make the students understand the interrelationship between society and health.

iv) To make students to understand the issues related to community health and the healthcare delivery system

Learning Outcomes:

On successful completion of the course the students should be able to

i) Gain knowledge and understanding on the development of medical sociology
ii) Acquire a conceptual understanding about Health and the sociological approaches on health.
iii) Understand the health issues with socio-cultural perspective.
iv) Understand an insight into hospital system.

6. COURSE TITLE: APPLIED PSYCHOLOGY

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
6	UCL19SE111	SE1	Applied Psychology	2	0	0	2	30/100

***The Course is offered by the Dept. of Clinical Psychology, SRIHER (DU)**

Syllabus
Learning Objectives:
This course aims to enable the students to

- Understand the behaviour and mental processes
- Understand the theories and principles of psychology may be applied to individual, societal and global issue

Learning Outcomes:
After complete ting the course the student can able to

- Identify the emerging specialties
- Explain the behaviour and mental processes
- Discuss the theories and principles of psychology may be applied to individual, societal and global issue
- Explain the application of psychology in Allied Health Sciences

7. COURSE TITLE: ENGLISH

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
7	UCL19AE113	AE1	English	2	0	0	2	30/100

***This course is offered by the Dept. of Language, SRIHER (DU)**

Syllabus

Learning Objective:

This course is designed to build spoken and written English competency of the students needed to function effectively in academic setup.

Learning Outcomes:

This course is designed to help the students to

1. Speak and write grammatically correct sentences in English.
2. Develop effective writing skills.
3. Build fluency in English

SEMESTER – II

11. COURSE TITLE: RESEARCH METHODOLOGY AND APPLIED BIOSTATISTICS

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
11	UCL19CT102	CT5	Research Methodology and Applied Biostatistics	3	2	-	4	75/100

Syllabus

Learning Objectives

The objective of this course is to provide knowledge on:

- Types, organization and distribution of data
- Calculation of central tendencies (Mean, Median, Mode) Confidence interval, Standard Deviation, Standard Error, Regression and correlation
- Comparison of data between different groups-using null hypothesis and test of significance
- Analyses of results in clinical research and sample size calculation
- Research study designs, measures of risk and data distribution
- Introduction to common software packages used in clinical research

Learning Outcomes:

After completing the course, the student will be able to:

- Explain types, organization and distribution of data
- Perform Calculation of central tendencies Confidence interval, SD, SE, Regression and correlation
- Demonstrate ability to compare data between different groups-using null hypothesis and test of significance
- Describe analyses of results in clinical research and sample size calculation
- Describe Biostatistics related to design and analysis of randomized clinical trials
- Describe the clinical study designs and the measures of risk
- Demonstrate understanding of common software packages used in clinical research (SAS, oracle)

12 & 18. COURSE TITLE: MICROBIOLOGY

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
12	UCL19CT104	CT6	Microbiology (MCT006)	3	0	0	3	45/100
18	UCL19CL152	CL4	Microbiology Practical (MCL006)	0	0	2	1	30/100

- **This course is to be offered by Dept. of Microbiology, SRIHER (DU)**

Syllabus

Learning Objectives:
This course enables the students to

- Know the concepts of sterilization and disinfection procedures and their applications.
- Understand the basic principles of immunology.
- Understand the basic fundamental aspects of bacteria, virus, fungus and parasites, and study the common disease caused by them.

Learning Outcomes:
At the end of the semester the students should be able to

- Explain the morphology and functions of bacterial cell
- Describe the basic concepts of infection, sterilization and the disinfection process
- Describe the causes and treatment of common infectious and sexually transmitted diseases

13 & 19. COURSE TITLE: PHARMACOLOGY

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
13	UCL19CT106	CT7	Pharmacology (MCT005)	3	0	0	3	45/100
19	UCL19CL154	CL5	Pharmacology Practical (MCL005)	0	0	2	1	30/100

- **This course is to be offered by Dept. of Pharmacology, SRIHER (DU)**

Syllabus

Learning Objectives:

The objective of this course is to enable the students

To understand the terminologies and basic principles of pharmacokinetic and pharmacodynamic involved in the use of drugs.

To understand the pharmacological action and mechanism of action of common drugs used for different disease conditions.

To know the therapeutic uses and adverse effects of common drugs used for different disease conditions

Learning Outcomes:

After completing the course, the student will be able to:

- Explain the general pharmacological principles
- Describe the pharmacology, indications and contraindications of drugs acting on the diseases of the human body systems

Pharmacology Practical

Learning Objective

This module is intended to discuss the various modalities of drug delivery and instruments relevant to it.

Instruments

Needles Intravenous
Intrathecal
Spinal
Intra arterial

Students Discussion Syringes: Tuberculin
Insulin
I.V cannula
Scalp. Vein set

Students Discussion Enema can
Inhalers
Spacers
Nebulizers

Students Discussion Tablets – Enteric coated, Sustained release, Sub-lingual

Students Discussion Capsules, Spansules, Pessary, Suppository

Students Discussion Topical Preparation, Ointment, Lotion, Powder,
Drops – eye / ear

Charts: Mechanism of action of drugs, adverse effects, toxicology

Spotters: drugs

Text books suggested for reading:

1. Text book of pharmacology for Dental &Allied Health Science 2rd edition Padmaja Udaykumar
2. Pharmacology for dental students Tara V Shanbhag, Smita Shenoy, Veena Nayak
3. Principles of pharmacology 2rd edition H. L. Sharma & KK Sharma

14 & 20. COURSE TITLE: PRE-CLINICAL TOXICOLOGY

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
14	UCL19CT108	CT7	Pre-Clinical Toxicology	3	2	0	4	75/100
20	UCL19CL156	CL6	Pre-Clinical Toxicology Practical	0	0	4	2	60/100

Learning Objectives

The objective of this course is to provide knowledge on:

- basic terms and types of toxicity studies.
- the most prevalent poisonings in different animal species including their causes, clinical signs and pathological findings
- importance of ethical and regulatory requirements for toxicity studies.

Learning Outcomes:

After completing the course, the student will be able to:

- Describe the kinetics and mechanism of action of toxic compounds
- Understand the principles of collecting and sending biological samples in case of poisoning
- Describe the basic diagnostic analysis and interpret their results

  Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Assess the risk for human health and environment on the basis of poisoning observed in animals and identify measures to prevent those risks.

Pre-Clinical Toxicology Practical

1. Determination of acute oral toxicity (LD50) of a drug from a given data as per OECD guidelines (3)
2. Determination of acute skin irritation / corrosion of a test substance as per OECD guidelines.(2)
3. Determination of acute eye irritation / corrosion of a test substance (2)

4. Repeated dose toxicity studies- Serum biochemical, hematological, urine analysis, functional observation tests and histological studies (1)
5. Drug mutagenicity study using mice bone-marrow chromosomal aberration test (2)

16. COURSE TITLE: ENVIRONMENTAL SCIENCE

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
16	UCL19AE112	AE2	Environmental Science (AAE 004)	2	0	0	2	30/100

***This course is offered by Dept. of Environmental Health Engineering, SRIHER (DU)**

Syllabus

Course description

This course has been designed on the study of the natural world and how it is influenced by people. It will emphasize the need of increasing awareness of the consequences of environmental degradation and human population growth, together with the need to conserve biodiversity. This course is to train students in a multidisciplinary environmental concepts drawing from various basic and applied disciplines.

Learning Objectives:

This course will enable students –

- To anticipate, identify, assess, and manage green environment and its probable ways occupational settings.
- To integrate and apply knowledge from the appropriate areas of basic science, economics, and policy to address problems caused by ecosystem degradation and from physical alteration of the environment and chemical contaminants from industrial activities, agriculture, food production, and inadequate resource management to participate in outreach activities including environmental applications and problem solving in off-campus community settings.

Learning Outcomes

Upon completion of the program, students will be able to:

- Identify the implications of environmental policies and standards on compliance with regulatory, standard setting organizations and International policies.

- Apply management practices to environmental and occupational health issues.
- Understand and describe the processes and mechanisms by which hazards are produced, released, transported, and modified in the environment and affect health.

SEMESTER III

21 & 29. COURSE TITLE: BIOMARKERS AND DIAGNOSTICS / PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
21	UCL19CT201	CT9	Biomarkers and diagnostics	2	2	0	3	60/100
29	UCL19CL251	CL7	Biomarkers and diagnostics Practical	0	0	4	2	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- History and significance of diagnostics
- Different types of biomarkers and methods of applications
- Biomarkers for important human diseases
- Immunodiagnostic and antibody production techniques
- Quality control, ethical and legal implications

Learning outcomes:

After completing the course, the student will be able to:

- Describe the history and significance of diagnostics
- Describe different types of biomarkers and methods of applications
- Explain known biomarkers for important human diseases
- Explain the Immunodiagnostic and antibody production techniques
- Discuss the quality control, ethical and legal implications of diagnostics
- Perform immunotechniques - Agglutination and Precipitation Techniques

22 & 30.COURSE TITLE: BIOANALYTICAL TECHNIQUES / PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
22	UCL19CT203	CT10	Bioanalytical techniques	2	2	0	3	60/100
30	UCL19CL253	CL8	Bioanalytical techniques Practical	0	0	4	2	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Basic principles of different analytical techniques
- Procedures of spectroscopy and radioactivity in biotechnological applications
- Microscopy, centrifugation, electrophoretic and chromatographic techniques.

Learning outcomes:

After completing the course, the student will be able to:

- Describe basic principles of different analytical techniques
- Explain procedures of spectroscopy and radioactivity in biotechnological applications
- Describe microscopy, centrifugation and electrophoretic techniques.
- Demonstrate principle and working of various instruments.
- Characterize certain functionalities of biomolecules by using spectroscopic techniques
- Perform separation of proteins/peptides by selecting appropriate separation techniques

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (c)	Total Hours/Marks
23	UCL19CT205	CT11	Basics of Drug Discovery And Development	2	2	0	3	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

a) Various stages of Drug discovery.
b) Importance of the role of genomics, proteomics and bioinformatics in drug discovery.
c) Various targets for Drug discovery.

Learning Outcomes:

After completing the course, the student will be able to:

a) Explain the various stages of Drug discovery.
b) Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
c) Explain various targets for Drug discovery.
d) Explain various lead seeking method and lead optimization.
e) Perform molecular docking studies
f) Perform QSAR studies

24. COURSE TITLE: BASICS IN CLINICAL RESEARCH

Cour*se Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
24	UCL19CT207	CT12	Basics in Clinical Research	3	2	0	4	75/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Various stages of Drug discovery.
- Basics in clinical research

Learning Outcomes:

After completing the course, the student will be able to:

- Explain the various stages of Drug discovery.
- Explain the terminologies in clinical research

25. COURSE TITLE: COMPUTER APPLICATIONS IN CLINICAL RESEARCH

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
25	UCL19DE209	DE2	Computer Applications in Clinical Research	3	0	0	3	45/100

Syllabus

Learning Objective:

The objective of this course is to provide knowledge on:

- Databases, Database Management system, computer application in clinical studies and use of databases

Learning outcomes:

After completing the course, the student will be able to:

- Explain the various application of computers in clinical research
- List the various types of databases in Clinical research
- State the various applications of databases in clinical research-

26. COURSE TITLE: FUNDAMENTALS OF TECHNICAL WRITING

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
26	UCL19DE211	DE3	Fundamentals of technical writing	3	0	0	3	45/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Basic introduction to medical terminology and fundamentals of technical writing
- Fundamentals of Literature survey-Use of books and journals and internet.

- Designing and development of clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures

Learning outcomes:

After completing the course, the student will be able to:

- Define medical terminologies and describe the basic principles governing technical writing
- Explain the fundamentals of Literature survey-Use of books and journals and internet
- Describe in detail the process of Designing and developing clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures.
- Explain the salient features of Writing research report, clinical study report, manuscript, and preparation of patient narrative and educational materials for patients in clinical research
- Describe application of various software relevant to technical writing

28. COURSE TITLE: COMMUNICATION AND SOFT SKILLS

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
28	UCL19AE215	AE3	Communication and Soft Skill (AAE 003)	2	0	0	2	30/100

Learning Objective:

This course is designed to equip the students with essential soft skills needed for workplace and improve personality

Learning Outcome:

This course is designed to help the students to

- Foster healthy attitude.
- Develop effective inter and intra personal skills to be an effective team worker.
- Communicate effectively in both academic and professional setup

SEMESTER IV

31&38 COURSE TITLE: PRECLINICAL STUDIES & SAFETY MONITORING/ PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
31	UCR19CT202	CT13	Preclinical studies & Safety monitoring	3	2	0	4	75/100
38	UCL19CL252	CL9	Preclinical studies & Safety monitoring Practical	0	0	4	2	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Need for preclinical studies and safety monitoring
- Types of pre-clinical studies in animals
- Stages of preclinical development
- Ethical and regulatory considerations in preclinical studies

Learning Outcomes:

After completing the course, the student will be able to:

- Explain the need for preclinical studies and safety monitoring
- Describe types of pre-clinical studies in animals
- Discuss in detail stages of preclinical development
- Describe ethical and regulatory considerations in preclinical studies
- Perform pharmacological and toxicological studies as per ethical &regulatory considerations

32 & 39. COURSE TITLE: BIOPHARMACEUTICS AND PHARMACOKINETICS / PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
32	UCL19CT204	CT14	Biopharmaceutics and Pharmacokinetics	2	2	0	3	60/100
39	UCL19CL254	CL10	Biopharmaceutics	0	0	4	2	60/100

			and Pharmacokinetics Practical					

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Introduction and importance of biopharmaceutics and pharmacokinetics
- Salient features of Pharmacokinetic processes – absorption, distribution, metabolism and excretion
- Bioavailability and bioequivalence studies
- Pharmacokinetic models – one/multicompartment
- Non linear pharmacokinetics

Learning outcomes:

After completing the course, the student will be able to:

- Define biopharmaceutics and pharmacokinetics
- Describe the importance of clinical pharmacokinetics
- Describe the salient features of Pharmacokinetic processes – absorption, distribution, metabolism and excretion
- Describe in detail Bioavailability and bioequivalence studies
- Explain the various pharmacokinetic models
- Discuss in detail non linear pharmacokinetics
- Apply pharmacokinetics in new drug development, designing of dosage forms and novel drug delivery systems.
- Solve various pharmacokinetic problems

33 & 40. COURSE TITLE: ETHICS COMMITTEES AND INSTITUTIONAL REVIEW BOARD/PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
33	UCL19CT206	CT15	Ethics committees and institutional review board	2	2	0	3	60/100
40	UCL19CL256	CL11	Ethics committees and institutional review board Practical	0	0	4	2	60/100

Syllabus:

Learning Objectives:

The objective of this course is to provide knowledge on:

- Ethics principles underlying research in animals and human participants
- Need and functioning of Ethical committee
- Roles and Responsibilities, Requirements of ethical committee
- Decision Making and Related Issues of ethical committee
- Documents required for ethical committee clearance

Learning Outcomes:

After completing the course, the student will be able to:

- Explain medical ethics principles underlying research in human participants
- Describe Need and functioning of Ethical committee including composition
- Describe the roles and responsibilities, requirements of ethical committee
- Describe the process of Decision Making and Related Issues of ethical committee
- Explain about the Documents required for ethical committee clearance

34. COURSE TITLE: PRINCIPLES OF GOOD CLINICAL PRACTICES

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
34	UCL19CT208	CT16	Principles of Good Clinical Practices	2	2	0	3	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- The ethical requirement for conducting clinical trials
- The rights, safety and wellbeing of trial subjects
- Conceptualizing, designing, conducting, managing and reporting of clinical trials
- Preparing clinical study reports and reporting in common technical document
- Quality control and assurance in conduct of clinical trial

Learning Outcomes:

By the end of the course the student will be able to identify and describe:

- International Conference on Harmonization (ICH) process and its guidelines
- Its structure and relationships to roles and responsibilities of the sponsor and the investigator
- Adverse event reporting requirements for both investigators and sponsors

- The responsibilities of an Institutional Review Board / Independent Ethics Committee (IRB/IEC)
- Material and regulatory requirements for conducting clinical trials

35. COURSE TITLE: FUNCTIONS OF CROS AND SMOS

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
35	UCL19DE210	DE4	Functions of CROs and SMOs	3	0	0	3	45/100

Syllabus:

Learning Objectives:
The objective of this course is to provide knowledge on:

- Definition of CROs/SMOs
- Operations of CROs/SMOs with respect to site selection criteria, single/multi centric trials, investigator selection
- Role and Responsibilities of CROs/SMOs

Learning Outcomes:
After completing the course, the student will be able to:

- Define CRO/SMO
- Describe the salient features of site selection criteria, single/multi centric trials, investigator selection
- Explain the Different roles and responsibilities of CROs/SMOs

37. COURSE TITLE: BASICS OF IPR & PATENTING

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
37	UCL19AE214	AE4	Basics of IPR and Patenting	2	0	0	2	30/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Intellectual property rights, its types, enforcement and need for protection
- Patents, its granting process and need for protection
- Patent regulations with respect to Indian and International Scenario

Learning outcomes:

After completing the course, the student will be able to:

- Describe the various types of intellectual property rights and its laws of enforcement
- Discuss the salient features and need for protection of copyrights, related rights, trademarks, geographic indications, industrial designs
- Explain in detail the patent regulations with respect to Indian and International Scenario

SEMESTER V

41 & 48. COURSE TITLE: CLINICAL TRIAL DESIGNS AND PROJECT MANAGEMENT / PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
41	UCL19CT301	CT17	Clinical Trial Design and Project Management	3	2	0	4	75/100
48	UCL19CL351	CL12	Study Design and Development Practical	0	0	4	2	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Different types of study design
- CDM and documentation
- Quality data verification and management
- SAE reconciliation and quality documentation

Learning Outcomes:

After completing the course, the student will be able to:

- Demonstrate different types of study design.
- Demonstrate documentation regulation and data management
- Identify and document SAE based on the relevant regulations

42 & 49. COURSE TITLE: CLINICAL TRIAL DOCUMENTATION/PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
42	UCL19CT303	CT18	Clinical trial documentation	2	2	0	3	60/100
49	UCL19CL353	CL13	Clinical trial documentation Practical	0	0	4	2	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Need for documentation in clinical research
- The essential documents involved in clinical research
- Site initiation activities: Selection of Clinical trial sites, Clinical Investigators and making budget and vendor selection
- Site conduct activities including documents required and Contingency planning to prepare for unexpected situations
- Site close out activities like handling missing data, query and resolution Database lock

Learning outcomes:

After completing the course, the student will be able to:

- Explain different clinical trial documents and prepare the same
- Prepare a study protocol and Investigators Brochure
- Describe the Site initiation activities with respect to Selection of Clinical trial sites, Clinical Investigators and making budget and vendor selection
- Describe the Site conduct activities including documents required and Contingency planning to prepare for unexpected situations
- Describe the site close out activities like handling missing data, query and resolution Database lock
- Preparation of Site close-out report and Clinical study report

43 & 50. COURSE TITLE: CLINICAL DATA MANAGEMENT/PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
43	UCL19CT305	CT19	Clinical data management	2	2	0	3	60/100
50	UCL19CL355	CL14	Clinical data management & e –Clinical Software training Practical	0	0	2	2	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Introduction and work flow of data management process in clinical research
- Data management plan, data acquisition and CRF designing
- Database designing and implementation
- Salient features of data entry and verification and data analysis

Learning outcomes:

After completing the course, the student will be able to:

- Describe work flow of data management process in clinical research
- Explain in detail Data management plan, data acquisition and CRF designing
- Describe database designing and implementation
- Describe Salient features of data entry and verification and data analysis
- Design a database for a given mock clinical data set
- Preparation of e-CRF as per guidelines
- Demonstrate data entry and verification and data analysis skill in given mock clinical data sets

44. COURSE TITLE: REGULATORY BODIES AND REGULATIONS IN CLINICAL RESEARCH

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks

44	UCL18CT307	CT20	Regulatory bodies and Regulations in clinical research	2	2	0	3	60/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Basics of regulations and its related documents of various aspects of clinical research
- Regulatory aspects of medical devices, vaccines, prescription drugs and non prescription drugs
- Regulation of traditional and herbal remedies
- Basic regulations of BA/BE studies
- Schedule Y of Indian Drugs and Cosmetic Act. and Introduction to EMEA,OECD,ANVISA,TGA

Learning outcomes:

After completing the course, the student will be able to:

- Describe regulatory documents of various aspects of clinical research
- Explain in detail the Regulatory aspects of medical devices, vaccines, prescription drugs and non-prescription drugs
- Demonstrate understanding on Regulation of traditional and herbal remedies
- Elaborate the Basic regulations of BA/BE studies
- Describe the Schedule Y of Indian Drugs and Cosmetic Act., EMEA,OECD,ANVISA,TGA

45. COURSE TITLE: PHARMACOVIGILANCE AND DRUG SAFETY MONITORING

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
45	UCL19DE309	DE5	Pharmacovigilance and drug safety monitoring	3	0	0	3	45/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Terminologies of adverse events (AEs), serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs)
- Procedures involved in documentation, reporting and follow-up of adverse drug reactions according to known requirements
- Salient features of Global Pharmacovigilance & safety standards
- Principles and practices of post-marketing surveillance

Learning outcomes:

After completing the course, the student will be able to:

- Explain adverse events (AEs), serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs)
- Describe the procedures involved in documentation, reporting and follow-up of adverse drug reactions according to known requirements
- Discuss the role of safety reporting in the wider global context of pharmacovigilance
- Discuss the principles and practices of post-marketing surveillance

47. COURSE TITLE: CLINICAL TRIAL SOFTWARES AND ITS APPLICATIONS

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
47	UCL18AE313	AE5	Clinical trial software and its applications	2	0	0	2	30/100

Syllabus

Learning Objectives:

The objective of this course is to provide knowledge on:

- Functioning of available clinical trial soft-wears for data management

- Salient features of data entry with respect to first data, second data entry, QAQC in data entry and audit trail
- Aspects of tracking CRF pages and corrections, CRF work flow, tracking challenges and tracking of query forms
- Procedures and tools available for paper based and electronic data capture
- Significance and dictionaries for data coding and problems associated with it
- Process of Data cleaning/validation with respect to discrepancy management system, query management, cleaning data checklist, SAE reconciliation, managing laboratory data and data locking/freezing

Learning Outcomes:

After completing the course, the student will be able to:

- Elaborate on Functioning of available clinical trial soft-wears for data management
- Explain the Salient features of data entry with respect to first data, second data entry, QAQC in data entry and audit trail
- Describe the Aspects of tracking CRF pages and corrections, CRF work flow, tracking challenges and tracking of query forms
- Elaborate Procedures and tools available for paper based and electronic data capture
- Describe Significance and dictionaries for data coding and problems associated with it

a) Explain in detail Process of Data cleaning/validation with respect to discrepancy management system, query management, cleaning data checklist, SAE reconciliation, managing laboratory data and data locking/freezing

SRI RAMACHANDRA
INSTITUTE OF HIGHER EDUCATION AND RESEARCH
(DEEMED TO BE UNIVERSITY)
Porur, Chennai - 600 116

FACULTY OF CLINICAL RESEARCH

REGULATIONS AND SYLLABUS
FOR
M.Sc. CLINICAL RESEARCH DEGREE PROGRAM
(Under Choice Based Credit System)

Amended 2019

MASTER OF SCIENCE (CLINICAL RESEARCH) DEGREE PROGRAM [CPCR]

(Under Choice Based Credit System)

INTRODUCTION

Scope of the Program

This Professional Master's degree in Clinical Research would provide a platform for eligible candidates to acquire knowledge and skills in various aspects of clinical research. The clinical research industry is growing worldwide at unparalleled rate. It has opened up new horizon for employment for a large number of trained professionals. India is becoming a hub for clinical research; the demand for professionals in this field is growing rapidly.

This program would enable the candidates to meet the career demands in the field of Clinical Research.

Summary of the Program

1. M.Sc. Clinical Research program is a two year FULL TIME program under the Choice Based Credit System with four semesters. Each year is of two semesters with 27 credits each in semesters I to III and 19 credits in semester IV, totaling to 100 credits in 2 years.
2. The program comprises of a total of 30 courses including 18 theory courses, 9 practical courses, one clinical training course and 2 research projects in a clinical trial setting. No exemption shall be given from the period of study and training.
3. Medium of instructions and examinations is in English.
4. Annual intake of 15 students

Learning Objectives:

- To equip students/ participants with basics of methodologies adopted in clinical trials
- To prepare students/participants for a career in Clinical research organizations
- To update the knowledge of those who wish to broaden their career in the design, conduct, analysis and reporting of clinical trials

Learning outcomes:

Upon completion of the Program, the student will be able to:

- Explain the principles involved in the design, conduct, and analysis and reporting of a clinical trial.
- Discuss the basics of pharmacology and Pharmacokinetics and Pharmacodynamics of the drugs
- Apply the principles of Good Clinical Practice and regulations when designing and conducting clinical research.
- Identify the various trial designs that can be applied for a clinical trial and perform appropriate sample size calculations, randomization, outcome selection and tests of significance.

- Form a research question, design and plan a clinical research project that complies with industry and government standards and protocols
- Explain the purposes of patient and public involvement, and the methods of their selection in clinical research.
- Respect and protect the rights and welfare of individuals participating in research and Incorporate ethical practices in all stages of the clinical trial.
- Develop an Informed consent and obtain approval from the Institutional ethics Committee for the conduct of a clinical research
- Demonstrate skills to effectively collect, maintain, critically appraise and interpret the clinical trial data
- Explain various pharmacovigilance activities and its reporting system
- Apply the principles of quality assurance in all aspects of clinical research.
- Develop interdisciplinary research collaborations and demonstrate project management skills needed for successful management of clinical trials

SYLLABUS

SEMESTER-I

1 & 7. COURSE TITLE: CLINICAL RESEARCH METHODOLOGIES/PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits ©	Total Hours/Marks
1	PCR18CT101	CT1	Clinical Research Methodologies	3	2	0	4	75/100
7	PCR18CL151	CL1	Practical aspects of Clinical Research (Practical)	0	0	4	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a) Basics of research and designs b) Various aspects of research, sampling methods and data collection c) Drug discovery and development d) Various phases of Clinical trial e) Roles and responsibilities of key stakeholders – IEC, Regulatory Authorities Sponsor, Investigator/CRO etc.	After completing the course, the student will be able to: a) identify and justify the basic components of the research framework, relevant to the given research problem. b) explain and justify how researchers will collect research data. c) Demonstrate terminologies and definitions in clinical research d) Demonstrate the different types of Clinical trial phases e) Explain the Indian and International perspective of Clinical trials and clinical trial market f) Explain and demonstrate key stakeholders responsibilities

2 & 8. COURSE TITLE: CLINICAL PHARMACOLOGY/ PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
2	PCR18CT103	CT2	Clinical Pharmacology	3	2	0	4	75/100
8	PCR18CL153	CL2	Clinical Pharmacology (Practical)	0	0	4	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a. Introduction to Clinical Pharmacology b. Concept of Pharmacokinetics c. Essentials of drug metabolism and transport d. Pharmacokinetics and Drug Therapy in Special Populations e. Process involved in the evaluation of drug effects f. Pharmacogenomics and Pharmacotherapy g. Policies on rational, safe and cost effective prescribing	After completing the course, the student will be able to: a. Explain Pharmacokinetic and pharmacodynamic properties of a drug b. Explain biochemical mechanisms of drug toxicity c. Describe the pathways and transporters in drug metabolism d. Discuss the principles and process involved in the evaluation of drug effects e. Explain in detail pharmacogenomics in pharmacotherapy f. Elaborate on policies governing rational, safe and cost effective prescribing

3. COURSE TITLE: ETHICS GUIDELINES & ETHICS COMMITTEES

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
3	PCR18CT105	CT3	Ethics Guidelines & Ethics Committees	3	2	0	4	75/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a. History of ethics guidelines in clinical research b. Guidelines of International conference on Harmonization, GCP c. Types, composition and functioning of ethics committees d. Documents required for ethics clearance	After completing the course, the student will be able to: a. Explain history of ethics guidelines in clinical research b. Describe guidelines of International conference on Harmonization, GCP c. Elaborate on Types, composition and functioning of ethics committees d. Illustrate the Documents required for ethics clearance

4 & 9. COURSE TITLE: PRECLINICAL STUDIES FOR SAFETY, TOXICOLOGY & EFFICACY / PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
4	PCR18CT107	CT4	Preclinical studies for safety, toxicology & efficacy	3	2	0	4	75/100
9	PCR18CL155	CL3	Preclinical studies for safety, toxicology & efficacy (Practical)	0	0	4	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a. Need for preclinical studies for safety, toxicity & efficacy b. Types of pre-clinical studies in animals c. Stages of preclinical development d. Ethical and regulatory considerations in preclinical studies e. Quality control and safety measures f. Alternative methods of toxicity assessments	After completing the course, the student will be able to: a. Explain the need for preclinical studies and safety monitoring b. Describe types of pre-clinical studies in animals c. Discuss in detail stages of preclinical development d. Describe ethical and regulatory considerations in preclinical studies e. Explain the quality control and safety measures f. Describe Alternative methods of toxicity assessments g. Perform pharmacological and toxicological studies as per ethical &regulatory considerations

5. COURSE TITLE: REGULATORY BODIES, ACTS/STATUTES & REGULATORY GUIDELINES

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
5	PCR18DE109	DE1	Regulatory bodies, Acts/Statutes & Regulatory guidelines	3	0	0	3	45/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: **a.** Basics of regulations and its related documents of various aspects of clinical research **b.** Regulatory aspects of medical devices, vaccines, prescription drugs and non prescription drugs **c.** Regulation of traditional and herbal remedies **d.** Basic regulations of BA/BE studies **e.** Schedule Y of Indian Drugs and Cosmetic Act. and Introduction to EMEA,OECD,ANVISA,TGA	After completing the course, the student will be able to: a. Describe regulatory documents of various aspects of clinical research b. Explain in detail the Regulatory aspects of medical devices, vaccines, prescription drugs and non prescription drugs c. Demonstrate understanding on Regulation of traditional and herbal remedies d. Elaborate the Basic regulations of BA/BE studies e. Describe the Schedule Y of Indian Drugs and Cosmetic Act., EMEA,OECD,ANVISA,TGA

6. COURSE TITLE: MEDICAL WRITING AND CODING

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
6	PCR18AE111	AE1	Medical writing and coding	2	0	0	2	30/100

Learning Objectives	Learning outcomes

The objective of this course is to provide knowledge on: **a)** Basic introduction to medical terminology and fundamentals of medical writing **b)** Fundamentals of Literature survey-Use of books and journals and internet. **c)** Designing and development of clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures **d)** Writing research report, clinical study report, manuscript, and preparation of patient narrative and educational materials for patients in clinical research **e)** Introduction and application of softwares relevant to technical write	After completing the course, the student will be able to: **a)** Define medical terminologies and describe the basic principles governing medical writing **b)** Explain the fundamentals of Literature survey-Use of books and journals and internet **c)** Describe in detail the process of Designing and developing clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures. **d)** Explain the salient features of Writing research report, clinical study report, manuscript, and preparation of patient narrative and educational materials for patients in clinical research **e)** Describe application of various softwares relevant to technical writing **f)** Describe the importance of medical coding and explain the salient features of ICD-10-CM

SEMESTER-II

10 &16. COURSE TITLE: DOCUMENTS FOR CLINICAL RESEARCH & REGULATORY AFFAIRS / PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
10	PCR18CT102	CT5	Documents for Clinical Research & Regulatory affairs	3	2	0	4	75/100
16	PCR18CL152	CL4	Documents for Clinical Research & Regulatory affairs (Practical)	0	0	6	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a. The essential documents involved in clinical research	After completing the course, the student will be able to: a. Explain different clinical trial documents and prepare the same. b. Prepare a study protocol and Investigators

b. The basics of the regulations and guidelines involved in clinical research c. The regulatory and legal documents needed for conduct of a clinical research	Brochure c. Demonstrate a basic understanding of regulations and guidelines associated with clinical research d. Identify the regulatory and legal documents associated with a clinical research project or study.

11 & 17. COURSE TITLE: CLINICAL RESEARCH DESIGNS & MONITORING/PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
11	PCR18CT104	CT6	Clinical trial designs & monitoring	3	2	0	4	75/100
17	PCR18CL154	CL5	Clinical trial designs & monitoring (Practical)	0	0	6	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: **a.** Different types of study design **b.** CDM and documentation **c.** Quality data verification and management **d.** SAE reconciliation and quality documentation	After completing the course, the student will be able to: a. Demonstrate different types of study design. b. Demonstrate documentation regulation and data management c. Identify and document SAE based on the relevant regulations

12 &18. COURSE TITLE: PHARMACOVIGILANCE & POST MARKETING SURVEILLANCE /PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
12	PCR18CT106	CT7	Pharmacovigilance &	3	2	0	4	75/100

			Post marketing surveillance					
18	PCR18CL156	CL6	Pharmacovigilance & Post marketing surveillance (Practical)	0	0	6	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a) Terminologies of adverse events (AEs), serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) b) Procedures involved in documentation, reporting and follow-up of adverse drug reactions according to known requirements c) Salient features of Global Pharmacovigilance & safety standards d) Principles and practices of post-marketing surveillance	After completing the course, the student will be able to: a) Explain adverse events (AEs), serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) b) Describe the procedures involved in documentation, reporting and follow-up of adverse drug reactions according to known requirements c) Discuss the role of safety reporting in the wider global context of pharmacovigilance d) Discuss the principles and practices of post-marketing surveillance e) Perform ADR assessment using various scales f) Document ADRs in the softwares

13. COURSE TITLE: CLINICAL RESEARCH FOR THERANOSTICS

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
13	PCR18DE108	DE2	Clinical Research for Theranostics	3	0	0	3	45/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a. Definition and types of botanicals, medical devices, nutraceuticals, cosmeceuticals and personal care products b. Informed consent process and IRB process for botanicals, medical devices, nutraceuticals, cosmeceuticals and	After completing the course, the student will be able to: a. Explain the types and procedures involved in clinical trial of botanicals, medical devices, nutraceuticals, cosmeceuticals and personal care products b. Prepare and Submit the documents to

personal care products	IRB c. Prepare and document Informed consent

14. COURSE TITLE: INTELLECTUAL PROPERTY RIGHTS & PATENTS

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
14	PCR18DE110	DE3	Intellectual Property Rights & Patents	3	0	0	3	45/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a) Intellectual property rights, its types, enforcement and need for protection b) Patents, its granting process and need for protection c) Patent regulations with respect to Indian and International Scenario	After completing the course, the student will be able to: a) Describe the various types of intellectual property rights and its laws of enforcement b) Discuss the salient features and need for protection of copyrights, related rights, trademarks, geographic indications, industrial designs c) Explain in detail the patent regulations with respect to Indian and International Scenario

COURSE TITLE: TO BE CHOSEN BY THE STUDENT

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
15	PCR18GE112	GE1	To be chosen by the student	3	0	0	3	45/100

SEMESTER - III

19 & 25. COURSE TITLE: STUDY SITE DEVELOPMENT, E-SOFTWARES AND CLINICAL RESEARCH MANAGEMENT / PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
19	PCR18CT201	CT8	Study site development, e-softwares and clinical research management	3	2	0	4	75/100
25	PCR18CL251	CL7	Study site development, e-softwares and clinical research management (Practical)	0	0	6	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: **a)** Phases of clinical trials of drug development **b)** Procedures involved in clinical trial conduct and management with respect to protocol development, case report form designing and IRB submission **c)** Procedures involved in trial site selection, pre- study visits and site initiation **d)** Process of subject recruitment and retention planning **e)** Salient features of site contract and budgeting **f)** Functioning of available clinical trial e-soft-wears for data management	After completing the course, the student will be able to: **a)** Describe the phases of clinical trials of drug development **b)** Explain in detail the process of protocol development, case report form designing and IRB submission **c)** Prepare a protocol and case report form **d)** Describe in detail the procedures involved in trial site selection, pre- study visits and site initiation **e)** Explain the process of subject recruitment and retention planning **f)** Elaborate on the salient features of site contract and budgeting **g)** Prepare a site selection checklist and a site contract **h)** Recruit study subjects based on inclusion and exclusion criteria **g)** Elaborate on Functioning of available clinical trial e-soft-wears for data management

20. COURSE TITLE: MISCONDUCT AND FRAUDULENCE IN CLINICAL RESEARCH

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits ©	Total Hours/Marks
20	PCR18CT203	CT9	Misconduct and fraudulence in Clinical research	3	2	0	4	75/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a) Knowledge on research integrity and misconduct. b) Conflict of Interest c) Different types of misconduct /fraudulences	After completing the course, the student will be able to identify : a) Protocol deviation/Violations b) Inadequate completion of ICF c) Misleading reporting of results

21 & 26. COURSE TITLE: AUDIT/INSPECTIONS REPORT PREPARATION /PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
21	PCR18CT205	CT10	Audit/Inspections report preparation	3	2	0	4	75/100
26	PCR18CL253	CL8	Audit/Inspection report preparation (Practical)	0	0	6	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a) Regulatory requirements of quality Assurance(QA) and Quality Control (QC) in Clinical Research b) Role and Responsibilities of QA personnel c) Different types of Audit in Clinical research d) Quality System, Quality Policy and Continual Process Improvement e) Contents and procedure of inspection f) Clinical trial audit and inspection report preparation	After completing the course, the student will be able to: a) Describe the Regulatory requirements of quality Assurance(QA) and Quality Control (QC) in Clinical Research b) Discuss the Roles and Responsibilities of QA personnel c) Explain the Different types of Audit in Clinical research d) Perform and document the auditing process e) Elaborate on Quality System, Quality Policy and Continual Process Improvement f) Describe the contents and procedure of inspection g) Prepare report of clinical trial audit and inspection

22 & 27. COURSE TITLE: SOPs/MANUALS IN CLINICAL RESEARCH /PRACTICAL

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits ©	Total Hours/Marks
22	PCR18CT207	CT11	SOPs/Manuals in Clinical research	3	2	0	4	75/100
27	PCR18CL255	CL9	SOPs/Manuals development (Practical)	0	0	6	2	60/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a. Need of SOPs and manuals in clinical research &IEC as per regulatory requirements b. Contents, types and benefits of SOPs and manuals used in clinical research c. Guidelines in preparation of SOPs for clinical research &IEC d. Implementation and monitoring of SOPs in clinical research & IEC	After completing the course, the student will be able to: a. Enumerate the reasons for need of SOPs and manuals in clinical research &IEC. b. Describe the Contents, types and benefits of SOPs and manuals c. Discuss the guidelines in SOPs d. Explain the process of implementation and monitoring of SOPs e. Prepare SOP for Clinical research and IEC

23. COURSE TITLE: TO BE CHOSEN BY THE STUDENT

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
23	PCR18GE209	GE2	To be chosen by the student	3	0	0	3	45/100

24. COURSE TITLE: STRATEGIC MANAGEMENT AND ORGANISATIONAL CHANGES IN CLINICAL RESEARCH INDUSTRY

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
24	PCR18AE211	AE2	Strategic management and Organisational changes in Clinical research Industry	2	0	0	2	30/100

Learning Objectives	Learning outcomes
The objective of this course is to provide knowledge on: a) Definition of CROs/SMOs b) Operations of CROs/SMOs with respect to site selection criteria, single/multi centric trials, investigator selection c) Role and Responsibilities of CROs/SMOs	After completing the course, the student will be able to: a) Define CRO/SMO b) Describe the salient features of site selection criteria, single/multi centric trials, investigator selection c). Explain the Different roles and responsibilities of CROs/SMOs

SEMESTER – IV

28. COURSE TITLE: CLINICAL TRAINING

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
28	PCR18CR252	CR1	Clinical training	0	0	21	7	315/100

29. COURSE TITLE: PROJECT WORK ON ETHICS COMMITTEE SUBMISSION/SOP & MANUAL DEVELOPMENT**

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
29	PCR18RP254	RP1	Project work on ethics committee submission/SOP & manual development**	0	0	12	6	180/100

30. COURSE TITLE: PROJECT WORK ON REGULATORY DOSSIER/ CLINICAL TRIAL REPORT DEVELOPMENT FOR SPONSORS**

Course Number	Course Code	Course Category	Course Title	Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project	Total Credits (C)	Total Hours/Marks
30	PCR18RP256	RP2	Project work on Regulatory dossier/ Clinical trial report development for sponsors**	0	0	12	6	180/100

Project work

A 360 hours comprising of two research projects (180 hours each) is to be undertaken by each student independently to demonstrate their learning ability and interest in advancing their knowledge through the pursuit of independent research and/ or development work in an area related to clinical research. The research project is undertaken either in a CRO, clinical research site, hospital or academic facility. During the research project the candidate will be allotted a research guide/mentor/supervisor to help them in establishing themselves as a clinical research professional.

The first project work is on preparation and submission of a protocol for ethics committee approval and development and submission of a SOP & manual for a clinical trial in real time or on simulation basis which lasts for 180 hours and involves application of the theories and skills acquired by the student during the course of study and in the clinical training undergone in the Clinical/Contract research Organization (CRO) on various documents required to be prepared and furnished for ethics committee approval for a clinical trial and SOP/manual preparation for CRO/EC.

The second project work lasts for 180 hours and involves preparation and submission of Regulatory dossier and a Clinical trial report development for sponsors by application of the knowledge and skills acquired by the student during the course of study and in the clinical training course.

Project Submission:

Upon completion of the project, the candidate is expected to submit two separate project books duly signed by the respective guide/mentor/supervisor and the Head of the department for final evaluation during the end semester examination. The project report shall be submitted in triplicate (typed & bound with not less than 50 pages).

The internal and external examiner appointed by the University shall evaluate the project report before the defence and viva-voce examinations. Students shall be evaluated in groups for four hours

(i.e., about half an hour for a group of five students). The projects shall be evaluated individually as per the criteria given below.

Evaluation of Project Book

Content of the work done		15 Marks
Methodology adopted		15 Marks
Report preparation		10 Marks
Conclusions and Outcomes		10 Marks
	Total	**50 Marks**

Evaluation of Presentation:

Presentation of work		15 Marks
Communication skills		15 Marks
Viva –voce		20 Marks
	Total	**50 Marks**

SRI RAMACHANDRA
INSTITUTE OF HIGHER EDUCATION AND RESEARCH
(Category - I Deemed to be University) Porur, Chennai

FACULTY OF CLINICAL RESEARCH

REGULATIONS & SYLLABUS

FOR

M.Sc. (STEM CELL AND REGENERATIVE BIOLOGY) DEGREE PROGRAM

(Under Choice Based Credit System)

MASTER OF SCIENCE (STEM CELL AND REGENERATIVE BIOLOGY) DEGREE PROGRAM

INTRODUCTION

The M.Sc. (Stem Cell and Regenerative Biology) program is a two-year post graduate course that offers an interdisciplinary education in the field of stem cells, regeneration biology and tissue engineering for the rapidly evolving field of regenerative medicine. The course provides aspiring life science professionals a strong theoretical foundation in molecular, cellular and developmental biology together with extensive hands on training in laboratory skills in stem cells, scaffold fabrication and bio-analytical techniques. The course gives a unique perspective to students who choose to follow a research-based career in this dynamic field and who plan to pursue a career in research or work in pharmaceutical and biomedical companies in the field all over the world.

Scope:

Following completion, graduates will be equipped with the theoretical and practical skills to pursue a career in Academia and Research towards a PhD in Institutes around the globe, Industry (e.g. regenerative medicine, Biotechnology sector research/sales, pharma, toxicology), Patenting and IP, Science writing and Policy Regulation.

Program Summary

1. Master of Science (Stem Cell and Regenerative Biology) degree program is a postgraduate degree program offered under CBCS.
2. It is a 2-year program (four semesters) of study carrying a total **credit of 90** under the Faculty of Clinical Research.
3. Students register for core theory (CT), core lab (CL), electives and ability enhancement courses.
4. The program offers a research project for each student.
5. Evaluation is based on the UGC recommended 10-point grading system. Grades and classes will be declared as per Deemed to be University rules.

Intake: 15 students per academic year

SYLLABUS

First Year – Semester – I								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
1	**PCB20CT101**	**CT1**	**CELL BIOLOGY AND MACROMOLECULES**	**3**	**1**	**0**	**4**	**75**

Objectives	Learning outcomes
To train the student on: • The basics of cell and its components. • The importance of biological macromolecules • knowledge in the quantitative and qualitative estimation of biomolecules • The influence and role of structure in reactivity of biomolecules	At the end of the course, the student will • Have a strong foundation on the components and functions of the cell • Have a thorough understanding on the role and functions of biomolecules

First Year – Semester – I								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
2	**PCB20CT103**	**CT2**	**FUNDAMENTALS OF MOLECULAR BIOLOGY**	**3**	**1**	**0**	**4**	**75**

Objectives	Learning outcomes
To train the student on: • DNA and RNA organization at the molecular level. • Transcription and Translation Mechanisms • Control of Gene Expression • Damage and Repair mechanisms • Molecular Signaling Mechanisms	At the end of the course, the student will be able to identify and describe: • principles of gene organization and expression in both prokaryotic and eukaryotic organisms. • gene regulation and protein function including signal transduction, mutational and epigenetic changes in gene function.

First Year – Semester – I								
Course Number	**Course Code**	**Course category**	**Course Title**	**Lecture (L)**	**Tutorial (T)**	**Practical (P)**	**Total Credits (C)**	**Total Hours**
3	**PCB20CT105**	**CT3**	**TISSUE AND ORGAN DEVELOPMENT**	**2**	**1**	**0**	**3**	**60**

Objectives	Learning outcomes
To train the student on: • the molecular and cellular mechanisms that underlie the early development of organisms • Mechanisms controlling the behavior of cells in the processes of differentiation, morphogenesis and growth of various organ systems	At the end of the course, the student will be able to identify and describe: • Anatomical and morphological changes during development • Understanding gene regulation and signaling in organ development

First Year – Semester – I								
Course Number	**Course Code**	**Course category**	**Course Title**	**Lecture (L)**	**Tutorial (T)**	**Practical (P)**	**Total Credits (C)**	**Total Hours**
4	**PCB20DE107**	**DE1**	**INTRODUCTION TO BASIC MEDICAL SCIENCE**	**4**	**0**	**0**	**4**	**60**

Objectives
• To familiarize students on human body systems • To understand communicable and non-communicable diseases

First Year – Semester – I								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
5	**PCB20DE109**	**DE2**	**RESEARCH ETHICS**	**3**	**0**	**0**	**3**	**45**

Objectives	Learning outcomes
To train the student on: • The ethical requirement for conducting clinical trials • The rights, safety and wellbeing of trial subjects • Conceptualizing, designing, conducting, managing and reporting of clinical trials • Preparing clinical study reports and reporting in common technical document • Quality control and assurance in conduct of clinical trial	At the end of the course, the student will be able to identify and describe: • International Conference on Harmonization (ICH) process and its guidelines • Its structure and relationships to roles and responsibilities of the sponsor and the investigator • Adverse event reporting requirements for both investigators and sponsors • The responsibilities of an Institutional Review Board / Independent Ethics Committee (IRB/IEC) • Material and regulatory requirements for conducting clinical trials

First Year – Semester – I								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Total Credits (C)	Total Hours
6	PCB20CL151	CL1	CELL BIOLOGY (PRACTICALS)	0	0	3	3	90

First Year – Semester – I								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Total Credits (C)	Total Hours
7	PCB20CL153	CL2	MOLECULAR BIOLOGY (PRACTICALS)	0	0	3	3	90

First Year – Semester – II								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Total Credits (C)	Total Hours
8	PCB20CT102	CT4	IMMUNOBIOLOGY	4	0	0	4	60

Objectives	Learning outcomes

To train the student on: • overview of the immune system including organs, cells and receptors • molecular basis of antigen recognition, antigen-antibody reactions • principles of immunology and its applications	At the end of the course, the student will be able to identify and describe: • basic mechanisms that regulate immune responses and maintain tolerance • Molecular basis of complex, cellular processes involved in inflammation and immunity, in states of health and disease

First Year – Semester – II								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Total Credits (C)	Total Hours
9	PCB20CT104	CT5	STEM CELL BIOLOGY- I	4	0	0	4	60

Objectives	Learning outcomes
To train the student on: • understanding of stem cells types, mobilization and mechanisms controlling potency • Ethics, regulations and applications of Stem Cells	At the end of the course, the student will be able to identify and describe: • embryonic, adult and induced pluripotent stem cells and differentiated cells. • Signaling pathways in Stem Cells • Regenerative potential of different stem cell types

First Year – Semester – II								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Total Credits (C)	Total Hours
10	PCB20CT106	CT6	BIO-INSTRUMENTATION	3	0	0	3	45

Objectives	Learning outcomes
To train the student on: • Fundamentals of Spectroscopy, Chromatography, Microscopy • Working Principles of Biomedical Instrumentation relevant for the Stem Cell Field	At the end of the course, the student will be able to identify and describe: • Principles of Biomedical Instrumentation

First Year – Semester – II								
Course Number	**Course Code**	**Course category**	**Course Title**	**Lecture (L)**	**Tutorial (T)**	**Practical (P)**	**Total Credits (C)**	**Total Hours**
11	**PCB20DE108**	**DE3**	**RESEARCH METHODOLOGY & BIOSTATISTICS**	**4**	**0**	**0**	**4**	**60**

First Year – Semester – II								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
12	**PCB20DE110**	**DE4**	**Bioinformatics**	**2**	**0**	**1**	**3**	**60**

Objectives	Learning outcomes
• To know the importance of computers in biology • To understand software tools for biological sequence analysis • To learn the concepts associated to Genomics and apply the same in various fields	On successful completion of the course, the student will be able to • Get to know effective use of Office package • Understand the biological sequence analysis • The student will be able to understand the concepts associated to Genomics and apply the same in various fields

First Year – Semester – II								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
13	**PCB20CL152**	**CL3**	**CELL CULTURE TECHNIQUES (PRACTICALS)**	**0**	**0**	**3**	**3**	**90**

1. Basics of Cell culture and instrumentation
2. Cryopreservation and thawing.
3. Cell counting
4. Cell Viability Assays – MTT, Acridine Orange/ Propidium Iodide
5. Annexin - Apoptosis Assay
6. Primary MSC isolation from Wharton's Jelly
7. Primary MSC isolation from Adipose Tissue
8. Primary MSC isolation from Dental Pulp
9. Colony Forming Unit Assay
10. Tri- Lineage Differentiation Assay
11. Alizarin Red Staining
12. Oil Red O Staining

First Year – Semester – II								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
14	**PCB20CL154**	**CL4**	**BIO-INSTRUMENTATION (PRACTICALS)**	**0**	**0**	**3**	**3**	**90**

1. Immunofluorescence Staining for Biomarkers
2. Fluorescence Microscopy
3. Image Processing and Analysis
4. Cell surface Marker analysis by Flow cytometry
5. Flow cytometry Data Analysis
6. Magnetic Cell Sorting (MACS)
7. HPTLC – Cell membrane isolation, lipid separation;

Demonstrations

1. GC- MS – protein peak separation
2. NMR – standard amino acid structure
3. HPLC – Bio-molecule analysis demonstration; including the protein and lipid separation
4. FT-IR – amino acid structure
5. UV and IR Spectroscopy

Second Year – Semester – III								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
15	**PCB20CT201**	**CT7**	**STEM CELL BIOLOGY- II**	**4**	**0**	**0**	**4**	**60**

Objectives	Learning outcomes
To train the student on: • Techniques in generation and characterization of stem cells types. • Approaches and Challenges in Regenerative Applications.	At the end of the course, the student will be able to identify and describe: • Stem cell Methodology and Characterization • Lineage specific differentiation pathways • Current Application in Regenerative Medicine

Second Year – Semester – III								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
16	**PCB20CT203**	**CT8**	**TISSUE ENGINEERING**	**4**	**0**	**0**	**4**	**60**

Objectives	Learning outcomes
To train the student on: • Enabling technologies to generate new tissues through combination of biomaterials, cells, bio physical factors	At the end of the course, the student will be able to identify and describe: • Currrent applications and challenges in Tissue Engineering and research

Second Year – Semester – III								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
17	**PCB20DE205**	**DE5**	**BIOLOGICAL MODELS**	**3**	**0**	**0**	**3**	**45**

Objectives	Learning outcomes
To train the student on: • Fundamental concepts in Biological Model Systems, their advantages and limitations • Current Techniques in Modeling	At the end of the course, the student will be able to identify and describe: • Challenges and Applications of Model Systems at the Organoid/ Organ and Organism levels

Second Year – Semester – III								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
18	**PCB20GE207**	**GE1**	**TO BE CHOSEN BY STUDENT**	**3**	**0**	**0**	**3**	**45**

Second Year – Semester – III								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
19	**PCB20CL251**	**CL5**	**CELL MANIPULATION TECHNIQUES**	**0**	**0**	**3**	**3**	**90**

1. Vector Designing and Construction
2. Liposomal Transfection
3. Gene Over-Expression studies
4. Q PCR Analysis
5. Gene Silencing.
6. Western Blotting
7. Culturing MEF
8. Culturing of Pluripotent Stem Cells.
9. Gene Editing Tools (Demonstration)

Second Year – Semester – III								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
20	**PCB20CL253**	**CL6**	**TISSUE ENGINEERING (PRACTICALS)**	**0**	**0**	**3**	**3**	**90**

1. 3D Organoid Culture
2. Hydrogel Scaffolds
3. Electrospun Nanofiber Scaffolds
4. Solvent Casting of 3D scaffolds
5. 3D Printed Scaffolds
6. Cell viability on 3D scaffolds
7. Perfusion Bio Reactor Set up for Culture on 3D Constructs
8. Osteogenic Differentiation on 3D scaffolds
9. Evaluation of Osteogenesis by PCR.

Second Year – Semester – III								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
21	**PCB20RP255**	**RP1**	**Project Proposal**	**0**	**0**	**4**	**4**	**120**

Objectives	Learning outcomes
• To understand basic research concepts and importance of projects. • To know about research designs and various sampling methods	At the end of the course the student will be able to • Formulate a research question and prepare a research protocol • Submit Proposal for evaluation by appropriate ethical committees.

21. Project Proposal **Time allotted: 120 hours**

All candidates registered to undergo M.Sc. Stem Cell and Regenerative Biology Degree course will have to submit a Project Proposal in the 3rd Semester that will lead to their dissertation in the 4th Semester as part of the degree programme.

Each candidate would be assigned a recognized guide at the beginning of third semester. Where necessary, Candidates will be also assigned a recognized Co-Guide from a Clinical or another relevant Department. The topics assigned to the candidates will be intimated to the Controller of Examination of this university at the end of the third semester.

- Students are expected to read background information regarding the topic of their study and do a literature survey and prepare a project outline (research proposal) in consultation with the faculty.
- The Project Proposal will be evaluated as a presentation. It should contain (Literature review, Proposed Methodology, Work Plan and Proposed Outcome).
- The Project Proposal should be submitted in appropriate format to Relevant Ethics Committees for scrutiny.

Second Year – Semester – IV								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**
22	**PCB20GE202**	**GE2**	**To be chosen by student**	**3**	**0**	**0**	**3**	**45**

Second Year – Semester – IV								
Course Number	Course Code	Course category	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	**Total Credits (C)**	**Total Hours**

23	**PCB20RP252**	**RP2**	**Dissertation and Viva-Voce**	**0**	**0**	**15**	**15**	**450**

Objectives	Learning outcomes
• To understand basic research concepts and importance of projects. • To know about research designs and various sampling methods • To understand the importance of ethics in research	At the end of the course the student will be able to • Formulate a research question and prepare a research protocol • Implement the research protocol and use appropriate statistical methods for analyzing the data and write a research article

23. Dissertation and Viva-Voce **Time allotted: 450 hours**

Each candidate, as part of course completion requirements, should submit a dissertation in the domain of Stem Cell and Regenerative Biology. Candidates would be assigned a recognized guide at the beginning of third semester. Where necessary, Candidates will be also assigned a recognized Co-Guide from a Clinical or other relevant Department within the University or in recognized external organizations. The topics assigned to the candidates will be intimated to the Controller of Examination of this university at the end of the third semester.

- **Obtaining ethics clearance from appropriate committees for the proposal is compulsory.**

- The research project work will be laboratory based. Permission may be granted to select number of students, to carry-out a part of their lab work in external institutions, based on the needs assessment and scientific depth of the research and as part of collaborations.
- The faculty supervisor by periodic monitoring will guide the work of the student. The student will spend roughly 90 working days in the fourth- semester on the allotted project.
- The dissertation work will be individual dissertation and will consist of experimental work and data collection. The dissertation copy shall be submitted for evaluation in a bound volume not exceeding 75 pages (1.5-line spacing and on one side of A4 size paper) excluding references.
- Only one soft copy and one hard copy shall be submitted one month prior to the commencement of the University examination and forwarded to the Controller of Examination of the University.
- Another hard copy can be used during assessments and maintained in the department. External or Inter-departmental Examiners for end semester Viva shall be appointed.
- It is desirable that the student be encouraged to submit one publication or presentation from out of the thesis before appearing for the university examinations. This will be culmination of the three semesters of research orientation of the students, which will be an asset to any organization employing them.

The summative evaluation of the project would be done by University examination on the basis of content and output of the submitted dissertation; and dissertation *viva voce* before the examiners.